

## Research Champions

### Clinician (Lymphoma):

Dr Graham Collins: graham.collins@orh.nhs.uk

**Clinician (CLL):** Dr Anna Schuh: anna.schuh@ndcls.ox.ac.uk

**Research Nurse:** Juliette Dye:

Juliette.dye@royalberkshire.nhs.uk

Research Team Contact Information		
Oxford Oncology	Tracy Mitchell-Floyd Lymphoma trials	Tracy.Mitchell-Floyd@orh.nhs.uk 01865 743233
	Chris Levett (Research Nurse) CLL trials	Christoper.Levett@orh.nhs.uk 01865 743232
Royal Berkshire NHS Foundation Trust	Juliette Dye	Juliette.Dye@royalberkshire.nhs.uk 0118 322 7898
Buckinghamshire Healthcare NHS Trust	Emma Hogbin (WGH Research Nurse)	Emma.Hogbin@buckshealthcare.nhs.uk 01494 426233
	Maggie Aldersley (WGH Research Nurse)	Maggie.Aldersley@buckshealthcare.nhs.uk
Heatherwood & Wexham Park Hospitals NHS	Victoria Robinson (Research Nurse)	Victoria.Robinson@hwph-tr.nhs.uk 01753 634191/364
Great Western Hospitals NHS Foundation Trust	Nicola Cowling (Research Nurse)	Nicola.Cowling@gwh.nhs.uk
	Vivian Zinyemba (Research Nurse)	Vivian.Zinyemba@gwh.nhs.uk 01793 605918
Milton Keynes Hospital NHS Foundation Trust	Heini Alderman (Research Nurse)	Heini.Alderman@mkhospital.nhs.uk 01908 826638
Research Nurses Early Phase Trials (Oxford)	Sandie Wellman	Sandie.Wellman@medonc.ox.ac.uk
	Lesley Chick (Admin)	01865 235469

### Thames Valley Cancer Research Network Central Team

Clinical Lead for Research– Ricky.Sharma@rob.ox.ac.uk

Training & Education Lead– Sean.Chinnathumby@orh.nhs.uk

Research Network Manager– Susan.Palmer@orh.nhs.uk

Information Systems Officer- Olivia.Hunt@orh.nhs.uk

TVCRN Coordinator (Veronica Sinclair) TVCNRESEARCH@orh.nhs.uk

Address: TVCRN, Block 8, Nuffield Orthopaedic Centre NHS Trust, Windmill Rd, Headington, Oxford, OX3 7LD



WINDMILL & OLIPHANT

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National Institute for  
Health Research

Thames Valley Cancer Research Network

Berkshire, Buckinghamshire, Oxfordshire, Swindon

### CLINICAL TRIALS OPEN/IN SET UP

Indication	Study Acromym	NIHR number	RCT/Non RCT	BHT	GWH	HWPFT	MKFT	ORH	RBFT
<b>Chronic Lymphocytic Leukaemia (CLL)</b>									
1st line GO-GO patients	ARCTIC	7136	RCT	open				open	
DLBCL RICHTER's transformation	CHOP-OR							open	
Maintenance after 2nd line treatment SLOW-GO/GO-GO	CONTINUUM	non NIHR	RCT					open	
	GENMAB 416	non NIHR	Non-RCT					open	
	FCLL	6404	Non-RCT	considering	open				
1st and 2nd line SLOW-GO patients	M022468 (MABLE)	non NIHR	RCT					open	
Fludarabine-refractory bulky B-CLL SLOW-GO	NCRN042	5079	RCT		open				in set up
1st line SLOW-GO patients	OMB110911 (COMPLEMENT 1)	non NIHR	RCT					open	
<b>Lymphoma</b>									
Relapsed / refractory DLBCL not suitable for high dose therapy	AZD1152	non NIHR							in set up
Relapsed mantle cell lymphoma	Bortezomib study	2256	RCT	open	in set up	open			in set up
Untreated intestinal T-cell lymphoma	ITCL	1418	Non-RCT		open				
Untreated mantle cell lymphoma	Mantle Cell P3	2188	RCT	open	open	open			
Relapsed / refractory DLBCL suitable for high dose therapy	NCRN069	6269	RCT					open	
Classical Hodgkin's Lymphoma	NSHLG	7891	Non-RCT	open	open		open		
Untreated follicular lymphoma	PACIFICO	6898	RCT		open	in set up			
Untreated advanced classical Hodgkin's Lymphoma	RATHL	4488	RCT					open	
Untreated high risk DLBCL / Burkitt's lymphoma	R-CODOX-M/IVAC for DLBCL	2194	RCT		open			open	
Relapsed / refractory mantle cell lymphoma	SPRINT	non NIHR	RCT					open	
<b>CLL and Lymphoma</b>									
Relapsed/refractory B-cell malignancy	HGS 1029	non NIHR	Non-RCT					open	

### HORIZON SCANNING

- NCRN210 due to open in Spring 2011
- YM155-CL031
- PTCL maintenance study
- REMODEL-B
- IELSG-32

## Trials open to recruitment

### Lymphoma

#### **AZD1152**

Phase IIa study of an aurora kinase B inhibitor in relapsed / refractory diffuse large B-cell lymphoma. In set up in Oxford only.

#### **Bortezomib study**

A parallel randomised phase II trial of CHOP chemotherapy with or without Bortezomib in relapsed mantle cell lymphoma

#### **ITCL**

A phase II evaluation of high dose chemotherapy and autologous bone marrow transplantation for intestinal T cell lymphomas.

#### **Mantle Cell P3**

A randomised controlled trial of fludarabine/cyclophosphamide combination with or without rituximab in patients with untreated mantle cell lymphoma

#### **NCRN069**

A phase III randomised trial in relapsed / refractory diffuse large B-cell lymphoma fit for high dose therapy (contact centre for more details)

#### **NSHLG**

National Study of Hodgkin's Lymphoma Genetics

#### **PACIFICO**

Alkylator Combination In Follicular lymphoma Immuno-Chemotherapy for Older patients: a phase III comparison of first-line R-CVP versus R-FC (previous acronym: RiCH FLO)

#### **RATHL**

A randomised phase III trial to assess response adapted therapy using FDG-PET imaging in patients with newly diagnosed, advanced hodgkin lymphoma

#### **RCODOX**

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 (DLBCL) or Burkitt's Lymphoma (BL) of International Prognostic Index High or High-Intermediate Risk

#### **SPRINT**

A phase III randomised trial in relapsed / refractory mantle cell lymphoma (contact centre for more details)

### Lymphoma & CLL

#### **HGS 1029**

A phase I first into man study investigating the safety, tolerability and pharmacokinetics of a novel compound in patients with relapsed / refractory B-cell malignancies. Open in Oxford only.

## Trials open to recruitment

### Chronic Lymphocytic Leukaemia (CLL)

#### **ARCTIC**

A randomised, phase IIB trial in previously untreated patients with CLL to compare fludarabine, cyclophosphamide & rituximab (FCR) with FC, mitoxantrone and low dose rituximab (FCM-miniR)

#### **CHOP-OR**

Phase IIa study assessing efficacy of ofatumumab compared with rituximab in combination with CHOP in patients with a high grade (Richter's) transformation. Open in Oxford only.

#### **FCLL**

A Genetic Study of Chronic Lymphocytic Leukaemia and Other Lymphoproliferative Disease

#### **NCRN042**

Phase III, Open Label, RCT of Ofatumumab in combination with Fludarabine-Cyclophosphamide vs. Fludarabine-Cyclophosphamide Combination in Subjects with Relapsed CLL

#### **RESPECT**

Revlimid Early Stage Poor prognosis CLL Trial - A single arm phase II study to investigate the use of Lenalidomide in the treatment of patients with early stage CLL with poor prognostic factors

#### **CONTINUUM**

Phase 3, multicentre, double-blind, placebo-controlled, parallel-group RCT of the efficacy and safety of Lenalidomide (REVLIMID) as maintenance therapy for patients with B-cell CLL following second-line therapy

#### **GENMAB 416**

Single-arm, international, multi-centre trial investigating the efficacy and safety of Ofatumumab retreatment and maintenance treatment in pts with B-cell CLL who progressed following response or stable disease after Ofatumumab treatment in Hx-CD20-406

#### **OMB110911 (COMPLEMENT 1)**

Phase III, open label, multi-centre RCT of Ofatumumab added to Chlorambucil vs. Chlorambucil Monotherapy in previously untreated pts

#### **M022468 (MABLE)**

RCT comparison of rituximab in combination with either chlorambucil or bendamustine, 1st line or 2nd line, in patients with co-morbidities

#### **Horizon scanning**

**YM155-CL031:** phase II study investigating the activity of a novel agent in relapsed/ refractory DLBCL

**PTCL maintenance study:** phase II study investigating the efficacy of investigational agent as maintenance after remission induction with CHOP-like chemotherapy in peripheral T-cell lymphoma

**REMODEL-B:** phase III study investigating CHOP-R chemotherapy in combination with bortezomib or placebo in untreated diffuse large B-cell lymphoma

**IELSG-32:** phase III study in untreated primary CNS lymphoma assessing the benefit of thiotepa & rituximab in induction & comparing radiotherapy with high dose therapy as consolidation.

**NCRN210:** fludarabine-refractory/TP53 deleted B-CLL GO-GO