

## **NCRI Lymphoma Clinical Studies Group**

### **Introduction**

This has been a productive year for the Group. We have been well-represented at the three major clinical meetings, with three oral presentations at the American Society of Hematology in December 2008, one at the American Society of Clinical Oncology in May 2009 and one at the European Haematology Association in June 2009. At each meeting several poster presentations were also accepted and members of the Group have been prominent in giving education sessions. All of this activity has helped to raise the profile of the Group internationally, resulting in increased opportunities for collaboration and interest from pharmaceutical companies.

In the course of this year the Group has defined the standard of care in advanced Hodgkin lymphoma and Burkitt lymphoma, and completed recruitment to studies which will do the same for early follicular lymphoma and diffuse large B-cell lymphoma once the data has matured. The excellent result in the latter trial, with an overall survival figure of over 80% at 2 years, is among the best in the world and is a clear indication of the Group's ability to conduct large randomized trials across the country, with 119 sites recruiting over 1000 patients in less than 4 years. Similarly, the study of expectant management versus antibody therapy in asymptomatic follicular lymphoma will ultimately give information about the approach to initial management which could not have been generated by any other group.

The Group has been very successful in establishing trials to determine the value of FDG-PET, and is currently running two in Hodgkin Lymphoma, one prospective study in Mediastinal Lymphoma and one sub-study in Diffuse Large B-cell Lymphoma, all of which are at the forefront internationally and will give important information about the use of response-adapted therapy. The work of the team at Guy's and St Thomas's in delivering quality-controlled scanning in multiple PET centres in real time has been pivotal to these studies and has rightly attracted international recognition. At a time when many groups are questioning the reproducibility and reliability of PET scanning, the UK is in the fortunate position of generating trial data of the highest possible quality to address such concerns. For the future there is an increasing emphasis upon designing studies to target specific molecular abnormalities, and the first of these is currently in planning. Just as the introduction of PET posed (and continues to pose) considerable logistic and commissioning difficulties so we anticipate that molecular typing will also prove a challenge, but this is another area in which the UK has the potential to take an important lead.

The trial in diffuse large B-cell lymphoma which closed in November 2008 was our largest and fastest-recruiting, and although a new study in advanced Hodgkin lymphoma has opened and two new studies in follicular lymphoma are planned, it is likely that there will be a temporary reduction in overall accrual before the newer studies pick up. The Group is still challenged by the multiplicity of lymphoma sub-types for which different studies are needed. We try to strike a balance between uncommon types for which international studies are required or in which only phase II designs are possible, and large trials in which simple questions can be addressed in the large number of potential centres. The Group continually reviews its portfolio on this basis, and we have started to discuss with the National Cancer Intelligence Network how we might gather prospective data on uncommon entities treated according to a standard protocol without the conduct of a formal trial

### **Membership and structure**

There has been minimal turnover in membership this year, following the major changes during the previous three. Attendance at main group meetings remains good, with most members contributing actively to the development of the trials portfolio and newer members increasingly involved in trial planning in the subgroups. The consumer members of the Group have been very effective, both in discussions at meetings and in reviewing trial materials, particularly patient information sheets.

The subgroups have undergone revision during this year, with the T-cell Subgroup amalgamated into the high-grade group and the establishment of a new Biological Studies Subgroup. The latter is a reflection of the importance of molecular pathology and sub-typing in modern lymphoma diagnosis, and the initial meetings of the subgroup have been helpful in identifying the breadth of work being undertaken already. The next steps will be to define clear algorithms for the various trials being conducted in order to make sure that we derive the maximum information from diagnostic material, and establish a network of laboratories which can collaborate effectively in this area.

The Low-Grade, High-Grade and Hodgkin Subgroups have a good range of trials to cover most important sub-types, either underway or in planning. The Extranodal Subgroup is increasingly working in collaboration with the IELSG, with new studies in testicular and primary CNS lymphoma planned internationally.

During the year we have had a project officer (Dr Lisa Lowry) working part time in the Lymphoma Trials Office to help with study set-up and manuscript preparation, and investigating ways in which to monitor for the late effects of treatment. Late effects of lymphoma therapy significantly impact on morbidity and mortality, and it is important to follow-up patients for a prolonged period of time to fully inform future generations of therapies and trials. With increasing accrual into lymphoma trials and improved survival, it has been recognized that the burden imposed by the collection of this data was set to increase, for staff at both the CTUs and trial sites. Dr Lowry has coordinated a review of this process and developed a minimum data set for long-term follow-up across different lymphoma trials. A long-term follow-up database and case report form (CRF) have been developed. Trials which have closed to recruitment and completed the early follow-up phase to meet the trial end-points will now be included in the long-term database, if it is anticipated that longer-term follow-up could yield valuable information. Annual requests for information will then be generated, using a standard CRF. It is hoped that this streamlined approach will greatly reduce the burden at the CTU, but also that staff at sites will become familiar with the standardized form, making it quicker and easier to provide the necessary information. The first set of follow-up requests has recently been sent to sites.

We hope that the burden of long-term follow-up can be reduced even further in the future, via the National Cancer Information Network (NCIN). The project officer and NCIN staff are currently exploring the feasibility of linking trial data with registry and HES data, in the hope of obtaining long-term follow-up information via this route, without the need for CRF reporting.

### Portfolio and accrual

The Group has a broad portfolio of studies and good numbers in development which will cover most of the important lymphoma sub-types. The set-up times for trials have generally improved, although the median time from grant activation to first patient recruited is still 8 months with a range of 4 to 28. The longer times are generally the result of prolonged negotiation with pharmaceutical companies regarding drug supply agreements, and we hope that these will fall as sponsors become more experienced in their contact with companies. The initiation times for sites show great variation according to the complexity of local R&D department procedures and this is still slowing the rate of initial accrual to trials, as well as dissuading some sites from opening trials at all in some of the less common types.

785 patients were recruited to lymphoma studies in 2008/9, 7.1% of incidence cases, 5.5% to RCTs and 1.6 to non RCTs. This compares with 584 patients five years previously. The continued steady rise in patient numbers recruited to trials is encouraging, although this still represents well below 10% of incident cases and there is scope for substantial improvement. We hope that that the numbers of patients recruited will be further improved by opening of our new studies in low grade and Hodgkin lymphoma particularly.

**Table 1: Lymphoma CSG portfolio**

Acronym	Title	PI(s)	Status
18-30	Phase 2 study evaluating the toxicity and efficacy of a modified German Paediatric Hodgkin's lymphoma protocol (HD95) in young adults (aged 18-30 years) with Hodgkin's Lymphoma	Dr Kirit Ardeshta	Open
AITL	Phase II trial of fludarabine and cyclophosphamide chemotherapy followed by Thalidomide maintenance treatment for angioimmunoblastic lymphoma.	Dr Claudius Rudin	Open
BNLI 60+	A phase III trial comparing CHOP to PMItCEBO with or without G-CSF in patients aged 60 plus with aggressive non-Hodgkin's lymphoma.	Professor David Cunningham	Closed
BNLI MCD vs FMD	BNLI RCT of MCD vs FMD in follicular NHL	Dr Andy Haynes	Closed
BNLI Radiation Dose	BNLI randomised trial of radiation dose in non-Hodgkin's lymphoma	Mr Paul Smith	Closed
BNLI Stanford V	Protocol for a randomised phase III study of the Stanford V regimen, compared with ABVD for the treatment of advanced Hodgkin's disease	Professor Peter Hoskin	Closed
Bortezomib Study (Symphony)	A parallel randomised phase II trial of CHOP chemotherapy with or without Bortezomiib in relapsed mantle cell lymphoma	Dr Simon Rule	Open

CHOP-Campath	Campath - A pilot study of CHOP plus alemtuzumab for the primary treatment of ALK-ve peripheral T cell lymphoma	Dr Rod Johnson	Open
CORAL	Randomised study of ICE + Rituximab (R-ICE) versus DHAP + Rituximab (R-DHAP) in previously treated patients with CD20 positive diffuse large B-cell Non-Hodgkins lymphoma, eligible for high dose chemotherapy followed by randomised maintenance treatment wit	Professor David Linch	Closed
EBMT-LYM1	Randomised study of Rituximab (MabThera) in patients with relapsed or resistant follicular lymphoma prior to high dose therapy as in vivo purging and to maintain remission following high dose therapy	Professor AH Goldstone	Closed
EORTC 20981	Chimeric anti-CD20 monoclonal antibody (Mabthera*) in remission induction and maintenance treatment of relapsed follicular non-Hodgkin's lymphoma : a phase III randomised clinical trial - Intergroup Collaborative Study (EORTC 20981) Including Amendment 4	Professor Anton Hagenbeek	Closed
EORTC 20992	Diffuse large B cell and peripheral T cell NHL in the frail elderly. Progressive and cautious treatment strategy in poor status patients. A phase II trial with emphasis on geriatric assessment and quality of life. Version 2.0 (13 December 2001)	Dr C Brammer	Closed
EORTC 21011	A randomised, open-label phase III trial to evaluate the efficacy and safety of Bexarotene (Targetin™) capsules combined with PUVA, compared to PUVA treatment alone in patients with mycosis fungoides	Dr Sean Whittaker	Open
Escalated ABVD	A phase I study to investigate dose escalation of doxorubicin in cycles 1-3 of ABVD chemotherapy for Hodgkin lymphoma and to correlate this with molecular markers of tumour response and toxicity	Professor John Radford	Open
Escalated BEACOPP (EORTC 20012)	- BEACOPP (4 cycles escalated + 4 cycles baseline) versus ABVD (8 cycles) in stage III & IV Hodgkin's Lymphoma – EORTC 20012	Professor Barry Hancock	Suspended
FORT	FORT	Professor Peter Hoskin	Open
GemBex	A phase II study of Gemcitabine and	Professor Tim	Open

	Bexarotene (GemBex) in the treatment of cutaneous T-cell lymphoma	Illidge	
HD 2007 10 (EuroNet Hodgkin's PHL-C1)	First International Inter-Group study for classical Hodgkin's Lymphoma in children and adolescents	Dr W. Hamish Wallace	Open
IELSG 26	A clinico-pathologic study of Primary Mediastinal B-cell lymphoma	Professor Peter Johnson	Open
IELSG19 (MALT Trial)	Multicentre randomized trial of Chlorambucil versus Chlorambucil plus Rituximab versus Rituximab alone in extranodal marginal zone B cell lymphoma of mucosa associated lymphoid tissue (Malt lymphoma)	Professor Peter Johnson	Open
Intestinal t-cell trial	A phase II evaluation of high dose chemotherapy and autologous bone marrow transplantation for intestinal T cell lymphomas.	Dr Anne Lennard	Open
LY T	BNLI/LRF phase II open label study of Thalidomide in patients with relapsed or refractory diffuse large B-cell non-hodgkins lymphoma. MREC /02/2/4	Dr Chris Hatton	Closed
LY02	A randomised trial to evaluate early high dose therapy and autologous bone marrow transplantation as part of planned initial therapy for poor risk intermediate/high grade non-hodgkin's lymphoma	Professor David Linch	Closed
LY07	A multicentre randomised trial of short neo-Adjuvant chemotherapy (VAPEC-B) plus involved field radiotherapy (MIT) versus mantle radiotherapy	Professor John Radford	Closed
LY09	A randomised trial of therapy in advanced hodgkin's disease	Professor Peter Johnson	Closed
LY10	A clinicopathological study in Burkitt's and Burkitt-like non-Hodgkin's Lymphoma.	Dr Ben Mead	Closed
Mantle Cell P3	A randomised controlled trial of fludarabine/cyclophosphomide combination with or without rituximab in patients with untreated mantle cell lymphoma	Dr Simon Rule	Open
MISTRAL	A randomised phase III trial of standard chemotherapy (CHOP regimen) versus sequential high-dose chemotherapy with autologous stem cell transplantation in patients with newly diagnosed aggressive Non-Hodgkin's lymphomas and poor prognostic factors	Professor David Linch	Closed
NCRI Mantle	Phase II randomised study of	Dr Simon Rule	Closed

Cell Lymphoma Trial	fludarabine/ cyclophosphamide combinaton with or without Rituximab in patients with untreated mantle cell lymphoma		
NCRN016 - INDUSTRY STUDY	A multi-center, randomized, double-blind, placebo-controlled phase III trial comparing the efficacy of Bevacizumab in combination with Rituximab and CHOP (RA CHOP) versus Rituximab and CHOP (R CHOP) with placebo in previously untreated patients with CD20 positive diffuse large B cell Lymphoma (DLBCL)		Open
NHL Good Risk	Phase III trial comparing CHOP to PMitCEBO in good risk stage II-IV patients with histologically aggressive non-Hodgkin's lymphoma	Dr Ruth Pettengell	Closed
PACIFICO	Purine-Alkylator combination in follicular lymphoma immuno-chemotherapy for older patients: a phase III comparison of first-line R-CVP versus R-FC	Professor Andrew Pettit	Open
PET after 2 cycles in NHL	Blinded evaluation of prognostic value of FDG-PET after 2 cycles of chemotherapy in Diffuse Large B-cell Non-Hodgkin's Lymphom	Dr George Mikhaeel	Open
PET Trial in Hodgkin's Disease (RAPID)	A randomised Phase III trial to determine the role of FDG-PET Imaging in Clinical Stages IA/IIA Hodgkin's Disease.	Professor John Radford	Open
PRIMA	A multicentre, phase III, open-label, randomized study in patients with advanced follicular lymphoma evaluating the benefit of maintenance therapy with Rituximab (MabThera®) after induction of response with chemotherapy plus Rituximab in comparison with no maintenance therapy	Professor Andrew Lister	Closed
Primary CNS lymphoma	Phase I trial of escalating high dose methotrexate supported by glucarpidase to treat patients with primary central nervous system lymphoma (PCNSL)	Dr Rod Johnson	Open
RATHL	A randomised phase III trial to assess response adapted therapy using FDG-PET imaging in patients with newly	Professor Peter Johnson	Open

	diagnosed, advanced hodgkin lymphoma		
R-CHOP 14 vs 21	A phase III multicentre randomised clinical trial comparing rituximab with CHOP given every 14 days and rituximab with CHOP given every 21 days for the treatment of patients with newly diagnosed diffuse large B cell non-Hodgkin's lymphoma	Professor David Cunningham	Closed
R-CHOP-B	Feasibility study of R-CHOP plus Bevacizumab in patients with diffuse large B-cell lymphoma	Professor David Cunningham	Open
R-CODOX-M/IVAC for DLBCL	A Phase II Single Arm Study of the use of CODOX-M/IVAC with Rituximab (R-CODOX-M/IVAC) in the treatment of patients with Diffuse Large B-Cell Lymphoma (Age-Adjusted International Prognostic Index High or High-Intermediate Risk)	Dr Andrew McMillan	Open
RGCVP	A phase II multicentre clinical trial of Rituximab, CVP and Gemcitabine for the treatment of patients with newly diagnosed diffuse large B-cell lymphoma considered unsuitable for R-CHOP chemotherapy	Dr Paul Fields	Open
SCHRIFT	Short CHemo Radiolmmunotherapy in Follicular Lymphoma Trial - Ibritumomab tiuxetan (Zevalin <sup>TM</sup> ) as therapy for first and second relapse in Follicular Lymphoma	Professor Tim Illidge	Open
SHIELD Study	A phase II study, VEPEMB, in patients with Hodgkin's lymphoma aged greater than 60 years. (VEPEMB : Vinblastine, Endoxana (Cyclophosphamide), Procarbazine, Prednisolone, Etoposide, Mitozantrone, Bleomycin)	Professor Steve Proctor	Open
SIGNIFICANT	A randomised prospective double-blind, placebo controlled trial of prophylactic oral levofloxacin following chemotherapy for lymphoma and solid tumours.		Closed
SNLG NHL Va	A randomised study of high dose chemotherapy/radiotherapy and autologous bone marrow transplantation in patients with high grade malignant non-Hodgkin's lymphoma (Kiel Classification) according to prognostic groups. A	Dr Penny Taylor	Closed

	Scotland and Newcastle Lymphoma Group		
SP1984	Cytotoxic T Cell therapy for EBV associated tumours.	Professor Dorothy Crawford	Closed
Waldenstrom's study	A randomised trial of Chlorambucil vs Fludarabine as initial therapy of Waldenström's Macroglobulinaemia and Splenic lymphoma with villous lymphocytes	Dr Steve A Johnson	Open
Watch and Wait	An intergroup randomised trial of rituximab vs a watch and wait strategy in patients with advanced stage, asymptomatic non-bulky follicular lymphoma (grades 1, 2 and 3)	Dr Kirit Ardeszna	Closed

### **Trials in development**

The Group has a number of trials in development. Most notably:

#### ***Low Grade Subgroup:***

- A randomized study of R-Bendamustine vs R-CVP followed by maintenance Rituximab or 90-Y-Ibritumomab Tiuxetan in younger patients with previously untreated follicular lymphoma
- A phase II study of Bortezomib/Cyclophosphamide/Rituximab in recurrent Waldenstrom's macroglobulinaemia.

#### ***High Grade Subgroup:***

- A randomized study of R-CHOP versus R-CHOP and Bortezomib in Activated B-cell type Diffuse Large B-cell Lymphoma
- A study of dose-dense rituximab in older patients with Diffuse Large B-cell Lymphoma (in collaboration with the German High Grade NHL Study Group)
- A study of DHAP-Rituximab versus DHAP-Ofatumumab in recurrent Diffuse Large B-cell Lymphoma (in collaboration with GSK and the HOVON Group)

#### ***Extranodal Subgroup:***

- IELSG 30: A phase II study of R-CHOP with intensive CNS prophylaxis and scrotal irradiation in patients with primary testicular diffuse large B-cell lymphoma
- IELSG 32: A Randomized phase II trial on primary chemotherapy with high-dose methotrexate and high-dose cytarabine with or without thiotepa, and with or without rituximab, followed by brain irradiation vs. high-dose chemotherapy supported by autologous stem cells transplantation for immunocompetent patients with newly diagnosed primary CNS lymphoma

#### ***Hodgkin Subgroup:***

- Management of Nodular Lymphocyte Predominant Hodgkin Lymphoma, in collaboration with the UK CCLG.

### **Meetings**

The Group held a very successful trials meeting in London in November 2008 with over 200 delegates attending. The meeting included presentations of results from completed trials and progress reports on current trials and those in development. We were also

fortunate to have collaborators from Italy, Germany Denmark and USA presenting at the meeting. This meeting is crucial for disseminating trials results and allows investigators from around the UK to raise issues and concerns about current and future trials.

Members of the Group have also been involved in a number of other meetings including regional meetings in Scotland, Manchester and Birmingham which are aimed at increasing awareness about lymphoma among NCRN network staff. In addition members organized a national meeting for research nurses jointly with the Leukaemia Research Fund.

Members have also visited the Lymphoma Association to update Helpline staff about the trials portfolio.

### **Collaborations**

The Group has established links with a number of other organizations.

#### ***Trials Groups:***

IELSG: Dr Anne Lennard from the CSG is a member of the IELSG Board of Directors. Two IELSG prospective studies are running in the portfolio and two more are planned.

Other European Groups: GELA/Hovon/Nordic/IIL/SAKK/German: The UK group is in close contact with the main European groups, and has conducted several trials in collaboration with one or more of these recently. Currently recruiting trials with international collaboration include RATHL (Scandinavia, GISL, Australasia, Ireland), the Waldenstrom study (GELA) and SHIELD (German, Italian and French), and planned studies will involve working with the Dutch HOVON group as well as the German high grade NHL group

#### ***Other CSG's***

The areas of greatest overlap are with the Radiotherapy and Haematological Oncology CSGs, and the Teenage and Young Adult CSDG. We have had discussions with all of these, both formal and informal.

We have had meetings with the Teenage and Young Adults CSDG to discuss Hodgkin lymphoma and NHL. The 18-30 Hodgkin study is an attempt to apply a paediatric protocol (from the German/Austrian Group) to a young adult population as a feasibility study, and the results of this will be important to future study design. A protocol for Nodular LP Hodgkin Lymphoma in paediatric and adult cases has been discussed both in the UK and abroad, and we hope that this may be the first common paediatric/adult protocol.

With the reconfiguration of the CCLG there may be better opportunities for joint protocols in NHL among younger adults, and further meetings between the Group, the TYA CSG and the CCLG are planned to discuss this.

Discussions with the Myeloma Subgroup of the Haematological Oncology CSG have been focused upon a new protocol for Waldenstrom's macroglobulinaemia, and are progressing well. It is planned to submit a joint trial for treatment of recurrence for funding during 2008.

### ***Trials Units:***

The Lymphoma CSG has always had very close ties to the Lymphoma Trials Office (LTO) at University College London, the Senior Manager of which is also the Group Portfolio Coordinator. As the number of studies has increased, other CTU's have taken up some of the newer studies according to their links with the Chief Investigators.

The Liverpool Trials Unit is running the PACIFICO study in older patients with Follicular Lymphoma, the Southampton Trials Unit has taken the lead in running IELSG studies in the UK and the SCHRIFTT study, and the Plymouth Trials Unit is running the Symphony study.

### ***Industry:***

The Group has one pharma study in the portfolio, and has been approached about two others. The GSK study of Ofatumumab in recurrent DLBL has been adopted as a Group trial, and another trial in recurrent Follicular Lymphoma is under discussion.

### **3-year strategy**

The Lymphoma CSG has identified the following priorities for its research portfolio. These priorities have arisen from the NICE review of evidence in haematologic malignancy carried out in the preparation of the IOG framework in 2002 (Improving outcomes in Haematological Cancers: The Evidence. Centre for Reviews and Dissemination, York, 2003), from the comments of the Group's external reviewers in 2008, from members of the broad lymphoma research community, including patients via the Lymphoma Association with which the Group has close links, and the consumer members of the Group.

- ***Extend coverage in the portfolio to all common sub-types of lymphoma***

This is being undertaken successfully, and the portfolio of studies now covers most of the common lymphoma types.

- ***Increase correlative science in trials***

The Lymphoma Biological Studies Subgroup (Chair, Dr Sarah E. Coupland) has been established since January 2009 and aims to enhance correlative science with current and all future clinical trials in the UK. It has met twice: on February 24<sup>th</sup> addressing possible correlative studies associated with NCRI follicular lymphoma trials, and on June 25<sup>th</sup>, discussing those associated with NCRI high-grade lymphoma trials. The next planned meeting is mid-October with the theme being mantle cell lymphoma. It is hoped that through the Lymphoma Biological Studies Subgroup patient tumour and blood samples will be regularly collected and stored in a standardized manner for all lymphoma trials, resulting in the creation of lymphoma-related biobanks. Provisional flow diagrams for tissue/blood collection have been proposed and are currently under review. Following ethical and governance guidelines, these Biobanks would provide material for correlative science research projects, which would be assessed for suitability by the Lymphoma CSG and, possibly, by external reviewers. In this way, the aim is that immunohistology and molecular pathology should be brought to bear on lymphoma as successfully as FDG-PET has been.

- ***Evaluate new technologies and therapies***

The studies of FDG-PET scanning prospectively in early and advanced Hodgkin lymphoma, primary mediastinal lymphoma and diffuse large B-cell lymphoma are major strengths.

Radioimmunotherapy with nuclides conjugated to monoclonal antibodies also requires prospective evaluation. A trial in recurrent follicular lymphoma is underway to test this. A further phase III study is in planning to evaluate the role of radioimmunotherapy in consolidating first remission in Follicular Lymphoma.

A variety of new anti-lymphoma agents require evaluation, and the Group seeks to play its part in this. Studies are underway or planned to test Bortezomib in DLBL and recurrent mantle cell lymphoma, Bevacizumab in diffuse large B-cell lymphoma, and Glucarpidase as a means to escalate the methotrexate dose in primary CNS lymphoma. We are seeking to develop trials with companies using immunotoxin therapies in both Hodgkin and non-Hodgkin lymphomas.

Reduced intensity conditioning for allogeneic bone marrow transplant is an area of potential growth in lymphoma. The Group's first prospective study of this in mantle cell lymphoma was approved for funding by CTAAC in early 2008, and two further studies in resistant Hodgkin Lymphoma have been funded by CTAAC this year.

### **Priorities for next year**

The Lymphoma CSG's priorities for next year are:

- Opening trials in Follicular Lymphoma, and Diffuse Large B-cell Lymphoma, both first line and recurrent, and the new IELSG studies in Testis and CNS lymphoma.
- Develop the next generation of trials in Mantle Cell Lymphoma and Waldenstrom macroglobulinaemia
- Increase collaboration with the CCLG and TYA groups
- Expand the work of the Biology Studies sub-group and establish a network of laboratories carrying out molecular pathology studies.
- Expand our work with the NCIN in minimum datasets, trial follow up and registration of uncommon lymphoma types.
- Continue and enhance collaboration with pharma partners to bring novel drug therapy to trials in the UK

Professor Peter Johnson, Chair

## Appendix 1

### 2008/09 Publications and abstracts

#### *Oral and poster presentations*

Title	Speaker	Venue	Type of data presented
Randomised Comparison of the Stanford V (SV) Regimen and ABVD in the Treatment of Advanced Hodgkin Lymphoma (HL): Results from a UK NCRI Lymphoma Group Study, ISRCTN 64141244	Professor Peter Johnson	ASH 08	Major findings (oral presentation)
Results of the 2nd Planned Interim Analysis of the RAPID Trial (involved field radiotherapy versus no further treatment) in Patients with Clinical Stages 1A and 2A Hodgkin Lymphoma and a 'negative' FDG-PET Scan after 3 Cycles ABVD	Professor John Radford	ASH 08	Preliminary data (oral presentation)
Consolidation Radiotherapy Is Associated with Improved Outcomes after Chemotherapy for Advanced Hodgkin Lymphoma: Analysis of Results from the UKLG LY09 Trial (ISRCTN97144519).	Professor Peter Johnson	ASH 08	Secondary analysis (Oral presentation)
Quality Control of PET Imaging in a Multicentre Phase III Trial (RAPID) Involving Randomisation of Patients with Stages IA and IIA Hodgkin Lymphoma Who Are PET 'negative' after 3 Cycles of ABVD Chemotherapy.	Dr Sally Barrington	ASH 08	Secondary analysis (poster presentation)
Capturing expert opinion at an international meeting (IM) to define what constitutes a practice changing difference between randomised arms in an NCRN clinical trial featuring de-escalation of treatment in Hodgkin lymphoma (HL) RAPID	Professor John Radford	NCRI October 08	Preliminary data (oral presentation)
Quality of life measures in 'asymptomatic' patients With follicular lymphoma (fl) at presentation Watch & Wait	Dr Kirit Ardeshta	ICML – Lugano 2008	Secondary analysis (poster presentation)

Myeloablative therapy for recurrent Hodgkin Lymphoma: High Good success rates irrespective of previous treatments in the UKLG LY09 trial (ISRCTN97144519).	Professor Peter Johnson	ICML – Lugano 2008	Secondary analysis (oral presentation)
Early relapses and failure to achieve complete remission are the main prognostic factors in cd20 Diffuse large b-cell lymphomas (dlbcl) treated with RICE Or R-DHAP followed by stem cell transplantation in the CORAL study	Professor David Linch	ICML – Lugano 2008	Preliminary data (poster presentation)
A phase III trial comparing R-CHOP 14 and R-CHOP 21 for the treatment of newly diagnosed diffuse large B cell non-Hodgkin's lymphoma Results from a UK NCRI Lymphoma Group Study	Professor David Cunningham	ASCO 09	Preliminary data (oral presentation)
Application of the mantle international prognostic index (MIPI) to patients with mantle cell lymphoma treated with fludarabine/cyclophosphamide. Results from a UK NCRI Lymphoma Group study	Dr Simon Rule	ASCO 09	Secondary analysis (poster presentation)
Single arm phase II open label study of thalidomide in patients with refractory or relapsed diffuse large B cell lymphoma.	Dr Chris Hatton	BSH 09	Major findings (poster presentation)
Ki-67 does not predict survival in newly-diagnosed mantle cell lymphoma treated with fludarabine and cyclophosphamide (FC) with or without rituximab (R)	Dr Simon Rule	BSH 09	Secondary analysis (poster presentation)
Dr Richard Lush	EHA 09	Major Findings (oral presentation)	

Journal publications

**Mead GM, Barrans SL, Qian W, Walewski J, Radford JA, Wolf M, Clawson SM, Stenning SP, Yule CL, Jack AS** A prospective clinicopathologic study of dose-modified CODOX-M/IVAC in patients with sporadic Burkitt lymphoma defined using cytogenetic and immunophenotypic criteria (MRC/NCRI LY10 trial). *Blood*. 2008 Sep 15;112(6):2248-60.

**Eve H, Smith P, Linch D, Qian W, et al.** (Feb 2009). Toxicity of fludarabine and cyclophosphamide (FC) ± rituximab (R) as initial therapy for patients with previously-

untreated mantle cell lymphoma: results of a randomised phase II study. *Leuk Lymphoma*, 50:211-5.

**Hancock BW, Qian W, Linch D, Delchier JC, Smith P, Jakupovic I, Burton C, Souhami R, Wotherspoon A, Copie-Bergmann C, Capella C, Traulle C, Levy M, Cortelazzo S, Ferreri AJ, Ambrosetti A, Pinotti G, Martinelli G, Vitolo U, Cavalli F, Gisselbrecht C, and Zucca E.** (Feb 2009). Chlorambucil versus observation after anti-Helicobacter therapy in gastric MALT lymphomas: results of the international randomised LY03 trial. *Br J Haematol*, 144: 367-375.

**Sharma R, Cunningham D, Smith P, Robertson G, Dent O and Clarke S.J.** (May 2009) Inflammatory (B) symptoms are independent predictors of myelosuppression from chemotherapy in Non-Hodgkin Lymphoma (NHL) patients – analysis of data from a British National Lymphoma Investigation phase III trial comparing CHOP to PMitCEBO. *BMC Cancer* 2009, 9:153

**Hoskin P, Lowry L, Horwich A, Jack A, Mead G, Hancock B, Smith P, Qian W, Patrick P, Popova B, Pettitt P, Cunningham D, Pettengell P, Sweetenham J, Linch D and Johnson P.W.M.** Randomised Comparison of the Stanford V Regimen and ABVD in the Treatment of Advanced Hodgkin Lymphoma: Results from a UK NCRI Lymphoma Group Study, ISRCTN 64141244 *J Clin Oncol* (in press)

**Recruitment from 01/07/08 to 30/06/09**

<b>Trial name</b>	<b>No of patients recruited</b>	<b>Comments</b>
AITL	1	
CHOP - Campath	8	16 patients screened
FoRT	109	
GEMBEX	7	
18-30	15	
Intestinal T-cell lymphoma	0	
Mantle cell	58	
RAPID	88	Number registered
Primary CNS	3	
RATHL	36	Number registered
RCHOP14 vs 21	142	
RCODOXM/IVAC	9	
RGCVP	16	
Watch and Wait	122	
SHIELD	55	28 to VEPEMB, 27 registration.
NCRN016	6	
Escalated ABVD	8	
EBV associated NK/T cell malignancies	4	
SCHRIFT	24	
IELSG26	1	
IELSG19	15	
Bortezomib	8	
WM1	43	
<b>Total</b>	<b>778</b>	