

NCRI Clinical Studies Groups: **A prospectus**



Partners in cancer research



NCRI Clinical Studies Groups: A prospectus

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Introduction



NCR Director of Clinical Research
Professor Matthew Seymour

The NCR Clinical Studies Groups – the CSGs – are the engine-house of clinical cancer research in the UK. Clinical research – research involving patients – is crucial when it comes to putting new ideas to the test and finding ever better ways to fight cancer and improve the lives of patients. We hope that you will find this booklet interesting, and that you may be inspired to support or work with them.

Over the past few decades, cancer research has been making great progress, and many thousands of patients can now be diagnosed earlier and treated more effectively. But progress could have been even faster. Too often, great new ideas from our laboratory scientists become held up at the final hurdle because clinical research is complicated to design and difficult to carry out.

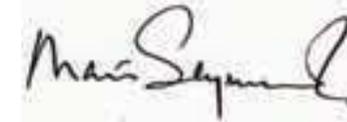
So, in 2001, cancer charities and the government in the UK formed a partnership with doctors, scientists, industry and patients themselves: the National Cancer Research Institute (NCRI). One of the NCRI's first decisions was to provide funds to bring together groups of doctors, scientists and patients – the CSGs – and to give them the task of developing new clinical research studies and providing help for other researchers, so that we could establish a national 'portfolio' of high-quality studies. At the same time, the UK health departments set up a national network – the NCRN – so that the new portfolio of studies could be offered to patients throughout the NHS.

We hope you will agree that twelve years has seen some impressive progress. We now have 21 CSGs and over 70 CSG Subgroups, all working to bring research to cancer patients. Our national portfolio has grown from 172 clinical cancer studies in 2001 to 754 studies open today, most of which were either developed by CSGs or with their help. Consequently, the UK is now world-leading in the number of cancer patients participating in research: 56,673 last year, that's one in five of all UK cancer patients. In the USA the figure is near 1 in 20.

This success means that we have been able to broaden our horizons. We have formed alliances with pharmaceutical companies and the UK Experimental Cancer Medicine Centres (ECMC), so that promising new

cancer drugs can be evaluated more quickly and brought to patients with less common cancers. For patients with the very rarest cancers, we have worked with Cancer Research UK and global partners to establish the International Rare Cancers Initiative (IRCI), which is now opening clinical trials across the world. Some of our new priorities are research to prevent cancer from developing or to detect it earlier, trials of radiotherapy treatment and surgery, and trials to test new molecular techniques to help select the most beneficial treatment for individual patients.

We know that research leads to progress, and we can be confident that the work of the CSGs is already contributing to longer and better lives for cancer patients in the UK and around the world. But there's a lot more to do. We hope that as you read this booklet you will get a flavour of the vision and dedication of our CSGs as we move forwards.



Matt Seymour

NCRI Director of Clinical Research, and Director of NCRN (the NIHR Cancer Research Network)

For more information about the work of the CSGs, please visit our website <http://csg.ncri.org.uk> or contact the secretariat at ncricsg@ncri.org.uk

An overview of the Clinical Studies Groups



An overview of the Clinical Studies Groups

These are our CSGs (left). Sixteen groups are “site-specific” (teal) – they develop and coordinate research for cancers arising in particular regions of the body, including one group for cancers which affect children. A further five CSGs are “cross cutting” (orange), and work on research into issues which may affect patients with many different cancers, often in partnership with the site-specific groups. These include cancers affecting teenagers and young people, and important research into supportive, end-of-life and psychological care.

Each CSG has around 15-25 core members including cancer clinicians, scientists and cancer patients or their carers, appointed for 3-5 years through a competitive national appointment process. Being a CSG member is a serious commitment: the group meets every 4-6 months, and a lot of work is done by the members between meetings. Each CSG has several subgroups which meet at other times to work on new research ideas and draw in other experts. Many also have an annual open meeting bringing together several hundred people to report trial results and promote the portfolio, and a strategy day for longer-term planning and ‘blue sky’ thinking. Most of our CSGs have links with researchers abroad, and with the research divisions of commercial companies.

The NCR also supports several other research groups who work with the CSGs. For example, **CTRad**, the Clinical and Translational Radiotherapy Working Group, develops clinical and laboratory research involving radiation therapy (see page 51); **SPED**, the Screening, Prevention and Early Diagnosis Advisory Group, (see page 50), is our group which brings together researchers involved in trials of cancer screening, prevention and earlier diagnosis; **GRIST**, Growing Recruitment in Surgical Trials, promotes research involving surgery; and **CLG**, the Consumer Liaison Group (see page 52) brings together the patients and carers from all the CSGs to provide support and education.

Biomarkers & Imaging Clinical Studies Group



Chair
Professor Bob Brown

Subgroups
Technology &
Bioresources
Professor Craig Robson

Imaging
Professor Fiona Gilbert

One of the biggest challenges in current cancer research is identifying and directing appropriate treatments to the patients most likely to benefit from them. This requires effective translational biomedical research and developing approaches through evidence-based medicine and clinical trials. The remit of the Biomarkers & Imaging CSG (BI CSG) is to promote high quality translational science within the NCRN portfolio of clinical trials. Our Group consists of members spanning expertise from basic sciences to direct clinical practice, one of whom is a consumer member.

The BI CSG has four main workstreams: Imaging integration and harmonisation; biomarker technologies and applications; bioinformatics and biostatistics in biomarker study design; education in biomarkers and personalised medicines. These workstreams were developed to focus on the initial discovery of new diagnostic biomarkers and imaging techniques within cancer research, and to follow this on through to their use in clinical trials, diagnostics and personalised cancer treatments.

An important part of the Group's work is to provide expertise in the form of advice or input for other CSG-supported studies that include research on biomarkers and imaging and to organise workshops of relevance to the other CSGs. The workshops run to date include 'Expanding the use of PET in clinical cancer

research' (September 2011), 'Potential and pitfalls of tissue micro-arrays' (May 2012) and 'Biomarkers, biostatistics and novel clinical trial design' (September 2012). A workshop on 'Cell-free DNA' is due to be held in early 2014. These workshops are always well attended and have attracted excellent feedback from researchers, clinicians and consumers.

Further success has been achieved through collaborative interaction with the Head & Neck CSG. This collaboration has led to a joint session at the 2012 NCRI Cancer Conference, a focused-ideas workshop and support for the development of a biomarker funding application.

Specific advice from 'expert subgroups' of the BI CSG has also been given to the Brain CSG on DNA methylation, and to the Gynaecological, Renal

In 2012-13, 7062 patients were recruited to BICSG studies, accounting for 11.2% of all cancer patients entering into clinical studies in the UK.



Scientist at work in the lab.
Image library, Cancer Research UK.

and Melanoma CSGs on trials in development. The Group has also published 'Guidelines and considerations for conducting experiments using tissue microarrays' in the *Journal of Histopathology*.

This group focuses on many cancer types and due to this 'cross-cutting nature, the Group has had few trials within its own portfolio. Most of the biomarker protocols and clinical trials are managed and owned by the tumour-specific CSGs.

The Group currently has seven studies on its portfolio and at least one BI CSG study is open within 11 cancer research networks in the UK. In 2012-13, 7062 patients were recruited to BI CSG studies, accounting for 11.2% of all cancer patients entering into clinical studies in the UK. In that

same period, three new studies in Biomarkers and Imaging opened to recruitment.

Key current aims for the Group include developing a guidance review on translational research infrastructure with Cancer Research UK (CRUK) and European Organisation for Research and Treatment of Cancer (EORTC); developing study protocols and funding applications with the Primary Care CSG and the NCRI Screening Prevention and Early Diagnosis (SPED - see page 50) Advisory Group; and early involvement in developing molecular biomarker trial protocols with other CSGs, based on molecular genotyping and phenotyping. The Group had a successful progress review in June 2012. The next progress review is scheduled for June 2015.

“The nature of the Group's deliberations are scientifically complex, but my opinions as a consumer are always actively sought and valued by the scientists, and I feel empowered to make a real contribution to the work of the Biomarkers & Imaging CSG
Dr Mike Kemp, consumer member.”

Bladder Cancer Clinical Studies Group



Chair
Dr Alison Birtle

Subgroups
Advanced Bladder Cancer
Professor John Chester

Penile Cancer
Dr Amit Bahl

T2 & Below
Ms Jo Cresswell

The vision of the Bladder Cancer CSG is to reduce mortality rates and increase quality of life in survivors of bladder cancer. Our CSG aims to do this through collaborating research efforts and identifying patient barriers to clinical trials in bladder cancer and metastatic disease. Chaired by Dr Alison Birtle, the Bladder Cancer CSG is structured to provide robust representation from the sphere of bladder cancer, including the views of patients, carers and public through the input of two consumer members.

As the sixth most common cancer in the UK, bladder cancer remains the largest consumer of health care resources. Key challenges faced by the Group are changing clinician perception into advanced bladder cancer treatment, engaging urologists in surgical studies, particularly non-muscle invasive bladder cancer, as well as exploring barriers to recruitment. To tackle these issues, their work has concentrated on developing 'real-world' studies to deliver on recruitment together with collaboration with industry across the portfolio and advance research on systemic therapies.

The Bladder Cancer CSG is committed to promoting the concept of 'A Trial for Every Patient' and has directly supported high impacting studies such as SUCCINCT, the first multi-centre

trial of molecular targeted therapy in first-line metastatic bladder cancer in the UK. Similarly, the Group's collaborative work with the UK Network of Uro-oncology in bladder cancer has enabled successful recruitment to target with the phase III BOXIT study, a study determining whether the addition of the oral COX-2 inhibitor, celecoxib, to standard therapy, is more effective for recurrence-free survival, and the LaMB study, which looked at maintenance therapy after first-line chemotherapy in advanced and metastatic disease.

Collaborative work both nationally and internationally underpins the Group's strategy. This has seen the opening of the POUT trial, the first study of peri-operative chemotherapy versus surveillance in resected upper tract TCC.

As the sixth most common cancer in the UK, Bladder cancer remains the largest consumer of health care resources.



Polarized light micrograph of urea crystals. Urea is produced in the liver to remove toxic ammonia from the body. Urea travels in the blood to the kidneys where it is excreted via the bladder in the urine.

Spike Walker, Wellcome Images.

Currently, there are 13 open studies on the Bladder Cancer CSG portfolio and a further nine studies are in set-up. In 2012-13 alone, five of these studies opened to recruitment. Seven open studies are focusing on first-line metastatic disease in muscle invasive bladder cancer. International collaborative efforts have led to two studies opening outside the UK and active participation in the International Rare Cancers Initiative (IRCI).

At least one bladder cancer study is currently active in 33 research networks in the UK. In 2012-13, 324 bladder cancer patients were recruited into clinical studies, including the recruitment of 24 patients into industry-developed studies supported by the Bladder Cancer CSG. These patients represent 3.1% of the total incidence of bladder cancer in the

UK and 0.5% of all cancer patients entered into clinical trials within the UK.

Future priorities of this Group include: building upon the success of collaborative work with industry to design a study of maintenance therapy, including imaging and biomarkers within studies (once an appropriate biomarker has been identified) and addressing the unmet needs of patients presenting with node positive disease.

The Bladder Cancer CSG has worked with the Testis, Prostate and Renal CSGs to host the annual Uro-oncology Trials Meeting. This continues to receive extremely positive feedback and attracts over 200 delegates. The CSG also had a successful progress review in June, 2011. The next review is due in June, 2014.

As a PPI representative I provide a patient and carer perspective during the meeting, and provide a lay review for proposals brought to the meeting and via email or conference call between meetings

Mrs Jean Gallagher, consumer member.

Brain Tumour Clinical Studies Group



Chair
Dr Colin Watts

Subgroups
Translational & Novel
Agents
Professor Anthony
Chalmers

Imaging & Technological
Development
Dr Adam Waldman

Quality of Life &
Palliative Care
Dr Jane Fleming

The remit of the Brain Tumour CSG is to develop a portfolio of high quality clinical trials across many different brain tumour types, and at different stages of the treatment pathway. A major challenge includes developing trials for the many patients for whom there is currently no opportunity to participate while maintaining routine collections of standardised, high-quality datasets to support robust results. The Brain Tumour CSG has one consumer representing the views of patients, carers and the public.

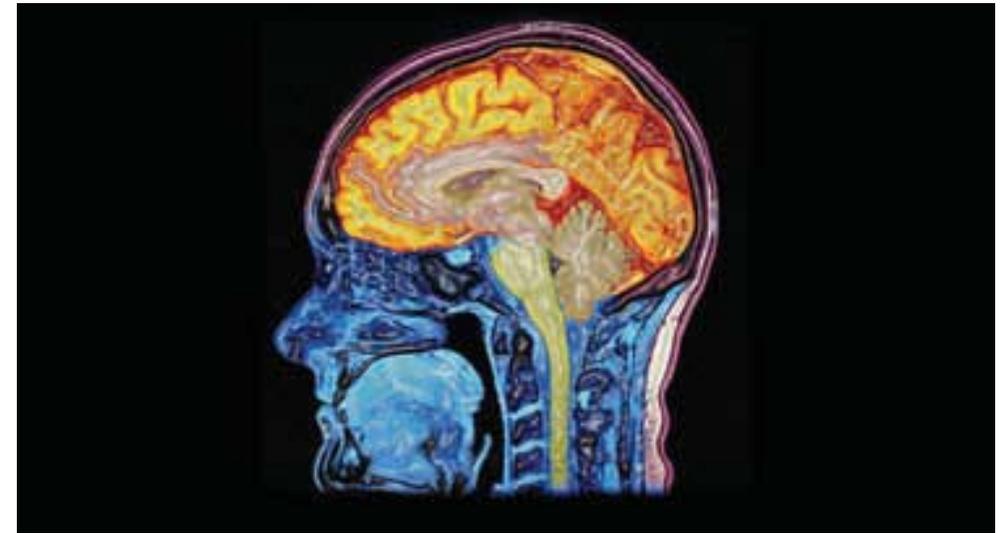
The Group currently has 16 studies on its portfolio including an industry-developed study; five studies involve international cooperation. In 2012–13, a total of five studies opened, including an industry-driven study. In addition, the Group currently has three studies in set-up and at least one brain study is open in 38 research networks within the UK. The Group also actively participates in the International Rare Cancers Initiative (IRCI).

The Brain Tumour CSG has supported trials which have led to improvements in treatment and changes in clinical practice. The BR12 trial, which looked into comparing temozolomide with PCV chemotherapy in the treatment of recurrent malignant glioma, has helped organise the management of patients with recurrent glioblastoma in the UK. The combination of chemotherapy used in this trial has been incorporated

into clinical practice. Similarly, the EORTC 22952, a randomised trial examining the role of whole brain radiotherapy after surgical removal or radiosurgery for patients with 1–3 brain metastases, influenced the management of patients with brain tumour metastases.

The Group achieved much success with the GALA-5 trial which assessed combining 5-amino-levalulinic acid (5-ALA) with Gliadel in the surgical management of primary glioblastoma. The GALA-5 trial was the first surgical trial in patients with brain cancer in the UK. With direct support from the Brain Tumour CSG, recruitment for this trial was completed two months ahead of schedule and analysis of results is still ongoing. Further success was seen with the OPARATIC trial, the first trial of a PARP inhibitor in glioma and the first study to use neoadjuvant therapy with surgery to confirm drug entry into brain.

The GALA-5 trial was the first surgical trial in patients with brain cancer in the UK.



Digitally enhanced MRI of the human head showing the brain and spinal cord in orange/yellow and the other tissues in blue and pink.
Mark Lythgoe & Chloe Hutton, Wellcome Images.

In 2012–13, 1095 patients were recruited to studies supported by the Brain Tumour CSG. This represents 23% of brain tumour patients within the UK for that year. A total of 3.5% of patients recruited to brain tumour studies in 2012–13 were entered into interventional studies.

The Group's aims are to continue progress towards developing a national network of trial competent centres and to identify an appropriate clinical trial to pilot this initiative, while identifying and overcoming barriers to

recruitment. Other priorities include developing trials that yield high-resolution imaging and biological datasets and to outline a proposal for an imaging study in patients with low grade glioma. The Group successfully passed their progress review in December 2010. The date of their next progress review is December 2013.

“ I am delighted that the role of the consumer acts as a key forum so that we can improve the quality and value of cancer research for patient benefit. It really is a privilege to have a voice as a consumer on the Brain Tumour CSG so that together we can address these issues.
Dr Helen Bulbeck, consumer member. ”

Breast Cancer Clinical Studies Group



Chair
Professor Alastair Thompson

Subgroups
Advanced Disease
Dr Alistair Ring

Translational & Imaging
Dr Abeer Shaaban

Early Disease (UK Breast Intergroup)
Professor Judith Bliss

The Breast Cancer CSG supports a vast portfolio of studies which continue to change practices in surgery, radiotherapy, endocrine therapy, chemotherapy and targeted therapy of breast cancer. Our Group contributes substantially to the overall NIHR cancer studies portfolio and continues to encourage widespread involvement with new researchers, in both academic and industry-led clinical and translational studies. Chaired by Professor Alastair Thompson, our Group's multi-disciplinary membership includes two consumer members to inform on patient and public views.

The Breast Cancer CSG oversees a vast portfolio of 120 open studies in breast cancer. There are 27 industry developed studies open on the breast cancer portfolio and 19 of all open studies are focusing on a range of second-line metastatic breast cancers. In 2012-13 alone, 35 studies opened to recruitment. At least one breast cancer study is open in 40 UK research networks which allows widespread recruitment. International collaboration has seen 39 studies opening outside the UK.

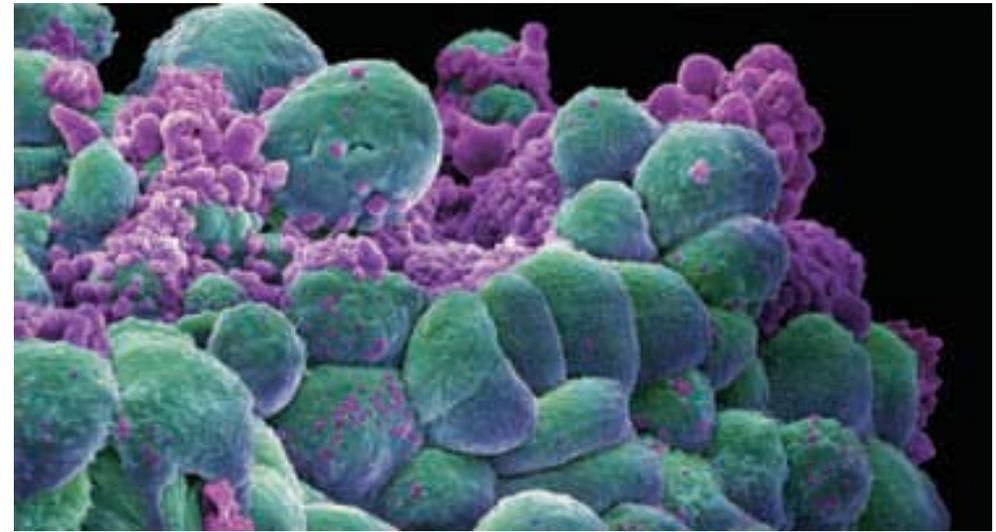
In 2012-13, 13,748 breast cancer patients were recruited into clinical studies supported by the Group; this accounted for 28.1% of the total incidence of breast cancer in the UK and 22% of all cancer patients entered into clinical trials within the UK, in that year. Overall, 7.8% of all breast cancer patients recruited into clinical trials in 2012-13, were entered into

interventional studies and 4.7% of the recruited patients entered industry supported studies.

The Breast Cancer CSG is heavily involved in high-impact and practice-changing research. An example of this was seen with the ALMANAC trial, a surgery study which compared sentinel node guided axillary therapy with standard axillary therapy in early stage breast cancer. This trial has opened throughout the UK, transforming axillary surgery and reducing morbidity as a consequence.

Further improvements in treatment were identified with the AMAROS trial, a phase III study comparing a complete axillary lymph node dissection with radiotherapy to the axilla in sentinel biopsy positive patients. The results of this study confirmed the equivalence of radiotherapy vs axillary clearance for disease control.

In 2012-13, 13,748 breast cancer patients were recruited into clinical studies supported by the Group; this accounted for 28.1% of the total incidence of breast cancer in the UK.



A scanning electron micrograph of breast cancer cells showing visual evidence of programmed cell death (apoptosis)

Annie Cavanagh,
Wellcome Images.

In 2012-13, the Breast Cancer CSG achieved great success by securing funding or endorsement of seven trials from the funding streams CTAAC and HTA, providing outstanding opportunities for future improvements in clinical practice.

Future aims and priorities of the Breast Cancer CSG include supporting the opening of trials, recruiting to these trials within agreed time frames and identifying future trials for current and emerging gaps in the portfolio, such as molecular subtype-driven trials in the metastatic setting. Despite the increasing complexity of breast cancer subtypes and clinical studies processes, recruitment is on a steady increase;

however, the challenge remains to further develop studies of specialised therapies for specific breast cancer subtypes. Another key challenge for the forthcoming year is to continue to develop new trials linked with industry.

The Breast Cancer CSG holds an Annual Trials Meeting, which continues to be accessible to over 300 trialists from a wide range of disciplines throughout the geographically diverse breast cancer community, encouraging discussions and collaboration. The Breast Cancer CSG enjoyed a successful progress review in August 2010, with the next review due in early 2014.



As a patient advocate with metastatic breast cancer, I have found the Breast Cancer CSG very welcoming. Breast cancer symptom management has been my interest [...] and the Breast Cancer CSG has been very supportive, helping me set up a working party into symptom management.

Dr Adrienne Morgan, consumer member

As a consumer representative participating in the CSG is a great opportunity to provide a patient perspective and experience that is greatly acknowledged and highly valued.

Mrs Katrina Randle, consumer member



Children's Cancer & Leukaemia Clinical Studies Group



Chair (outgoing)
Dr Chris Mitchell



Chair (incoming)
Dr Meriel Jenney

Subgroups
Central nervous system
Dr Antony Michalski

Leukaemia
Professor Ajay Vora

Germ Cell Tumour
Dr James Nicholson

Hepatobiliary
Dr Derek Roebuck

Neuroblastoma
Dr Kate Wheeler

Novel Agents
Professor Andrew Pearson

Renal
Mr Mark Powis

The Children's Cancer & Leukaemia (CCL) CSG has been in existence for three years, having taken over the trials portfolio of the Children's Cancer and Leukaemia Group (CCLG). The priority of our CSG is to ensure that there are trials available for the treatment of all major childhood cancers, including those that have relapsed. Previously chaired by Dr Chris Mitchell, Dr Meriel Jenney has now been appointed as Chair. The CCL CSG has a wide range of representation within the field of paediatric oncology, including the input of two consumer members.

Due to the rarity of childhood cancer, novel methods of conducting trials with only small numbers of patients is needed and international collaboration is essential in most trials.

The Group aims to develop and support studies that improve treatment and, therefore, change standard clinical practice in children's cancer. An example of this was seen in UKALL2003, a study evaluating whether treatment can be reduced without compromising efficacy in a low risk group of patients defined by a molecular minimal residual disease (MRD) technique. This study affirmed the use of MRD monitoring as part of standard clinical care for children with acute lymphoblastic leukaemia (ALL). It has shown that children at low risk of relapse, as identified by MRD, can safely have their treatment reduced and those children who

are at high risk of relapse (i.e. identified by MRD, regardless of speed of response), will benefit from intensifying treatment.

These results, overall, are world-leading. The successor trial, UKALL2011 builds on this knowledge and should lead to further treatment refinement. The LDE225 industry-led study of LDE225 in paediatric patients with recurrent or refractory medulloblastoma, identified genetic characteristics which help predict outcome. Patients with medulloblastoma are now classified according to risk and treated accordingly.

The Group currently has 39 studies on its portfolio, ten of which are industry-developed and 20 of which involve international cooperation. In 2012-13, a total of eight studies opened. The majority of these studies

Cancer affects one in 650 children between 0-16 years.



Boys paddling in the sea.

Image library,
Cancer Research UK.

are in leukaemia. In addition, the Group currently has eight studies in set-up. 21 research networks within the UK run at least one CCL study.

Cancer affects one in 650 children between 0-16 years. In 2012-13, 1115 patients were recruited to CCL studies, with 39 patients being recruited to industry-driven studies on the portfolio. Overall, 1.8% of all cancer patients going into clinical studies were recruited to CCL studies.

The CCL CSG supported three successful applications to CTAAC in 2012-13, and has been highly successful in previous years. In June 2013 they held their first CCL CSG Annual Trials Meeting. The CCL CSG has also developed and maintained strong links with

a variety of other groups, including Birmingham Cancer Research UK Clinical Trials Unit (CRCTU), Paediatric Oncology Reference Team (PORT), Sarcoma and Lymphoma CSGs and the NCRN Children's Cancer & Leukaemia Network.

Future targets of the CCL CSG include continuing the development of the portfolio. The major priorities are the improvement of treatment for cancers where survival remains low, such as high-risk neuroblastoma, or where there is major long-term morbidity due to treatment, as is the case with many types of brain tumour. The Group had a successful progress review in July 2013, with the next one scheduled for July 2016.

“This is a robust and enthusiastic CSG, composed of dedicated professionals seeking to improve the survival and late effects from children's cancers and the necessary treatments for these pernicious diseases.
Mrs Danielle Horton Taylor, consumer member

Colorectal Cancer Clinical Studies Group



Chair
Professor Will Steward

Subgroups
Surgical
Mr Simon Bach

Prevention & Screening
Professor Bob Steele

Advanced & Adjuvant
Dr Richard Wilson

Anorectal Cancer
Dr Richard Adams

The Colorectal Cancer CSG aims to develop clinical trials which address important questions, potentially leading to a reduced incidence of colorectal cancer or increased survival. To achieve this, our Group has active subgroups which design studies covering screening, prevention and treatment of colon, rectal and anal cancers. There is an increasing move to develop trials which are informed by molecular signatures of tumours. To this end the flagship trial, FOCUS4, a programme of molecular selection of therapy in colorectal cancer, will open late 2013/ early 2014. Our CSG has a wide-ranging membership including two consumer members.

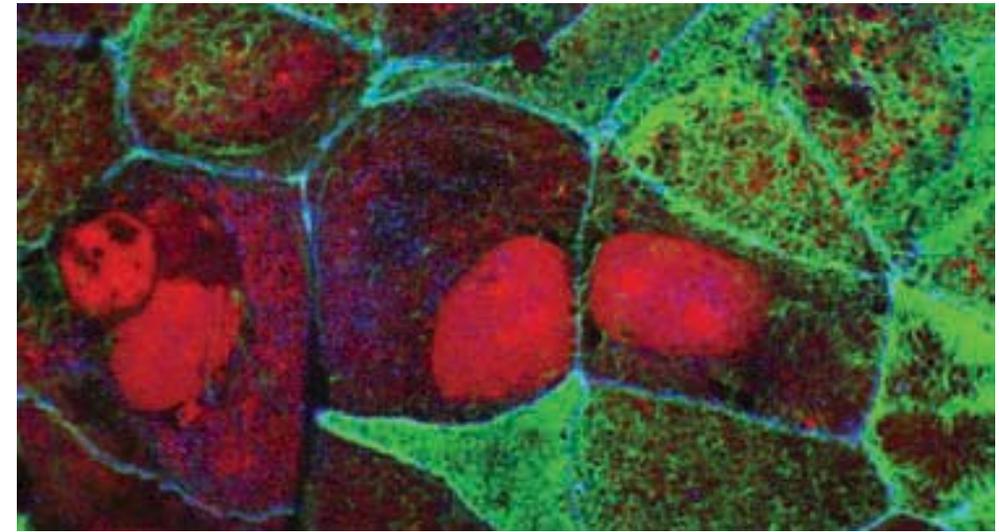
The Colorectal Cancer CSG is committed to developing and supporting practice-changing studies which improve treatment and patient outcomes. The Group has successfully supported many high-impacting studies like the CRO7 study, a trial comparing pre-operative radiotherapy and selective post-operative chemoradiotherapy in rectal cancer. The CRO7 study demonstrated the benefits of short-course radiotherapy for rectal cancer over long-course treatment, leading to a wide change in practice in radiotherapy centres across the UK and other nations.

Further improvements to current standards of care were established in the MERCURY trials, which looked into the use of MRI in rectal cancer. The MERCURY trial has resulted in MRI being routinely introduced to centres undertaking rectal cancer surgery as a standard of care for both disease control and quality of life in patients. Building on these findings, the MERCURY 2 trial was developed and has recruited well.

Early data suggests this study could have profound effects on the management of rectal cancer in the future.

One of the most ground-breaking studies to have changed routine practice has been the FLEXI-Sig study. As a result, the Government has embraced these results to fund routine single screening sigmoidoscopy throughout England. Similarly, the COIN study, comparing chemotherapy practices, informed clinicians that breaks in routine treatment of combination cetuximab with capecitabine, do not seriously impact on survival, allowing a better quality of life for patients.

The Group currently has 60 studies on its portfolio, five of which are industry-led studies and 12 of which involve international cooperation. In addition, the Group currently has 14 studies in set-up. In 2012-13, a total of 15 studies opened, three were industry-developed studies and 40 research networks within the UK ran at least one colorectal study. In 2012-13, 6584 patients were



Human colon cancer cell line confocal micrograph. Cell line derived from a human colon cancer. Tight junctions form between the cells and can be seen in blue. The actin cytoskeleton can be seen in green and the nuclei in red.

S.Schuller, Wellcome Images.

recruited to colorectal studies, representing 16.3% of colorectal cancer cases in the UK and 10.5% of all cancer patients going into clinical studies. During that year, a total of 68 patients were recruited into industry supported studies. The Group also actively participates in the International Rare Cancers Initiative (IRCI), for international collaboration in the research of rarer cancers.

Future aims of the Colorectal Cancer CSG are: to encourage the Royal College of Pathologists and NIHR to increase the focus

on training new academic pathologists, as molecular pathology will underpin major developments in colorectal cancer; to increase the number of radiologists with an interest in research, as they are needed to advise on new developments in imaging and support trials; to complete negotiations with pharmaceutical companies to support all arms of the FOCUS 4 trial to enable a successful launch across the UK. The Group had a successful progress review in 2011. The review is due in 2014.



It has been a privilege to attend the meetings. Consumer experience was used to add useful comments to proposed trials and the patient consent forms and patient information sheets.

Mr Alf Oliver, consumer member

From the very first CSG meeting I attended I was made to feel welcome and that the contributions I made were of interest and value to discussions. Any questions I have are always respected. The meetings are always lively and we cover all the items in a timely manner.

Mrs Ann Russell, consumer member



Gynaecological Cancer Clinical Studies Group



Chair
Professor Jonathan Ledermann

Subgroups
Cervical & Vulval
Professor Nick Reed

Endometrial
Professor Richard Edmondson

Ovarian
Professor Iain McNeish

Gynaecological cancers include cancer of the ovary, endometrium and cervix. Although there are clinical studies for each of these types already in existence, many subtypes of gynaecological cancer are now recognised. This has resulted in a need to develop more specialised gynaecological cancer studies. To meet this need, the Gynaecological Cancer CSG, with a long history of leading and recruiting to practice-changing clinical studies, is made up of members from diverse specialities and includes two consumer members.

The Group has successfully developed trials that have improved clinical practice. An example of this is OV05, a follow-up to the CA125 study of Relapse with Ovarian Carcinoma, which showed that early implementation of second-line chemotherapy for recurrent ovarian cancer has no advantage for patients. As a result of these findings, patients are less likely to undergo unnecessary treatment.

Similarly, ASTEC, a trial in stage I endometrial cancer, demonstrated that patients undergoing lymphadenectomy and post-operative radiotherapy had no survival benefit and so this course of treatment is no longer deemed necessary.

Further key achievements of the Group include its contribution to EORTC 55971, a trial comparing primary (neoadjuvant) chemotherapy with primary surgery followed by chemotherapy. This led to a subsequent trial,

CHORUS, with a similar design. Together, these trials confirmed that delaying surgery does not reduce survival in women with advanced disease, leading to practice change in the UK, Europe and some of the US.

The Group has a portfolio of studies that involve both industry and international collaboration. It currently has 36 studies open on its portfolio, 15 of which were opened in 2012–13, alone. At total 36 studies, five are industry-developed and 15 involve international cooperation. The

Gynaecological Cancer CSG also has strong links nationally, with 38 research networks within the UK running at least one of its gynaecological studies. Overall, 937 patients were recruited to gynaecological studies supported by the Group in the UK in 2012–13, representing 1.5% of all UK cancer patients and 5.3% of the total number of gynaecological

The Group has a wide-reaching portfolio of studies that involve both industry and international collaboration.



A cervical cancer vaccine clinical trial.

[Image Library, Cancer Research UK](#)

cancer cases in the UK. The Group focuses on boosting study coverage for the rarer gynaecological cancers by actively participating in International Rare Cancers Initiative (IRCI).

The CSG has succeeded in recruiting 50 patients per month to the internationally run ICON 8 trial, which looked into dose-fractionated chemotherapy compared to standard three-weekly chemotherapy. This is a remarkable achievement and with more centres opening or in set-up in Korea, Australia, New Zealand, Mexico and Ireland, patient recruitment will continue to rise. The Group held its first national meeting with the BGCS in London in July 2012 and the second annual 'road show' in the West Midlands.

Future priorities of the

Gynaecological Cancer CSG are to secure funding for the ICON 8 B trials, the follow-on trial to ICON 8. By increasing the number of open sites both in the UK and internationally, the Group aims to enhance recruitment in some existing trials, such as the INTERLACE trial which compares chemotherapy and chemoradiation vs standard chemoradiation alone, in patients with locally advanced cervical cancer.

Furthermore, the Group will continue to help nurture an environment for UK led, multi-national studies by informing NIHR processes and being part of NCRI's involvement in international industrial trial development. The Group had a successful progress review in October 2010. The next progress review is scheduled for October 2013.

“As a lay member such lengthy science-based meetings seemed a daunting prospect at first, but with support from the Chair, I have got to know the other members much better and now feel part of the team. I particularly liked the road-shows initiative of the CSG to encourage gynaecological research out in the regions.”

Mrs Hilary Stobart, consumer member

Haematological Oncology Clinical Studies Group



Chair
Professor Andrew Pettitt

Subgroups

Chronic Lymphocytic
Leukaemia (CLL)
Professor Peter Hillmen

Chronic Myeloid
Leukaemia (CML)
Professor Richard Clark

Acute Myeloid
Leukaemia (AML)
Professor Nigel Russell

Acute Lymphocytic
Leukaemia (ALL)
Dr Adele Fielding

Myelodysplastic
Syndromes (MDS)
Dr Dominic Culligan

Myeloproliferative
Neoplasms (MPN)
Professor Claire Harrison

Myeloma
Dr Faith Davies

The size and complexity of the Haematological Oncology CSG portfolio has reached unprecedented levels, due to the adoption of the greatest number of industry-developed studies of all the CSGs. Delivering core trials to time and target is challenging, owing to the number of industry-sponsored studies which sometimes compete for niche study populations and clinical research infrastructure. The Haematological Oncology CSG's communication with other CSGs and industry partners is critical for the successful delivery of both academic and industry studies. To meet these needs, current members of the Haematological Oncology CSG cover a wide range of expertise in the field of haematological oncology, including two consumer members.

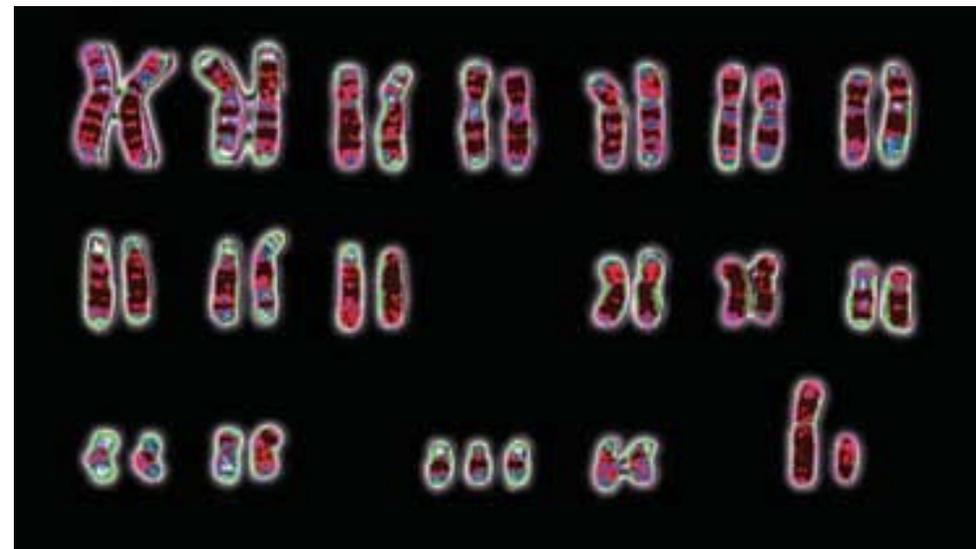
The CSG is heavily committed to developing and supporting trials which improve upon current standards of medical practice. An example of this was seen with the CLL206 study, which looked into campath in combination with high-dose methylprednisolone in CLL patients with p53 tumour suppressor gene deletion. The results of this trial have now led to the use of alemtuzumab combination with pulsed high-dose glucocorticoids being recommended as the treatment of choice in the 2012 British Committee for Standards in Haematology (BCSH) Guidelines.

Similarly, changes were encouraged by the SPIRIT2 data, which compared imatinib with dasatinib in patients with newly-diagnosed chronic phase chronic myeloid leukaemia. The results of this trial coupled with similar data from a recent German trial, has led to the adoption of the 'less than 10% at three months' target

as part of the 2013 ELN guidelines for CML management.

Further improvements of international scale in prognostic medicine, was seen with Myeloma IX, a randomised trial comparing treatment with bisphosphonates, induction chemotherapy regimens and thalidomide maintenance compared with no maintenance therapy. The data generated from this trial has led to zolendronic acid becoming the internationally recognised standard of care for patients and led to the routine application of genetic testing for prognostic purposes.

The Group currently has 87 studies on its portfolio and seven studies in setup; 29 studies have been developed in industry and 37 studies involve international cooperation. In 2012-13, a total of 26 studies opened, half of these were industry developed studies. Haematological oncology studies are conducted across the UK with at least one study open in



Human male karyotype 47, XY, +21. This male has a full chromosome complement plus an extra chromosome 21. Symptoms of this condition include acute leukaemia.

Wessex Reg. Genetics Centre, Wellcome Images.

40 research networks.

In 2012-13, 5671 patients were recruited to haematological Oncology studies, representing 43% of the haematological cancer cases in the UK and 9.1% of all cancer patients recruited into UK clinical studies in 2012-13.

In 2012-13, the key achievements of the Group were the successful completions of three major phase III trials including the AML16 trial, which evaluated several relevant therapeutic questions in Acute Myeloid Leukaemia, as well as the SPIRIT2 and Myeloma IX trials. The Haematological Oncology CSG also gained CTAAC approval for three new phase III trials in key areas, such as SPIRIT3, while

maintaining good recruitment to other key trials on the portfolio.

The main priorities of the Haematological Oncology CSG are to maintain recruitment into core NCRI studies across the portfolio and to develop and successfully deliver major trials. Gaps still exist in MDS and MPN, which are therefore priority areas for further development. A CSG member has also been newly appointed to oversee all transplant studies across the portfolio, which have struggled to recruit in the past.

The Group successfully passed their progress review in February 2012, with the next one scheduled for February 2015.

We've been impressed by the wide range of clinical studies carried out by the Group and know patient recruitment levels are amongst the highest of all the CSGs. The challenges for the Group are to keep abreast of the new drugs and treatments becoming available to trial and make sure we get the right ones from bench to bedside as quickly and safely as possible.

Mr John Reeve & Mrs Lesley Roberts, consumer members

Head & Neck Cancer Clinical Studies Group



Chair
Professor Hisham
Mehanna

Subgroups
Thyroid
Dr Laura Moss

Systemic Therapy &
Radiotherapy
Professor Kevin
Harrington

Survivorship
Professor Steven
Thomas

Surgery & Localised
Therapies
Professor Richard Shaw

The main aim of the Head and Neck Cancer CSG is to maintain the record levels of recruitment achieved in the previous year. Two gap areas were previously identified in the Head and Neck CSG portfolio: the elderly population and 'radiosensitisers'. Our Group has made great strides in developing studies in these areas. We have also developed fellowships in clinical trials, an initiative that is now being adopted in other CSGs to involve more widespread research talent. The Head & Neck CSG is chaired by Professor Hisham Mehanna and benefits from the input of two consumer members.

Committed to developing and supporting landmark, practice changing studies, the Group oversee a vast portfolio of studies. The HiLO study, which looked into to the use of radioiodine dosage and human thyroid stimulating hormone following surgery for thyroid cancer, has had results published in the *New England Journal of Medicine*. These results are now significantly changing the clinical practice of oncologists and endocrinologists giving post-operative radio-iodine ablation to thyroid cancer patients. Prescribed dosage has now been decreased considerably as a result of this study and adoption of this method has proceeded rapidly in the UK. In addition PARSPORT, A study of parotid-sparing radiotherapy, continues to aid head and neck centres in making the case for adopting intensity-modulated

radiation therapy (IMRT) as their routine treatment.

The Group's key successes in 2012-13 were increasing patient entry into studies to yet another record high; establishing several new studies in the target gap areas identified by the CSG and launching national fellowships to increase expertise in clinical trials in head and neck cancer.

The Group currently has 60 studies on its portfolio; 14 studies are in set-up, five are industry developed and 12 studies involve international cooperation. In 2012-13, a total of 15 head and neck studies opened to recruitment and trials are widespread in the UK with at least one study active in 40 research networks.

In 2012-13, 3055 patients were recruited to head and neck studies, representing 32.1% of the patients reported with head

The Group's key successes in 2012-13 were increasing patient entry into studies to yet another record high.



Patient on MRI scanner.

Thinkstock Images,
Image library, Cancer
Research UK

and neck cancers in the UK for that year. 4.9% of all cancer patients going into clinical studies were recruited to head and neck studies, and 7.2% of all patients recruited into head and neck cancer studies enrolled on interventional studies. The Group also actively participates in the International Rare Cancers Initiative (IRCI).

Future aims of the Head & Neck Cancer CSG are to maintain a track record of high recruitment; develop studies for the remaining gap areas and nurture stronger links with industrial partners and international groups.

The Group had a successful progress review in February 2012. The next review is scheduled for February 2015.

“It is a pleasure to be a consumer member of a group in which there is an atmosphere of complete respect between clinicians and consumers. The consumer members have played a part in all the Group's activities. Our involvement ranges from the review of patient information up to membership of trial steering committees or becoming a co-investigator. I particularly welcome the increasing emphasis on targeted treatments in the work of the Group.”

Mr Malcolm Babb, consumer member

Lung Cancer Clinical Studies Group



Chair
Dr Marianne Nicolson

Subgroups
Screening, Smoking Cessation & Early Diagnosis
Dr Robert Rintoul

Loco-regional Disease (LORD)
Dr Matthew Hatton

Mesothelioma
Professor Dean Fennell

Advanced Disease
Dr Sanjay Popat

The three main priorities for the Lung Cancer CSG are trial development and recruitment, exploitation of molecular advances and national promotion of good clinical practice through research. As lung cancer has now taken precedence in the CRUK Stratified Medicines Programme, recruitment to lung cancer studies will be prioritised in all UK regions, making it an exciting time for the Lung CSG. Chaired by Dr Marianne Nicolson, the Lung CGS has two consumer members who represent patient, carer and public views.

The CSG has supported and delivered on trials to improve treatments and outcomes for lung cancer patients. The BTOG2 drug study in stage IIIB/IV non-small cell lung cancer, showed 'doublet' chemotherapy using gemcitabine with carboplatin as being effective as gemcitabine and cisplatin. This study increased clinicians' confidence in administering higher doses of carboplatin and providing more effective treatments to patients.

Similarly, data from the FRAGMATIC study, a clinical trial investigating the effect of anticoagulant therapy added to standard therapy in patients with lung cancer will be presented at World Lung in October 2013. This study will guide practice in reducing thromboembolic risk in lung cancer patients.

The Group also has aims to collaborate in developing studies

which confront emerging issues in research, such as early diagnosis of lung cancer. The UK screening study has seen successful recruitment with careful and dynamic stewardship involving two CSG members who sit on the study steering group. There has also been great progress

in the subgroups developing radiotherapy trials and, in the near future, there will be an excellent array of studies for patients with stage III disease. Improvement of links with international

groups means the UK is well represented on EORTC, ETOP and the rare tumours group which includes thymoma. The active engagement of CSG members' ensures CSG involvement at an earlier stage of international study development, both in systemic and local therapies.

The Group currently has 57 studies on its portfolio; 19 are

Improvement of links with international groups means the UK is well represented on EORTC, ETOP and the rare tumours group which includes thymoma.



A doctor examining a chest x-ray

Thinkstock images.
Image Library Cancer Research UK

studies that have been developed in partnership with industry and 22 involve international collaboration. For 2012-13, a total of 18 studies opened, eleven of which were developed in industry and at least one lung cancer study is active in 40 research network within the UK, allowing widespread recruitment.

In 2012-13, 3199 patients were recruited to lung studies, representing 7.6% of all lung cancer patients within the UK; 2.8% of those recruited to lung cancer studies were recruited to interventional studies. During that same year, 5.1% of all UK cancer patients entering clinical trials were recruited to lung cancer studies. The Group actively participates in International Rare Cancer Initiative (IRCI).

The Group's aims are to organise, facilitate and encourage the wider lung cancer community to send biopsy samples for analysis and provide access for patients to receive novel targeted drugs as part of the CRUK Stratified Medicine Programme. With most therapy efforts focused on NSCLC and mesothelioma, the Lung CSG strives to ensure there is a balance on the portfolio by including the more challenging SCLC. The Lung Cancer CSG also continues to encourage group members to participate in the hard work that results from NICE reviews of lung cancer treatments. The Group had a successful progress review in January 2011, with the next one due in January 2014.

“Being a member of a CSG is both personally challenging and scientifically important. Assisting scientific and clinical colleagues maintain an appropriate focus on patient and public interest issues within programmes of research is my continuing priority.”

Mr Matthew Baker, consumer member

Lymphoma Clinical Studies Group



Chair
Professor John Radford

Subgroups
Low Grade Lymphoma
Professor Simon Rule

High Grade Lymphoma
Dr Andrew McMillan

Hodgkin Lymphoma
Dr Eve Gallop-Evans

Paediatric Non-Hodgkin
Lymphoma
Dr Amos Burke

With the central objective of improving patient outcomes, the Lymphoma CSG aims to design and perform relevant, internationally competitive and potentially practice-changing studies in lymphoma. In addition, for success in effective trial design and clinical study, our Group is developing strong collaborations with researchers in basic, translational science and industry. Chaired by Professor John Radford, the Lymphoma CSG has a range of clinical, consumer and scientific members.

Central to the aims of this CSG, the Group has developed studies which have led to improvements in lymphoma treatment for better patient outcomes and enhanced quality of life. For example LY09, a study of therapy in advanced Hodgkin lymphoma, comparing doxorubicin, bleomycin, vinblastine, and dacarbazine (ABVD) with two multidrug regimens, confirmed ABVD as the standard first-line therapy for advanced disease in the UK. In addition, the RAPID trial, which looked into the role of FDG-PET imaging across clinical stages IA/ IIA of Hodgkin lymphoma, revealed that patients with early stage disease and a negative PET scan after three cycles of ABVD have an excellent outcome without the addition of consolidation radiotherapy. These findings, which enhance quality of life by reducing unnecessary treatment, are beginning to influence treatment protocols worldwide for lymphoma patients.

The Lymphoma CSG has also supported trials which have produced high-impacting results in the lymphoma research community. The R-CHOP 14 vs 21 study, which looked into

extended intervals between treatments with the drug R-CHOP, for newly diagnosed patients with diffuse large B cell non-Hodgkin lymphoma, showed no advantage for accelerated treatment and confirmed R-CHOP given every three weeks, rather than two, as the first-line standard of care. These findings were published in *The Lancet*. The study also showed that R-CHOP given every two weeks with haemopoietic growth factor support could be safely delivered without excessive toxicity. Similarly, the RGCVP trial defined alternative drugs for patients with diffuse large B cell lymphoma whom are unsuitable for treatment with R-CHOP.

Other accomplishments of the Group include participation in an international study of ibrutinib in relapsed and refractory mantle cell lymphoma which showed an unprecedented response rate of 76% in their patient group. The RAPID and RATHL trials in Hodgkin lymphoma, where PET response adapted therapy was evaluated, have led to establishing a UK wide network of quality assured PET scanners linked to central review process, and the development of the five-point Deauville score for



Preparing a blood smear by spreading a drop of blood on a microscope slide using the edge of a second slide.

Sotiris Zafeiris,
Wellcome Images.

PET scan reporting, a system that is now used internationally.

The Group currently has 46 studies on its portfolio; 17 of these studies are industry developed and 24 involve international cooperation. In addition, there are 13 studies in set-up. In 2012-13, a total of eleven studies opened and recruitment was widespread with at least one lymphoma study open in 39 research networks within the UK.

In total, 4009 patients were recruited to lymphoma studies in 2012-13, including 294 patients being recruited to industry-developed studies. Collectively, this represents 28.9% of cases in the UK in 2012-13. During this time, 6.4% of all cancer patients going into clinical trials were recruited to lymphoma studies.

Future priorities of the Lymphoma CSG are to finalise new academic trial designs in early and advanced Hodgkin lymphoma, link these to

relevant translational studies and to secure funding. In aggressive non-Hodgkin lymphoma, the priority is to complete REMODL-B, a clinical trial of molecular guided therapy for diffuse large B-cell lymphoma with the drug bortezomib, and design an internationally competitive trial to replace it.

Another priority in indolent non-Hodgkin lymphoma is to complete PACIFICCO; a trial of alkylator drug combination in follicular lymphoma immuno-chemotherapy for older and frailer patients. Following this, the Group also endeavour to design a new trial testing relevant new molecules to replace the currently recruiting GALLIUM study; an industry supported trial comparing drug treatments for previously untreated patients with non-Hodgkin lymphoma. The Group had a successful progress review in May 2011, with the next scheduled for May 2014.

“ ‘I have thoroughly enjoyed being able to carry out this piece of work and feel privileged to be part of the Lymphoma Clinical Studies Group.’ ”

Mr Melyvn Rust, consumer member

Melanoma CSG Clinical Studies Group



Chair
Dr Pippa Corrie

Subgroups
Non-Melanoma Skin
Cancer
Dr Catherine Harwood

The Melanoma CSG is a multidisciplinary group developing new research studies in melanoma and non-melanoma skin cancer. Our Group is currently prioritising research in rare skin cancer subtypes, namely uveal and mucosal melanomas and Merkel cell cancer, as well as surgical and radiotherapy studies. In cutaneous melanoma, a busy portfolio is dominated by commercially sponsored studies. Through diverse membership, our CSG has representation from many disciplines within the field of melanoma and non-melanoma skin cancers and encompasses the views of patient and public via input of two consumer members.

In December 2012, the Melanoma CSG played a significant role in securing the final, positive NICE outcome; the first two drugs shown to significantly improve survival of metastatic melanoma patients (vemurafenib and ipilimumab) were approved by NICE. Both drugs had previously been evaluated in multicentre trials which included UK patients.

Members within the Melanoma CSG have also been active in securing UK involvement in a highly competitive international landscape and ensuring strategic placement with sites across the country, enabling new sites to be selected to work with industry for the first time, in some cases.

Currently, there are 23 studies open on the melanoma portfolio, eight of these being industry-sponsored studies. Eleven trials have opened within the past year, of which, six were industry-

sponsored studies. International collaboration is an important aspect of melanoma research. Ten of the melanoma portfolio studies are international multicentre trials. The CSG has worked through the international Rare Cancers Initiative (IRC) to establish a new trial for advanced uveal melanoma which will open in 2013.

In 2012–13, 674 melanoma cancer patients were recruited into clinical studies, representing 5.4% of the reported cases of melanoma and 1.1% of all cancer patients entered into a clinical trials in the UK for that year. 250 of these patients were recruited into industry supported studies. Recruitment is nationwide with least one melanoma study currently active in each of 35 regional research networks. This year, the results of three key Melanoma CSG-led national multicentre trials, AVAST-M, DOCMEK, a

In December 2012, the Melanoma CSG played a significant role in securing the final, positive NICE outcome.



Woman applying sunscreen.

Thinkstock images, Image Library, Cancer Research UK.

study looking at docetaxel with or without AZD6244 in wildtype BRAF advanced melanoma, and SUAVE, a trial comparing drug treatment in patients with metastatic uveal melanoma, were all presented at the ASCO 2013 conference.

The Group's future priorities are to secure new studies in uveal melanoma, surgery and radiotherapy and establish trials in non-melanoma skin cancer. Following the highly successful recruitment to AVAST-M, a study

of adjuvant therapy in high risk cutaneous melanoma, the group will seek opportunities to develop an adjuvant trial in wildtype BRAF patients at high risk of recurrence. The CSG contributes annually to the national melanoma conference, Focus on Melanoma, which was last held in October 2013 at the Royal College of Physicians, London. The CSG had a successful progress review in June of 2010. The next review is due in 2014.

“It is an honour to serve as a consumer member of the Melanoma CSG. Patient and carer representatives' views are listened to and it is possible – perhaps even routine – for us to make a contribution to the group's deliberations and decisions. Attending CSG meetings is also immensely helpful in improving my understanding of the latest developments in the fight against melanoma: insights that are valuable for me in my work for the new national melanoma charity: Melanoma Focus.

Mr Simon Rodwell, consumer member

Palliative & Supportive Care Clinical Studies Group



Chair
Professor Michael Bennett

Subgroups
Rehabilitation
Dr Andrew Wilcock

Vascular
Dr Vaughan Keeley

Pain & Neuropathy
Professor Marie Fallon

Gastrointestinal
Professor Sam Ahmedzai

By bringing together palliative care, supportive care and complementary therapy interests, the newly constituted Palliative & Supportive Care CSG aims to enable and improve research to focus on the symptoms or consequences of disease and of cancer treatment. To assist in the delivery of our Group's key aims, four subgroups have been established to build on the previous Palliative Care CSG successes. Each subgroup has a lead with particular expertise in that field and includes a mix of full CSG members and external members. Our group also benefits from the input of two consumer members.

Significant headway continues to be made across research networks to ensure awareness of what palliative care studies are available on the portfolio and to ensure there is peer support for palliative care nurses. There is now interest from specialist palliative care nurses to set up a Palliative Care Research Nurse Forum which could be hosted by networks on a rotational basis.

An ongoing priority is to build research capacity by developing a portfolio of palliative and supportive care studies within the National Cancer Research Networks and to have increased recruitment to these studies both academic and industry-developed. The focus of the individual subgroups in developing at least two studies each encourages greater participation from the research

community to consider new research questions which are multi-centred and funded.

Currently, there are 24 studies open on the portfolio; five studies are industry-developed; six trials opened in 2012-13 and 16 are in set-up. Seven open studies

are focusing on pain and neuropathy following treatment for cancer.

International collaboration has seen eight studies opening outside of the UK.

In 2012-13, 702 palliative and supportive care patients were recruited into clinical studies within the UK. Overall, 56% of these patients were enrolled in interventional studies and a total of 71 patients were recruited into industry supported studies. A total of 1.0% of all cancer patients entered into clinical trials were palliative and supportive care patients. At least

There is now interest from specialist palliative care nurses to set up a Palliative Care Research Nurse Forum which could be hosted by networks on a rotational basis.



A nurse offers advice to a patient.

Image library, Cancer Research UK

one palliative and supportive care study is currently active in 27 research networks.

The Group is committed to continuing to develop collaborative partnerships with industry for centre selection and set up via the NIHR industry lead, have greater involvement in end

of life studies for non-cancer patients and, where possible, assist in the set-up of additional local palliative care specialty groups.

The Palliative & Supportive Care CSG had a successful progress review in May of 2010. The next review is due in 2014.

“The Palliative and Supportive Care CSG is a new group (formed in September 2012) bringing together researchers, clinicians, and consumers interested in palliative care, supportive care and complementary therapies. In just one meeting the Group agreed on the formation of 4 new subgroups which are currently focusing and delivering on a small number of important areas for research. The consumer members have been asked to advise on trial protocols; have become co-applicants on trials; and have been asked to gather views on issues that are of concern to patients and carers such as “What are the optimal methods of managing missing data and disseminating findings in palliative care randomised controlled trials?”

The consumer members have felt valuable, useful, and have quickly become an integral part of the new team.

Mrs Lesley Turner, consumer member

”

Primary Care Clinical Studies Group



Chair
Professor Clare
Wilkinson

Subgroups
Survivorship
Professor Eila Watson

Screening
Dr Christine Campbell

Early Diagnosis
Professor Richard Neal

The work of the Primary Care CSG reflects the leading edge of primary care oncology research, both nationally and internationally. With recruitment of new national leaders in primary care to the Group, our CSG has ambitious aims for the future, particularly in the field of earlier diagnosis of primary cancers and of recurrent disease. There are various specialties represented in the membership of the Primary Care CSG including two consumer members.

A large proportion of the developing studies cover general practices and their patients, across England, Wales and Scotland. For example, the CANDID study, which seeks to work out which symptoms and examination findings are the most effective in the early prediction of lung or colon cancer, will recruit 20,000 patients, from eight centres in the UK, with 60-70 practices per centre, and about 200 general practitioners per centre.

As a cross-cutting group, links with other CSGs are very important for the Primary Care CSG. The Group has established strong links with Melanoma, Lung, TYA, and Psychosocial Oncology CSGs. Central to the Group's focus, the Group interacts with all CSGs on screening, prevention and early diagnosis via the NCRI Screening,

Prevention and Early Diagnosis (SPED; see page 50) Advisory Group.

The Group has succeeded in establishing international collaboration through its work with Ca-PRI (Cancer and Primary Care International Research Network) and the Chair's review of the Danish Cancer Society's International Research Centre for the diagnosis of cancer. The Group also had much success with the funding of TOPCAT-P and Prospective; 'quality of life' survivorship trials.

There are currently three studies open on the portfolio, one of which opened within the last reporting year and another is in set-up. At least one primary care study is currently open in 13 research networks. In 2012-13, 64 primary care patients were recruited into clinical studies within the UK.

The Group also had much success with the funding of TOPCAT-P and Prospective; 'quality of life' survivorship trials.



A doctor offers advice to a husband and wife.

Image library, Cancer Research UK

Recruitment data cannot be judged for this Group in the same manner as for cancer specific groups. This is for three reasons: firstly, primary care studies recruit patients who do not have cancer, as well as those who do; secondly, much of the high quality research conducted within primary care is epidemiological and does not involve randomised controlled trials, e.g. cohort studies, case-control studies, pilot trials; thirdly, there is wide overlap with the PCRN portfolio. These studies, however, reflect pioneering research within primary care oncology, in both national and international terms and will lead

to the primary care-based trials of the future.

Some of the priorities for the Group's forthcoming year include building on the progress of the major studies, and making a strong cross-NCRI contribution through collaborations, such as SPED. The CSG presented at a range of collaborative meetings throughout the year, such as the NCRI & NCIN conferences, to showcase existing trials and awareness of scientific practices. The CSG had a successful progress review in February of 2011. The next review is due in 2014.

“Consumer involvement at the Primary Care CSG is of true equality at the table, with its thoughtful dialogue considering survivorship, early diagnosis, screening and prevention directly influenced by our observations.”

Mr Paul Charlton, consumer member

Prostate Cancer Clinical Studies Group



Chair
Professor Malcolm
Mason

Subgroups
Advanced Disease
Dr Robert Jones

Localised Disease
Mr Vincent
Gnanapragasam

The Prostate Cancer CSG aims to implement and support the progress of trials ranging from translational to clinical studies. Our Group has been fortunate in attracting membership from an unprecedented number of talented individuals, spanning many medical disciplines. This, coupled with a sustained high level of activity in the portfolio, has ensured that the Prostate Cancer CSG remains dynamic. In recent years, there have been remarkable advances in prostate cancer research, which has shaped the priorities and activities of our Group.

This Group achieves impressive recruitment to major 'flagship' studies supported by the CSGs such as STAMPEDE, a study of systemic therapy in advancing or metastatic prostate cancer, and RADICALS, a study looking into radiotherapy and androgen deprivation in combination after local surgery.

The Prostate Cancer CSG also regularly interacts with other CSGs, principally the other urological CSGs and the NCRI Screening Prevention and Early Diagnosis (SPED; see page 50) Advisory Group for studies and initiatives. Future aims of the Group include expanding links with the cross-cutting CSGs in order to cover areas such as survivorship, supportive care and co-morbidities in prostate cancer.

There are currently 44 studies open on the prostate cancer portfolio. Seventeen studies

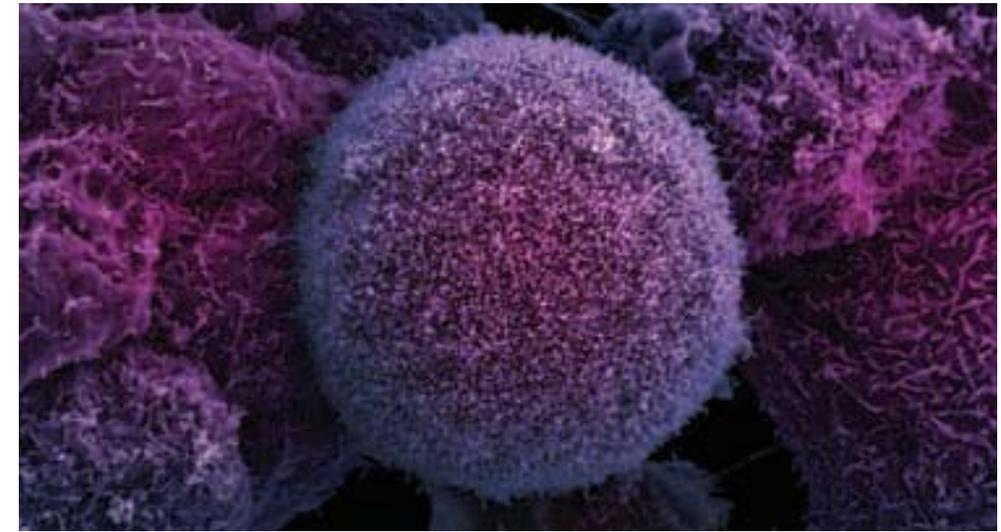
opened in 2012–13 alone, including six industry developed studies. In total, 29 studies are currently in setup and 13 have opened outside the UK. Overall, 16 of all open studies focus on treatment in refractory metastatic disease. Recruitment to studies is widespread with at least one prostate cancer study open in 40 research networks.

In 2012–13, 4623 prostate cancer patients were recruited into UK clinical studies, representing 11.4% of the total incidence of prostate cancer within the UK.

For this same period, 7.3% of all cancer patients entered into clinical trials within the UK were prostate cancer patients. Overall, 5.8% of prostate cancer patients enrolled into interventional studies.

Future key challenges for the Prostate Cancer CSG are meeting the growing demand for Group

In 2012–13, 4623 prostate cancer patients were recruited into UK clinical studies, representing 11.4% of the total incidence of prostate cancer within the UK.



Prostate Cancer cell image taken using a Scanning Electron Microscope.

EM Unit, London
Research Institute.

review with the increase in research activity. 2012–13 has seen the Group maintain and, in some areas, increase trial recruitment. This is, in part, a reflection of the unprecedented interest and enthusiasm of clinical researchers in the UK and the availability of a number of large-scale studies on the portfolio. Coupled with further review requests for industry studies and NICE appraisals, this reflects a source of great optimism for future research in prostate cancer and

also a working priority to maintain positive momentum.

The Prostate Cancer CSG, together with the Renal, Testis and Bladder CSGs has held three Urological Trials Meeting to encourage and advance discussions and collaboration for studies. The Prostate Cancer CSG had a successful progress review in May 2013, with the next review due in 2016.

“The Prostate Cancer CSG is highly proactive and gives me, as a consumer, the chance to be involved at the forefront of the scrutiny of the wide range of clinical trials which come before the committee.”

Dr Michael Phillips, consumer member

Psychosocial Oncology Clinical Studies Group



Chair
Dr Jo Armes

Subgroups
Service Delivery &
Evaluation
Dr Nick Hulbert-Williams

Lifestyle & Behavioural
Change
Dr Gill Hubbard

Patient Experience &
PROMS
Dr Lynn Calman

The aim of the Psychosocial Oncology CSG is to explore, endorse and support studies concerned with aspects of cancer that go beyond medical treatment and include lifestyle, psychological and social aspects of cancer. As this is a cross-cutting CSG, it is concerned with all types of cancer and a range of patient needs. Links with other tumour-specific CSGs are imperative for our group; there are strong links with Primary Care, Breast and Head & Neck Cancer CSGs. Collaborative efforts have extended internationally with CSG member Dr Hulbert-Williams' appointment to the Research Committee of the International Psycho-Oncology Society (IPOS), and acting as liaison between the NCRI and a number of international groups. This Group includes two consumer members.

Recently, the main achievements for the Group were gaining new members who represent many disciplines of treatment and research, the successful set-up of two of the new subgroups and developing a new group strategy. The Psychosocial Oncology CSG also organised a session for the annual conference of The British Psychosocial Oncology Society (BPOS) to establish and enhance collaborative efforts with BPOS. The Group also presented at IPOS, International Congress of Psycho-Oncology in Brisbane, Australia; 'Developing a nationally collaborative framework for psychosocial oncology research: a review of the UK NCRI Psychosocial Oncology Clinical Studies Group.'

Securing funding for psychosocial

In 2012-13, international collaboration saw seven trials opening outside the UK.

research is a common challenge for all the subgroups and in particular there is a lack of specific funding for survivorship, theory building and intervention development work. A further common challenge is agreeing payment of treatment costs under the AcoRD agreement for behavioural/non-drug interventions. Currently, there are 20 studies open on the portfolio, six of these have opened in the past year and a further eight are in set-up. In 2012-13, international collaboration saw seven trials opening outside the UK and a least one study active in 22 research networks.

In 2012-13, 2.1% of all patients entered into UK clinical trials were psychosocial oncology patients.



Research nurse with female patient.
Image Library, Cancer Research UK

This amounts to 1323 cancer patients being recruited into psychosocial oncology clinical studies with 12% of these patients entering interventional studies.

The Group's priorities include: successfully developing grant applications for research funding, visiting all CSGs over the next 12 months to outline the revised

strategy and subgroup structure and identify opportunities for collaborative research and ensuring the list of publications associated with studies registered in the Psychosocial Oncology portfolio is complete to demonstrate the value and contribution of the CSG.

“As a patient, I'd say the work of this Group has the potential to affect every cancer patient. The Group deals with studies in areas patients talk about all the time, so I relish being involved.”

Ms Carolyn Morris, consumer member.

Renal Cancer Clinical Studies Group



Chair
Dr James Larkin

Subgroup
Surgical
Mr Naem Soomro

The Renal Cancer CSG has been successful in expanding the trial portfolio and increasing recruitment with a balance of academically-led and industry adopted trials. The incidence of renal cancer is increasing, with 9639 cases and 4062 deaths in the UK in 2010. The development of new drugs for the treatment of renal cancer in the last 5 years and the use of new minimally invasive technologies to treat small tumours has changed the therapeutic landscape for renal cancer. The Group's current structure provides robust expertise in renal oncology, such as radiologists, surgeons, medical oncologists and basic science research. Our membership includes three active consumer members who provide focus and advice on patient and public views of treatment.

The Group has been successful in supporting trials developed with industry, such as A-PREDICT (Pfizer), a phase II study of axitinib in patients with metastatic renal cell cancer unsuitable for nephrectomy, which opened to recruitment in 2012 and ZEBRA (AstraZeneca) a randomised phase II study comparing AZD2014 vs everolimus in metastatic renal cancer and progression on VEGF targeted therapy, which opened to recruitment in 2013. Further joint trials are being developed with industry.

A key achievement for the Group has been effectively identifying and overcoming barriers to recruitment on trials supported by the CSG, resulting in overall increased recruitment trends since

The Group has been effectively identifying and over-coming barriers to recruitment on trials supported by the CSG, resulting in overall increased recruitment trends since 2007.

2007 and early full recruitment to the SORCE trial, a phase III study comparing sorafenib with placebo in patients with resected primary renal cell carcinoma at high or intermediate risk of relapse. Further success was seen with published results on intra-tumour heterogeneity from the E-Predict trial, a phase II study of preoperative everolimus in metastatic renal cell cancer in the *New England Journal of Medicine* (Gerlinger et al). This was the second most cited scientific paper published in 2012.

There are 25 studies currently open on the portfolio; six of these are industry developed and a further five studies are in set-up. Nine trials opened in 2012-13



Multipipette laboratory equipment
Image Library, Cancer Research UK

and seven of these studies are currently focusing on surgery in renal cancer. Three studies have opened outside the UK as a result of the Group's international collaboration and at least one renal study is currently open in 37 research networks.

In 2012-13, 1025 renal cancer patients were recruited into clinical studies, representing 12.6% of cases of renal cancer in the UK; of these, 97 patients were recruited into commercial studies and 8.6% of recruited patients were entered into interventional studies. In 2012-13, 1.6% of all cancer patients entered into clinical trials were renal cancer patients.

The main priority of the Group is to continue to manage the

ever-expanding renal portfolio, particularly with respect to poorly recruiting trials. Another key challenge is to address balance in the types of trials, so that full coverage is provided for all stages and types of renal cancer, avoiding overlap and duplication of topic and conflicting recruitment.

Following three successful NCRI Urological Trials Meetings, held in collaboration with the three other urological CSGs, another meeting is planned for 2014. The Renal Cancer recently enjoyed a successful progress review in June 2013. Then next review is due in 2016.

“Discussions on the development of research into renal cancer and on the associated portfolio of clinical trials are most helpful to consumer representatives sitting on trial management groups.”

Dr Pat Hanlon, consumer member

Sarcoma Clinical Studies Group



Chair
Professor Penella Woll

Subgroups
Bone Sarcoma
Professor Jeremy Whelan

Young Onset Soft Tissue
Sarcoma (YOSS)
Dr Bernadette Brennan

The Sarcoma CSG has a varied trial portfolio with a good balance of investigator-led, cooperative group and industry trials. The Group has participated in international trials for bone tumours and has demonstrated efficient delivery of national trials of radiotherapy and chemotherapy in soft tissue sarcomas. Fulfilling patient need and confronting emerging gaps in research, there are an increasing number of trials focusing on rare sarcoma subtypes. Our Group's membership is structured to cover all sarcoma diseases and includes two consumer members to advise on patient views.

The Sarcoma CSG has supported many studies which have led to changes in clinical practice. Recently, results from the Sarcoma CSG supported PALETTE trial (EORTC 62072) demonstrated that pazopanib improved progression-free survival in second- and third-line therapy for advanced soft tissue sarcoma. As a result, pazopanib is now available through the Cancer Drugs Fund (CDF). Similarly for bone sarcomas, studies such as EURAMOS-1, a randomised trial of the European and American osteosarcoma study group to optimise treatment strategies for resectable osteosarcoma, have shaped routine clinical practice.

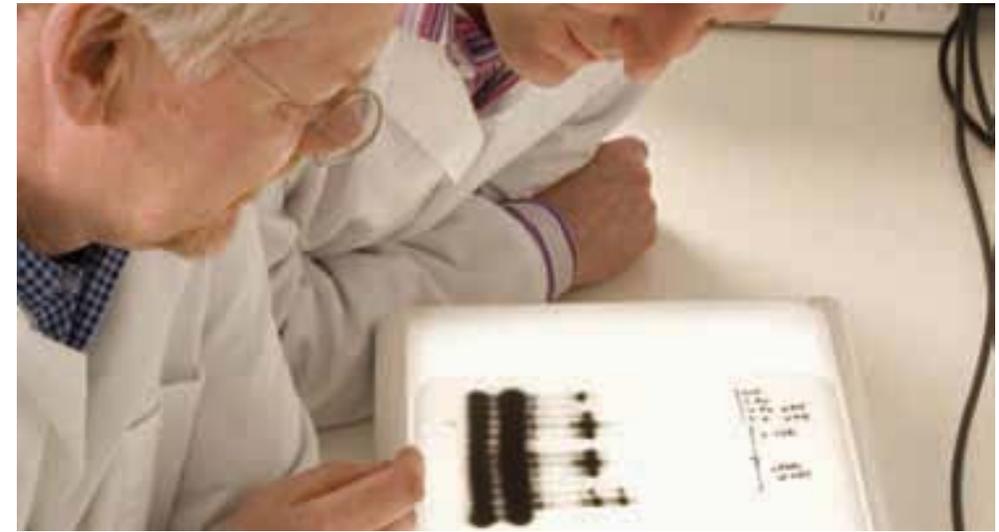
The routine management of bone and soft tissue sarcomas has been guided by NCRi trials. In particular, trials such as EORTC 62931 and EORTC 62012 are the foundation of sarcoma

management in the UK and Europe. EORTC 62931, the study of adjuvant chemotherapy with doxorubicin, ifosfamide and lenograstim for surgically removed soft tissue sarcoma, confirmed that adjuvant chemotherapy offers no survival advantage over observation alone, in resected high-risk soft tissue sarcoma.

EORTC 62012, a randomised trial of single-agent doxorubicin vs doxorubicin plus ifosfamide in the first-line treatment of advanced or metastatic soft tissue sarcoma, demonstrated no survival advantage for doxorubicin and ifosfamide over doxorubicin alone, in first-line chemotherapy for advanced soft tissue sarcoma. These results were presented at ECCO.

The Group currently has 17 studies on its portfolio; two are industry-sponsored studies and six are international collaborative studies.

The routine management of bone and soft tissue sarcomas has been guided by NCRi trials.



Scientists examining an autoradiograph
Image library, Cancer Research UK

In 2012–13, seven new studies opened and three were in set-up. The majority of these studies were in soft tissue sarcoma. Twenty-seven research networks within the UK participated in sarcoma trials in 2012–13.

In 2012–13, 423 patients participated in sarcoma studies, including ten patients in industry-sponsored studies. Overall, 7.8% of UK sarcoma patients took part in clinical studies in 2012–12. The Group also actively participates in the International Rare Cancers Initiative (IRCI) in order to develop studies in the rarer sarcomas.

The Group has further achievements in 2012–13 with the opening of two new early phase trials in rare sarcomas: SCART, for patients with AIDS-associated Kaposi's sarcoma and VIT-0910, for young people with relapsed rhabdomyosarcoma.

Forefront to the Group's aims is maintaining a balance between large randomised trials

in broad tumour groups such as EuroEWING-2012, for Ewing sarcoma, and smaller trials in rare sarcoma subtypes, such as CASPS in alveolar soft part sarcoma. These objectives will be driven through collaboration with international groups (including EORTC, IRCI, SARC) and industry partners. Further aims of the Group include increasing the yield of translational science from every trial by incorporating biomarker and imaging endpoints, with a purpose of improving methods and outcomes. The Sarcoma CSG also aims to continue to develop relationships with other cancer CSGs, including Biomarkers & Imaging, Gastrointestinal, Gynaecological, Psychosocial Oncology and TYA. The Group enjoyed a successful progress review in June 2013. The next one is scheduled for June 2016.

Teenage & Young Adults Clinical Studies Group



Chair
Professor Jeremy Whelan

Subgroups
Biological Studies
Dr Clare Rowntree

Health Services
Research (HSR)
Professor Faith Gibson

The Teenage & Young Adult (TYA) CSG has a remit to ensure that teenagers and young adults, broadly those aged 13–24 years at diagnosis, are considered during protocol development and have opportunities to enter relevant NIHR cancer studies. Additionally, the TYA CSG is charged with developing studies examining psychosocial factors, the biology of cancer and the optimal provision of healthcare for young people with cancer. Chaired by Professor Jeremy Whelan, our Group has a full time researcher, Dr Lorna Fern and membership includes two young people who represent the patient voice.

To date, the work of the Group has concentrated on improving access to cancer clinical trials for young people and a national evaluation of healthcare provision. The Group currently has three studies in its portfolio. BRIGHTLIGHT, which opened in 2012, is a NIHR-funded national evaluation of cancer services in England for young people with cancer. This study is open in 99 trusts and all 32 networks.

BRIGHTLIGHT is the largest cohort study of young people with cancer internationally; the study looks at cancer care received by young people aged 13–24 years at diagnosis, and will be used to improve cancer services for current and future patients. Results will emerge in late 2014. The TYA CSG also actively participates in the International Rare Cancer Initiatives (IRCI).

Following a campaign by the Group, there is now universal consensus that there are no scientific or ethical reasons for any trial to have a lower age limit of 18.

The TYA CSG began benchmarking and tracking recruitment to cancer clinical trials in 2006. The Group has identified barriers and facilitators to trial recruitment and since 2006 the proportion of young people entering clinical trials during 2005–2010 has improved. In particular,

identifying age eligibility criteria as a barrier has allowed the Group to work with the NIHR, CTAAC and now the ECMC Network to ensure that emerging studies have appropriate age eligibility criteria.

Following a campaign by the Group, there is now universal consensus that there are no scientific or ethical reasons for any trial to have a lower age limit of 18. All NIHR cancer trials entering the portfolio will now have a lower age of 16 years 'if' a lower age eligibility criteria must be set, unless there is justification



Teenagers and young adults.

Image library, Cancer Research UK

provided for it to be otherwise.

Another achievement of the Group was the POPP study, which investigated how best to support young people and professionals in discussions around trial entry. These data suggest that trial design, particularly the length of treatment, influences willingness to participate in trials. This information can be used for future trial design.

The Health Services Research Subgroup held a joint education day with the Teenagers and Young Adults with Cancer (TYAC) Research and Registration Subgroup in April 2013. The day,

'Make no bones about it – clinical trials aren't straight forward,' focused on bone sarcomas and issues around entering young people into clinical trials.

Priority areas for the CSG include optimising recruitment to BRIGHTLIGHT and obtaining funding for an NIHR early diagnosis programme grant for children, teenagers and young adults. The Group had a successful progress review in May 2012. The next review is scheduled for May 2015.

“Being part of a Clinical Studies Group helps benefit myself, other patients, the public and future scientific research. The TYA CSG encourages research relevant to teenagers and young adults with cancer, a cohort that requires a specific remit and work streams to address their needs.
Mr Stephen Sutton, consumer member”

Testis Cancer Clinical Studies Group



Chair
Dr Jonathan Joffe

Subgroups
Quality of Life
Dr Danish Mazhar

The Testis Cancer CSG delivers and develops practice-changing clinical studies of international relevance. The work of the Testis cancer CSG confronts a cancer which occurs less often in the population, but still has diverse subtypes of disease. This presents a challenge for designing clinical trials for patients and covering all testicular cancers. Despite these challenges, the CSG continues to punch above its weight, both in comparison with other CSGs within the UK and the international testicular cancer community. The CSG brings together a diverse group of members and includes two consumer members.

There are unique challenges for the Testis Cancer CSG due to the high cure rate already evident in most patient populations and in the small numbers of patients within groups of cancer subtypes. Incremental improvement in outcomes is therefore challenging both clinically and in terms of funding opportunities.

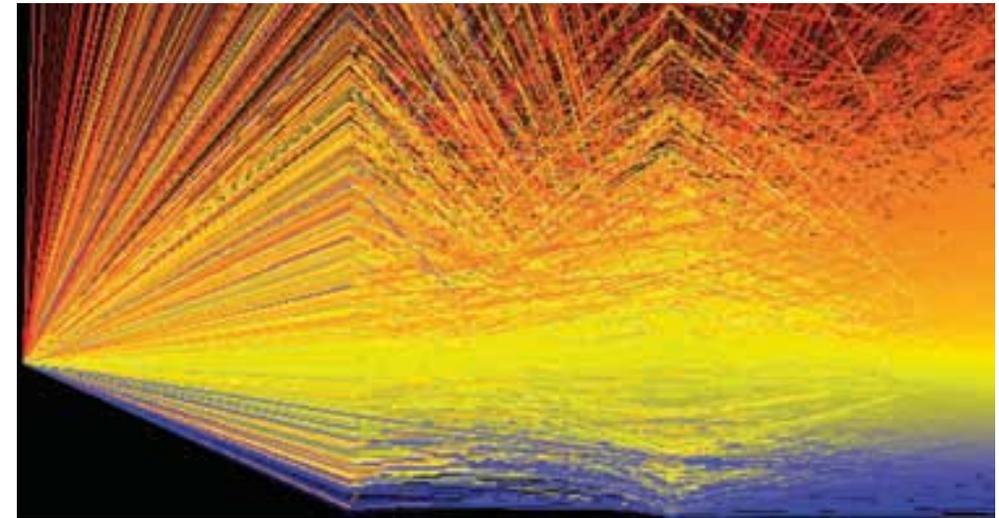
The Group's main motivations are on survivorship issues and understanding of the biology of cancers. This allows for the concentration of effort on developing novel therapies for those patients who may not be cured through current treatment strategies and to protect those who will be cured from the risks of unnecessary treatment, prolonged follow-up and over-investigation.

The Group has developed links with international collaborators in the US, Europe and Australasia to deliver the EA-001 study, a prospective randomised study in

salvage therapy for relapsed germ cell tumours. The Testis cancer CSG members were instrumental in developing this study, which promises to be the largest single prospective international study in this patient population and the UK will be one of the first countries to start recruitment.

Further achievements for the Testis Cancer CSG have been the completion of the UK arm of the European Organisation for Research and Treatment of Cancer (EORTC) Quality of Life (QoL) study in mid- to long-term survivors of testicular and prostate cancer, and the pilot phase of the RESTART feasibility study, a rehabilitation programme for testis cancer patients who have completed treatment. These, and the initial results of the TE03 study of bleomycin dosage for testicular cancer in good prognosis patients, were presented at the ASCO 2013 conference. The Group is also

In 2012-13, 1612 testis cancer patients were recruited into clinical studies, representing 72.2% of the total incidence of testis cancer in the UK.



Gene expression in normal and cancer cells. Computer analysis of data collected from four different DNA chips from normal and cancerous cells are treated. Red represents high levels of gene expression and blue represents low levels.

Veronique Blanc and
Qin Wang, Wellcome
Images

coordinating sample collection from previous trial participants that will allow important studies on prognostic factors and drug resistance.

In 2012-13, there were nine open studies on the portfolio. Two studies opened in 2012-13 and a further eight studies are in set-up. Six open studies are currently focusing on follow-up treatment and quality of life during and after testis cancer treatment. International collaboration has seen the opening of a trial outside the UK and nationwide recruitment is active with at least one testis cancer study currently open in 35 research networks.

In 2012-13, 1612 testis cancer patients were recruited into clinical studies, representing 72.2% of the total incidence of testis cancer in the UK. For the same year, 2.5% of all cancer patients entered into clinical trials were testis cancer patients and 12.4% of the testis cancer patients recruited were enrolled into interventional studies.

Future priorities for the Group are to strategically develop and enhance areas of the portfolio such as good and poor prognosis trials; survivorship and QoL studies; and develop studies on relapsed patient groups through international collaboration. The Group also aims to deliver output from the established translational studies and to maintain the trajectory of recruitment. To improve current clinical practice for diagnosis and treatment, the Group is currently designing a qualitative study of presentation of testicular tumours.

Through cross-representation of members across other CSGs and subgroups, the Testis Cancer CSG is closely linked with groups such as Teenage and Young Adult (TYA), Biomarkers & Imaging, Bladder and Prostate CSGs. The CSG has collaborated with the other urological CSGs over the last 3 years on Annual Urological Trials Meetings. The Testis Cancer CSG had a positive progress review in May 2011; their next review will take place in 2014.

Upper Gastro-intestinal Cancer Clinical Studies Group



Chair
Professor John Primrose

Subgroups
Oesophagogastric
Professor David
Cunningham

Hepatobiliary
Professor John
Bridgewater

Neuroendocrine
Professor Juan Valle

Pancreatic
Dr Stephen Falk

The Upper Gastro-intestinal (GI) Cancer CSG is a highly productive and successful CSG with an extensive portfolio of ongoing trials and a track record of delivering successfully completed studies which are practice changing. With four highly functional subgroups, it can claim to be the most successful grouping involved in upper GI cancer research in the world. Our Group membership, spans England Scotland and Wales and two consumer members, representing patients, carers and public.

High impact and practice-changing research is a recurring theme in this Group's outputs. The Group has had much success in delivering trials, notably Upper GI CSG-driven studies, such as the SCALOP and GEMCAP studies, both looking into treatments of patients with advanced pancreatic cancer; the New EPOC trial, focusing on patients with colorectal liver metastases requiring chemotherapy; and the COUGAR-02, SCOPE REAL-3 and COG trials which focus on a range of treatments for various stages of oesophago-gastric cancers. All of these studies have informed improvements in clinical practice, both nationally and internationally, in treatment of upper GI cancers.

Seven CSG-driven trials were completed in the in 2012-13. A large group of studies were

delivered as high profile presentations at ASCO or ASCO GI in 2013; namely, the NET-01 trial, which looks into neuroendocrine tumour treatment; the TELOVAC study, which compares drug treatments using a vaccine in locally advanced and metastatic pancreatic cancer; and the SCALOP, New EPOC, COUGAR-02, COG and SCOPE trials.

The Upper GI Cancer CSG has an expansive portfolio of 60 open studies; 19 are industry-supported trials. In 2012-13, a total of 17 studies opened to recruitment and 19 studies were in set-up. Responding to the needs of improving patient outcomes, five open studies are focusing on metastatic adenocarcinoma of the pancreas, with a further nine studies focusing on translational medicine in this area. Overall, 23 studies recruit outside of the UK and least

High impacting and practice changing research is a reoccurring theme in the Group's outputs.



Abdominal surgery
Image Library, Cancer
Research UK.

one upper GI cancer study is open in 40 research networks, allowing widespread recruitment to trials in upper GI cancer.

In 2012-13, 3741 upper GI cancer patients were recruited into clinical studies, representing 15.4% of the total incidence of upper GI cancer in the UK; 11.4% of upper GI patients recruited into clinical trials have entered into interventional studies. During this same period, 6% of all cancer patients entered into clinical trials were upper GI cancer patients.

The future priorities and targets for this highly productive group include developing translational strategy for tissues collected as part of trials, developing adaptive

trial approaches, and prioritising promotion of trial development in upper GI cancer. Other challenges are developing coherent biomarker-based adaptive trials in upper GI cancer and running trials of complex interventions, such as surgery and radiotherapy.

The Group's Annual Trials Meeting held in December 2012 had the largest attendance ever and was very rewarding, receiving excellent feedback. The new trials results session was especially outstanding. The Upper GI Cancer CSG enjoyed a positive and highly successful progress review in February 2013. The next review is due in 2016.

“It is clear that this Group is very committed to advancing the treatment of patients suffering from upper GI cancers by facilitating a variety of clinical trials of new treatments in development.”
Mr Phil Willan, consumer member

Advisory Groups

Screening, Prevention & Early Diagnosis (SPED)



Improvements in screening, prevention and early diagnosis research have the potential to deliver major and cost-effective impacts on cancer survival and quality of life in the UK¹⁻⁴. The Screening, Prevention and Early Diagnosis SPED Advisory Group was initiated in 2012 in response to concerns which highlighted a need for improving the quantity, design and methodology of studies dealing with screening, prevention and early diagnosis within the UK. Developed within the NCRI and initially accountable to the NCRN Operational Steering Group, the remit of SPED is to encourage, advise and facilitate the development of protocols, to aid in successfully delivering research into screening, prevention and early diagnosis of cancer. SPED has representation from each of the NCRI Clinical Study Groups (CSGs) and the NIHR Primary Care Research Network (PCRN)

Chaired by Professor Mahesh Parmar, SPED aims to help initiate and develop cross-disciplinary working opportunities across the NCRN, PCRN and CCRN. Investigators have the opportunity to submit early stage protocols to SPED for advice and help in developing the study. SPED, via its links with National Awareness and Early Diagnosis Initiative (NAEDI), also provides assistance in identifying and reviewing studies for the NAEDI portfolio. Initiatives, protocols and trials which have had input from SPED remain under the leadership of the originating individuals, and within the portfolio of the relevant CSG, with SPED playing an advisory role.

A particular aim of SPED is to facilitate working across cancer types by bringing together tumour-specific NCRI CSGs. An example is smoking as a common underlying cause of Lung, Bladder and Head & Neck cancers; SPED is working with these CSGs to explore possibilities of working together in this area. SPED is also expanding its wings beyond the CSGs, to other NCRI partners such as the Teenage Cancer Trust (TCT).

References

- (1) National Cancer Equality Initiative: Department of Health, Reducing Cancer Inequality: evidence, progress and making it happen (2010) p.3
- (2) National Cancer Intelligence Network, Routes to Diagnosis: NCIN Data Briefing (2010)
- (3) Mistry, M. et al., Cancer Incidence in the United Kingdom: projections to the year 2030, British Journal of Cancer (2011)
- (4) Cancer Research UK, CancerStats Key Facts: skin cancer (2012)



Advisory Groups

NCRI Clinical and Translational Radiotherapy Research Working Group (CTRAd)

The NCRI Board established the Clinical and Translational Radiotherapy Research Working Group (CTRAd) following a review of research in radiotherapy and radiobiology in 2008. CTRAd was set up in 2009 with a broad, strategic remit to develop an ambitious portfolio of practice-changing trials, to ensure coordination across all aspects of radiobiology and radiotherapy research, and to actively promote translation of new discoveries into practice. The on-going priorities for CTRAd are support for the development of radiotherapy trials, quality assurance within those trials, and developing academic radiotherapy environment in the UK.

CTRAd comprises four workstreams:

1. Science Base – to progress new targeted drugs into clinical evaluation in combination with radiotherapy; to identify those patients most likely to respond to treatment with radiotherapy ± chemotherapy ± targeted drugs; to be able to monitor response to therapy during and after treatment.
2. Phase I/II Trials – to develop a series of innovative phase I and II trials integrating current and novel systemic (or locoregional) therapies with either palliative or radical radiotherapy, supported with novel imaging and biomarker studies.
3. Phase III Trials and Methodology – to develop a series of phase III trials in collaboration with tumour-specific CSGs incorporating advanced radiotherapy techniques, translational and imaging studies, long term morbidity assessment; to develop new methodologies for evaluation of radiotherapy developments.
4. New Technology, Physics and Quality Assurance – to lead on the technical aspects of radiotherapy development and their evaluation and quality assurance in the trials programme.

CTRAd is currently chaired by Professor Neil Burnet (Cambridge), Professor Anthony Chalmers (Glasgow) is the Deputy Chair.

In its first three years of funding, radiotherapy clinical trial numbers and recruitment have increased and CTRAd has run twice yearly clinical trials review workshops. CTRAd has also set up the Radiotherapy Clinical Trials Advisory Service (RADCAS) to provide radiotherapy trial design advice and feedback to funding bodies. Additional central funding has been obtained for radiotherapy QA support for clinical trials (The RTTQA Group).

For more details about CTRAd please visit <http://www.ncri.org.uk/ctrad>

Consumer Liaison Group (CLG)



Chair, Consumer Liaison Group
Mr Richard Stephens

The Consumer Liaison Group (CLG) brings together individuals including patients, carers and relatives, representatives of cancer support organisations, researchers and other professionals, who wish to improve the quality of cancer research through consumer involvement in design and delivery of studies and dissemination of results. The CLG meets three times a year with additional contacts and discussions via project groups, email and teleconference.

In 2012, the CLG held a packed Dragon's Den event at the NCRI Conference, where researchers brought their ideas and challenges to groups of consumers and members of the public to talk them through and test opinion. In 2013, the CLG has launched a Patient Panel working with AstraZeneca, where a group of experienced consumers will review AstraZeneca's studies before they go to the relevant Clinical Studies Group, looking in particular at the 'participant pathway' for any patient wishing to join the study.

We have published two reports: 'Impact of Patient, Carer and Public Involvement in Cancer Research' looks at the CLG's achievements until 2012, whilst 'Action On Access' offers practical

suggestions to widen access to clinical trials. Both reports are available on the NCR website, www.ncrn.org.uk, under Consumer Liaison Group section.

The core members of the CLG are the consumers who sit on NCRI CSGs. These consumers deliver a comprehensive service, providing the 'patient voice' and playing an active role in discussions about strategic direction of the portfolio, evaluating individual studies, and providing comments for funding and ethics committees.

These high expectations and professional standards are welcomed by consumers. We sit on groups and committees as equal partners, and we can and do assess the value and impact of our contributions. We regularly have opportunities for new members to join us, as existing members complete their 3- or 5-year terms. If you would like to know more, please contact us at ppi@ncrn.org.uk

Richard Stephens
Cancer Patient and Chair of the Consumer Liaison Group, NCRN.

A note from the NCRI CSG Secretariat



Head, Clinical Studies Groups Secretariat
Dr Eileen Loucaides

It has been a pleasure to work with the CSGs as Head of the NCRI CSGs Secretariat over the last 10 years and to see the way the CSGs have grown, developed and extended in their remit. From the initial 16 groups there are now 21 with the increase accounting to the establishment of cross-cutting groups such as Psychosocial Oncology and Teenage and Young Adult CSGs. From a mere handful of subgroups - the engine rooms of the CSGs, we now have over 70. Consumer involvement is no longer peripheral or tokenistic, but an integral and valued component of CSG activities, with consumers being intricately involved throughout the research cycle, from a trial's first principles to dissemination of trial results. Support and training is provided to all consumers to ensure they become positively integrated into the Group's work.

An annual reporting cycle and system of triennial international progress reviews provide a clear governance framework and oversight of a group's activities. There are transparent and clear systems for appointing new Chairs and members. Fixed periods of tenure and regular rotations ensure that younger researchers are encouraged and nurtured at the start of their research journey. The CSGs' portfolios have broadened to cover the full spectrum in their disease areas

and many of the CSGs are embracing the challenges of biomarker driven research. The rapid increase in the number of commercial studies has enabled greater access to novel agents and treatments. The Groups are involved in an ever increasing number of NICE appraisals and commenting on HTA vignettes.

There have been other developments; We have strategy days, annual trials meetings for many of the Groups, portfolio maps pictorially representing a CSG's portfolio, cross-cutting workshops, joint meetings and new initiatives such as the Screening Prevention and Early Diagnosis (SPED) Advisory Group.

Without all the hard work and commitment of the CSG members and consumers who give their time, the CSG Secretariat who make it happen, and the patients who willingly participate in our trials, such changes and progress would not have been possible, so a personal thank you to all.

Best wishes,

Eileen Loucaides
Head, Clinical Studies Group Secretariat, NCRI.

Glossary of Terms

ABVD	Adriamycin + Bleomycin + Vincristine + Dacarbazine
ALL	Acute Lymphoblastic Leukaemia
AML	Acute Myeloid Leukaemia
ASCO	American Society of Clinical Oncology
ASH	American Society of Hematology
BICSG	Biomarkers and Imaging Clinical Studies Group
BGCS	British Gynaecological Cancer Society
BPOS	British Psychosocial Oncology Society
BCSH	British Committee for Standards in Haematology
CCL	Children's Cancer and Leukaemia
CDF	Cancer Drugs Fund
CHOP	Cyclophosphamide + Hydroxydaunorubicin + Oncovin + Prednisolone
CLL	Chronic Lymphocytic Leukaemia
CML	Chronic Myeloid Leukaemia
COX-2	Cyclooxygenase-2
CRCTU	Cancer Research Clinical Trials Unit
CRUK	Cancer Research UK
CSG	Clinical Studies Group
CTAAC	Clinical Trials Awards and Advisory Committee
DNA	Deoxyribonucleic Acid
ECCO	European Cancer Organisation
ECMC	Experimental Cancer Medicine Centre
EORTC	European Organisation for Research and Treatment of Cancer
ETOP	European Thoracic Oncology Platform
FDG	Fluorodeoxyglucose
GI	Gastrointestinal
GIST	Gastrointestinal Stromal tumours
GRIST	Growing Recruitment in Surgical Trials

Glossary of Terms

HTA	Health Technology Assessment
IMRT	Intensity-Modulated RadioTherapy
IPOS	International Congress of Psychosocial Oncology
IRCI	International Rare Cancers Initiative
MDS	Myelodysplastic Syndrome
MPN	Myeloproliferative Neoplasms
MRD	Minimal Residual Disease
MRI	Magnetic Resonance Imaging
NAEDI	National Awareness and Early Diagnosis Initiative
NCIN	National Cancer Intelligence Network
NCRI	National Cancer Research Institute
NCRN	NIHR Cancer Research Network
NEJM	New England Journal of Medicine
NICE	National Institute of Clinical Excellence
NIHR	National Institute of Health Research
NSCLC	Non Small Cell Lung Carcinoma
PCRN	Primary Care Research Network
PET	Positron Emission Topography
PORT	Paediatric Oncology Reference Team
PPI	Patient Public Involvement
RCT	Randomised Clinical Trial
QoL	Quality of Life
SARC	Sarcoma Alliance for Research through Collaboration
SCLC	Small Cell Lung Carcinoma
SPED	Screening, Prevention and Early Diagnosis
TCC	Transitional Cell Carcinoma
TYA	Teenagers and Young Adults

NCRI Partners



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