

Harrogate Trials Performance Report for 01 April 2010 to 26 August 2010							
Trial title	Disease site	Screened	Recruited	Cancer Waiting Time (a)		Annual Target	Recruitment % Target
				Screened %	Recruited %		
BBC-NCRN cohort	Breast	14	11	97		50	22%
COMPLETE (NCRN020)	Breast	0	0			6	0%
Glacier	Breast	10	2			10	20%
ICICLE	Breast	7	3			10	30%
ZICE	Breast	1	0			6	0%
POETIC	Breast	In Setup					
<b>Total</b>		<b>32</b>	<b>16</b>	<b>33.0%</b>	<b>16.5%</b>		
CReST	Colorectal	0	0	72		8	0%
FOXROT	Colorectal	4	0			4	0%
NSCCG	Colorectal	7	7				
QUASAR 2	Colorectal	2	0			5	0%
SCOT	Colorectal	3	0			12	0%
<b>Total</b>		<b>16</b>	<b>7</b>	<b>22.2%</b>	<b>9.7%</b>		
AML 16	Haematology	2	0	70		10	0%
ARCTIC	Haematology	0	0			3-5	0%
Bortezomib Study (aka 'CHOP Velcade' or 'Relapsed MC')	Haematology	0	0				
FCLL (Sample Study Familial CLL)	Haematology	0	0			3	
Mantle Cell PHASE 3 (LY05)	Haematology	2	0			5	0%
NSHLG	Haematology	0	0			6	0%
PT1 (MRC)	Haematology	0	0			1	0%
SPIRIT 2	Haematology	1	1			5	20%
MYELOMA XI	Haematology	In Setup				2	
PACIFICO	Haematology	In Setup					
<b>Total</b>		<b>5</b>	<b>1</b>	<b>7.1%</b>	<b>1.4%</b>		
FRAGMATIC	Lung	2	0	67		20	0%
LungStar	Lung	1	0			5	0%
MALCS	Lung	2	2			5	40%
QUARTZ	Lung	0	0			4	0%
CONVERT	Lung	In Setup					
<b>Total</b>		<b>5</b>	<b>2</b>	<b>7.5%</b>	<b>3.0%</b>		
Melanoma Cohort Study	Melanoma	1	1	60			
Melanoma Lifestyle Study	Melanoma	0	0				
<b>Total</b>		<b>1</b>	<b>1</b>	<b>2%</b>	<b>2%</b>		
ChOPIN	Upper GI	1	1	13		20	5%
<b>Total</b>		<b>1</b>	<b>1</b>	<b>8%</b>	<b>8%</b>		
UK Genetic Prostate Cancer Study	Urology	7	1	161		10	10%
<b>Total</b>		<b>7</b>	<b>1</b>	<b>4%</b>	<b>1%</b>		
<b>Grand Total</b>		<b>67</b>	<b>29</b>				
<b>Grand Total as % CWT (b)</b>		<b>11.9%</b>	<b>5.1%</b>				

(a) - Cancer Waiting Times data: Number of 31-day treatments by Trust by Disease site for 2008 is from National CWT database

(b) - Cancer Waiting Times (all disease) for Harrogate is 565.

	Trial is under set up
	Study is not run by local team
	Portfolio trial under 'Oral and Gastrointestinal' topic

## Recruitment since last PDO meeting (06.07.2010)

Trial title	Disease Site	Screened	Recruited
BBC-NCRN cohort	Breast	7	4
Glacier	Breast	6	1
ICICLE	Breast	6	1
SoFEA	Breast	2	0
FOxTROT	Colorectal	2	0
NSCCG	Colorectal	5	5
QUASAR 2	Colorectal	2	0
SCOT	Colorectal	0	0
AML 16	Haematology	0	0
FRAGMATIC	Lung	2	0
MALCS	Lung	2	2
ChOPIN	Upper Gastrointestinal	1	1
UK Genetic Prostate Cancer Study	Urology	2	0
<b>Total</b>		<b>37</b>	<b>14</b>

The above information is as accurate as of 26.08.2010

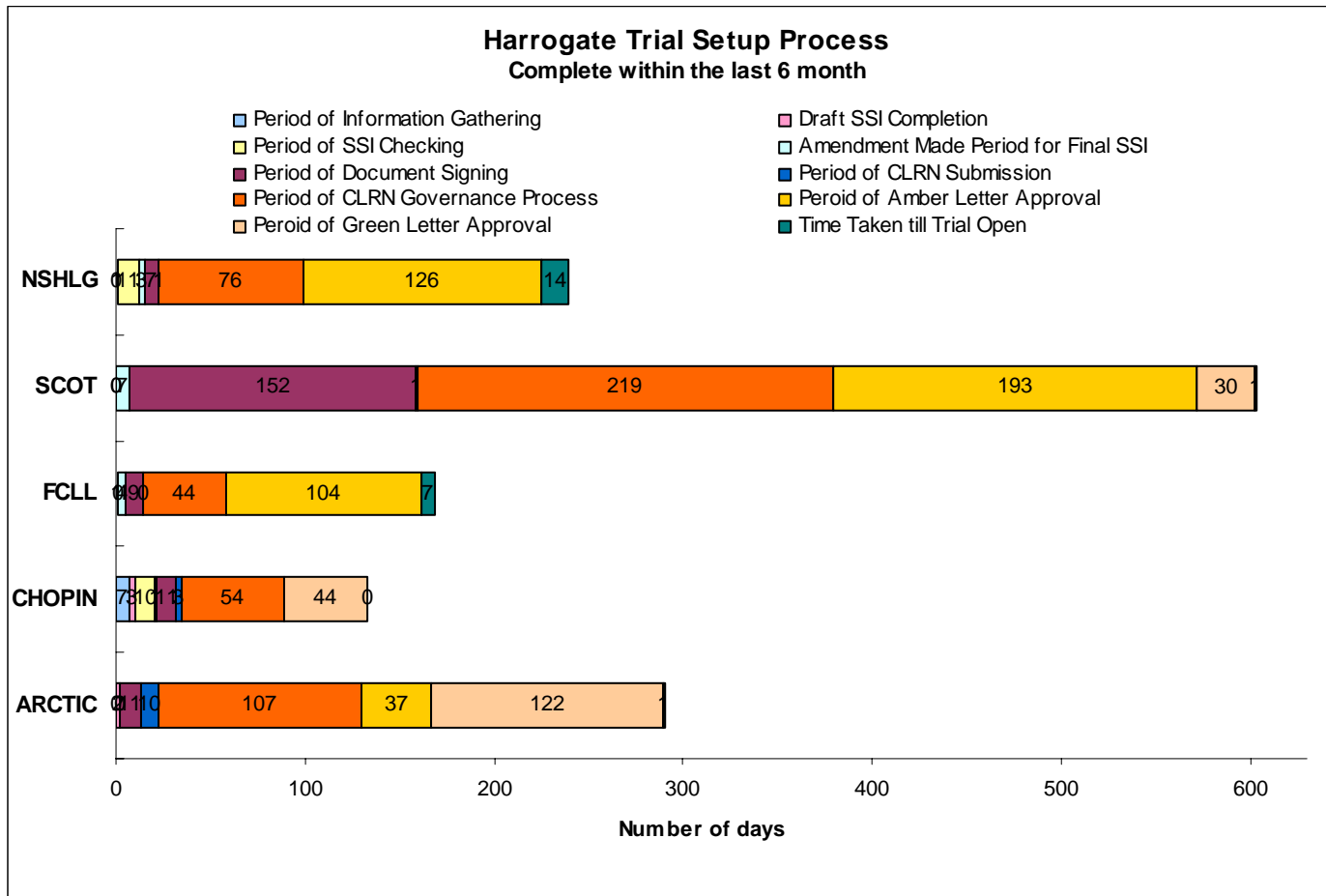
## Harrogate Recruitment within 1st April 10 to 26 August 2010

Trial title	Harrogate	Airedale	Bradford	C&H	Leeds	Mid Yokds	York
BBC-NCRN cohort	11	4	6	8		1	
Glacier	2				11	1	0
ICICLE	3				4	0	1
NCRN020 (COMPLETE)	0			0			0
ZICE	0					1	4
CRest	0		1		3	1	
FOxTROT	0		2	1	2		1
NSCCG	7	33	5	17	3	10	1
QUASAR 2	0	0	0	0	1	3	
SCOT	0	3	0		3		4
AML 16	0	0	0		3	3	0
ARCTIC	0				1		
Bortezomib Study (aka 'CHOP Velcade')	0		0		0		
FCLL (Sample Study Familial CLL)	0		1	0	0	22	18
Mantle Cell PHASE 3 (LY05)	0		0		0	0	0
PT1 (MRC)	0	0	0		0	0	
R-GCVP	0		0		0		
SPIRIT 2	1		0		3	1	0
FRAGMATIC	0				1		0
LungStar	0	2	0	1	2		0
MALCS	2	2		3	3	0	0
QUARTZ	0			2	1	0	
Melanoma Cohort Study	1	0	2	1	10	2	1
Melanoma Lifestyle Study	0		1		3	1	0
ChOPIN	1						
UK Genetic Prostate Cancer Study	1		1		0	3	0

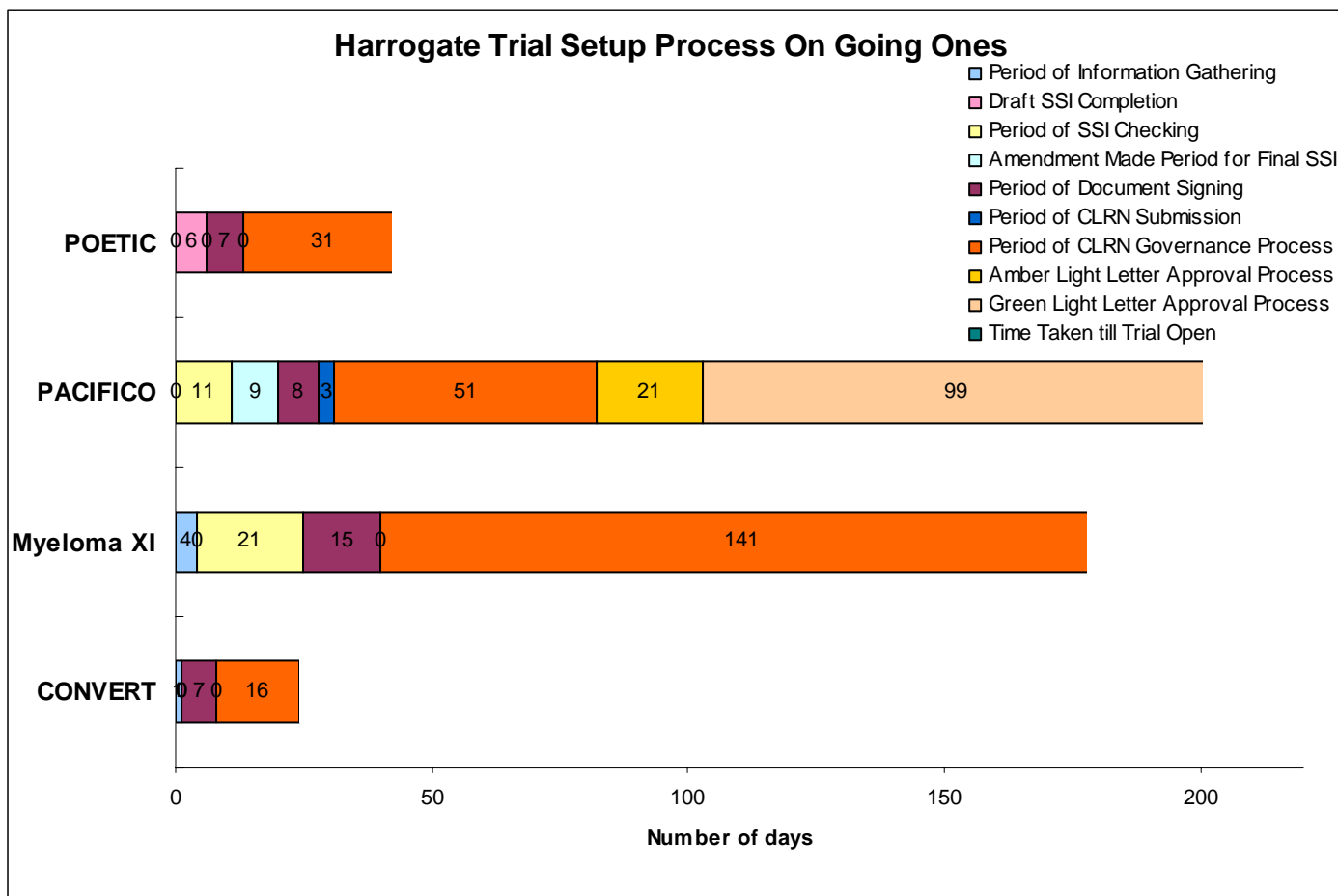
Study is not running by the LRN

Portfolio trial under 'Oral and Gastrointestinal' topic









Total recruitment for Harrogate to date is: 29





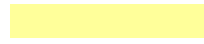

**CHOPIN:** It took 44 days from CLRN submission to Green Light Letter Approval Received. No Amber Light Letter Approval Date in Record, It may not have been a need to issue one as there were no outstanding issues.  
**NSHLG and FCLL:** No Amber Letter or Green Letter Approval date available.



The above information is as accurate as of 26 August 2010.

<b>TRIALS</b>	<b>Delayed Section</b>	<b>Reason for Delay</b>
<b>NSHLG</b>		17/02/10 - Last update from local team - still awaiting Data Protection approval.
<b>SCOT</b>	   	<p>27/08/08 - locked SSI sent to site for PI sign off but issues/discussions re. radiology delayed signing of form until 26/01/09.</p> <p>27/01/09 - R&amp;D Application submitted to NEYNL CLRN . Queries re funding of CT scans and whether they would be done in HG or York ongoing until IRMER fully signed on 13/05/09. Transferred application from NEYNL CLRN to Trust R&amp;D on 03/09/09, awaiting update</p> <p>10/09/09 - R&amp;D queried whereabouts of CTAs - replied to say that were sent to CLRN by YCRN on 28/01/09.</p> <p>11/09/09 - emailed Local Team to ask if CTU had been in touch re site initiation process.</p> <p>Issue with Clinical Trial Agreements took some time to resolve.</p>
<b>FCLL</b>	 	<p>CLRN handed over to R&amp;D on 14/05/10. YCRN had submitted application to CLRN on 31/3/10.</p> <p>Contracts sent from Harrogate to CTU on 28/06/2010. Have emailed R&amp;D to ask if amber light has been issued but have had no response.</p>
<b>CHOPIN</b>		<p>21/12/09 - received review of CTA document.</p> <p>23/12/09 - Confirmation from R&amp;D re safe receipt of hard copy application. Staff on leave till 11/01/2010, will review the application on return.</p> <p>08/01/10 - Send further information &amp; CI's c.v as requested.</p>

		<p>13/01/10 - Approval from Finance/Alison Layton already received. Data Protection approval outstanding.</p> <p>09/02/10 - All governance checks complete &amp; study will be presented to York R&amp;D on 10 Feb.</p> <p>Not yet heard about amber light letter.</p> <p>Presented to R&amp;D on 10th Feb. and green light letter issued on 26/3. May have gone straight to green if there were no outstanding issues (contract was sent with R&amp;D Application). Have emailed Hazel at York R&amp;D to check if amber light was issued.</p>
<b>ARCTIC</b>		<p>20/08/09 email received from CTU re various outstanding items, e.g. personnel log. Emailed to ask for information for IRMER approval application. Awaiting information to be sent through after staff returns from annual leave.</p> <p>27/08/09 - prepared IRMER application form and Oked by Research Nurse on 02/09/09</p> <p>10/09/09 - IRMER form sent to HG Radiology Manager for sign off. Signed copy was sent through post on 29/09/09.</p> <p>20/10/09 - received signed IRMER form.</p> <p>11/02/10 - confirmation re trial has amber light as of 8th January 2010 but awaiting notification of date of site initiation.</p> <p>13/03/10 - YCRN checked progress re whether or not the site initiation took place on 5th March and also checked whether or not the green light letter has been issued. RN confirmed that initiation has been postponed to the 9th April. CTU confirmed she has received fully signed copy of CTA and stating that other fully signed copy must be in post to R&amp;D or site team.</p> <p>Clinical Trial Agreements went missing between site and R&amp;D Office causing delay.</p>
<b>POETIC</b>		<p>Application submitted to CLRN on 26/07/2010.</p>

<b>PACIFICO</b>	 	<p>Submitted to CLRN on 08/03/2010. CLRN requested e-copy of R&amp;D application form on the 22/04/10 and then confirmed document has been transferred to R&amp;D on the 28/04/2010.</p> <p>Amber light letter received on 19/05/2010. Copied in on emails between Damon Foster and Harrogate site staff on 09/08/10 re. whereabouts of CTA. 19/08/2010 note on Clinical Tracker to say fully signed CTA sent by HG to Damon Foster and Shona Cameron liaising with CTU re date for site initiation.</p> <p>Green light letter will not be issued until DF has evidence that site initiation has taken place.</p>
<b>Myeloma XI</b>	 	<p>Complex study that needed to be discussed in detail with PI and Research Nurse. SSI checking process took longer than usual.</p> <p>Queries re pharmacy costs of drugs.</p>