

Calderdale & Huddersfield Trials Performance Report for 01 April 10 to 07 July 10									
Disease site	Trial title	Screened	Recruited	Cancer Waiting Time (a)		Annual Target	Recruitment % Target		
				Screened %	Recruited %				
Breast	AZURE (Bone Health Sub Study)	0	0	293		10	70%		
	BBC-NCRN cohort	7	7						
	CEREBEL (NCRN052)	1	1						
	COMPLETE (NCRN020)	0	0						
	IBIS-II DCIS	5	2						
	LATTE	19	19						
	SoFEA	0	0						
	TACT (Long Term)	0	0						
Breast Total		32	29	10.9%	9.9%				
Colorectal	FOCUS 3	3	0	160		5	0%		
	FOxTROT	3	0			7	0%		
	NSCCG	7	7			20	35%		
	PICCOLO	2	2			5	40%		
	QUASAR 2	6	0			5-10	0%		
Colorectal Total		21	9	13.1%	5.6%				
Gynaecology	CHORUS (Main trial - Phase III)	1	0	62		3	0%		
	RT3 VIN	In Setup							
Gynaecology Total		1	0	1.6%	0.0%	3	0%		
Lung	CONVERT	0	0	154		2	0%		
	ET Trial	7	0			6	0%		
	LungStar	9	0			4	0%		
	MALCS	5	3						
	QUARTZ	9	2			2	100%		
	FRAGMATIC	In Setup				5			
Lung Total		30	5	19.5%	3.2%				
Haematology	FCLL	0	0	79		12	17%		
	MYELOMA XI	5	2						
	MDSBio1	In Setup						7	
	PACIFICO	In Setup						6	0%
	RATHL	In Setup						6	0%
Haematology Total		5	2	6.3%	2.5%				
Melanoma	Melanoma Cohort Study	0	0	210					
Melanoma Total		0	0	0%	0%				
Upper GI	321-GO	2	0	101		2	0%		
	BILCAP	0	0			2	0%		
	COG	3	2			4	50%		
	OE05	7	2			4	50%		
	OE05 Transitional study (sub study)	0	0						
	REAL 3	3	1			12	8%		
	SOCS	0	0			10-12	0%		
	ST03	1	1			4	25%		
	TeloVac	0	0			5	0%		
	ESPAC-4	In Setup				2			
Upper GI Total		16	6	16%	6%				
Urology	LaMB	0	0	273		12	25%		
	STAMPEDE	8	3						
	TRAPEZE (PIII)	0	0					1	0%
Urology Total		8	3	3%	1%				
Grand Total (b)		113	54						
Grand Total as % CWT (c)		8.8%	4.2%						

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

(b) - Grand Total does not include 'not count' studies.

Recruitment since last PDO meeting (07.05.2010)

Trial title	Disease Site	Screened	Recruited
BBC-NCRN cohort	Breast	2	2
IBIS-II DCIS	Breast	0	1
LATTE	Breast	11	11
NCRN052 (CEREBEL)	Breast	1	1
Observational Breast Non-F	Breast	6	6
FOCUS 3	Colorectal	3	0
FOxTROT	Colorectal	3	0
NSCCG	Colorectal	7	7
PICCOLO	Colorectal	1	1
CHORUS (Main trial - Phas	Gynaecology	0	0
MYELOMA XI	Haematology	4	2
ET Trial	Lung	6	0
LungStar	Lung	7	0
MALCS	Lung	3	3
QUARTZ	Lung	6	2
321-GO	Upper Gastrointestinal	2	0
COG	Upper Gastrointestinal	1	2
OE05	Upper Gastrointestinal	5	1
REAL 3	Upper Gastrointestinal	2	0
ST03	Upper Gastrointestinal	0	1
ENTHUSE M0	Urology	1	1
STAMPEDE	Urology	5	1
Total		76	42

The recruitment information is as accurate as of 07 July 2010

Calderdale & Huddersfield Recruitment within 01 April 2010 to 07 July 2010

Trial title	C&H	Airedale	Bradford	Harrogate	Leeds	Mid Yokds	York
AZURE (Bone Health Sub Study)	0						
BBC-NCRN cohort	7	4	0	7		1	
IBIS-II DCIS	2		0		0	0	0
LATTE	19						
NCRN020 (COMPLETE)	0			0			0
NCRN052 (CEREBEL)	1						
SoFEA	0	1		0	1	0	0
TACT (Long Term)	0	0	0				
FOCUS 3	0				1		
FOxTROT	0		0	0	2		
NSCCG	7	24	4	2	0	7	1
PICCOLO	2	0	1		3		
QUASAR 2	0	0	0	0	1	3	
CHORUS (Main trial - Phase III)	0						
FCLL (Sample Study Familial CLL)	0		1		0	15	16
MYELOMA XI	2		0				
CONVERT	0		0		1		
ET Trial	0						
LungStar	0	1	0	0	0		0
MALCS	3	2		0	0	0	0
QUARTZ	2			0	1	0	
Melanoma Cohort Study	0	0	0	0	0	0	0
321-GO	0	1	2		1		0
BILCAP	0				0		
COG	2						
OE05	2		2		2		0
OE05 Transitional study (sub study)	0						
REAL 3	1	1	0		2		
SOCS	0	0	1		0		
ST03	1		0		0		
TeloVac	0						
LaMB	0				0		
STAMPEDE	3	3	0		0		
TRAPEZE (PIII)	0		0		4		

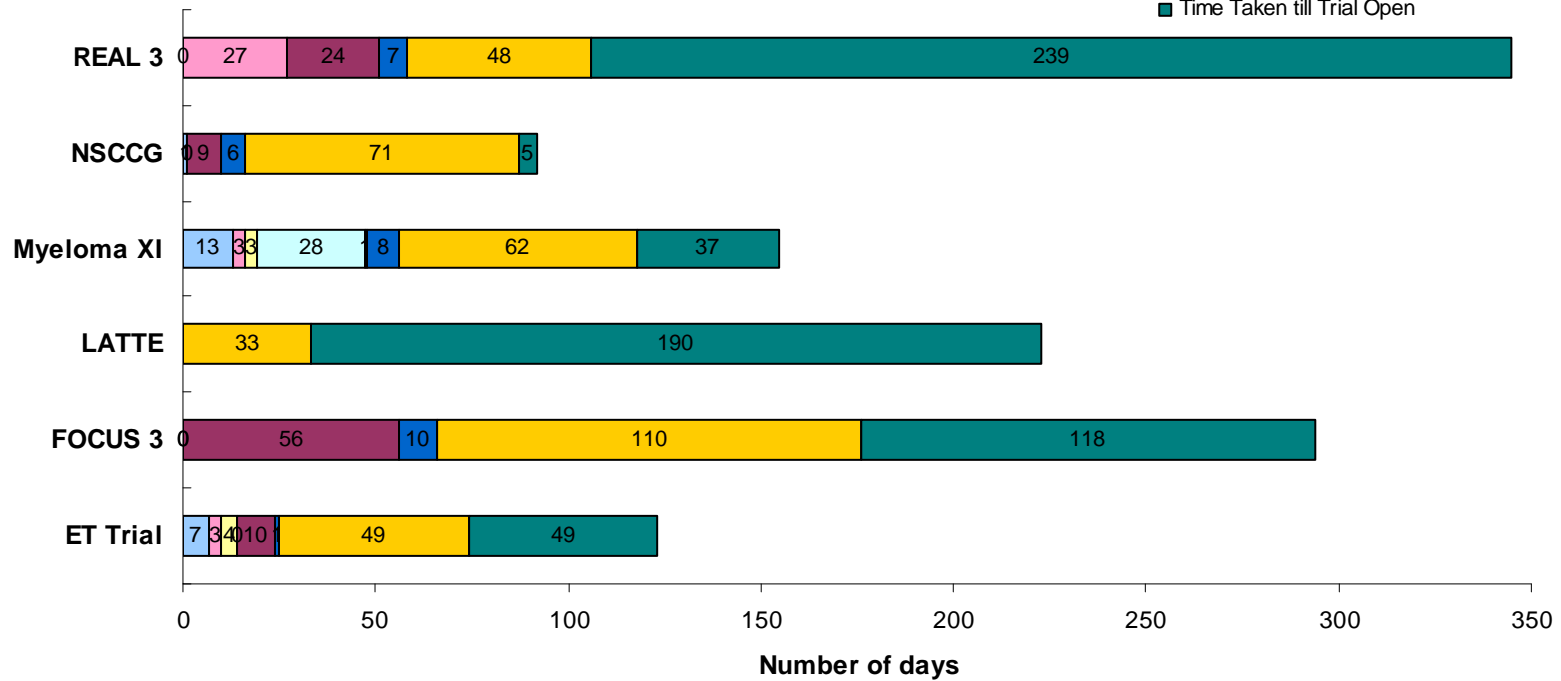
Do not count towards NCRN Primary Target
Study is not run by local team

Total recruitment for C&H: 54 (exc. 'not count' studies, non-portfolio studies and non-cancer studies)

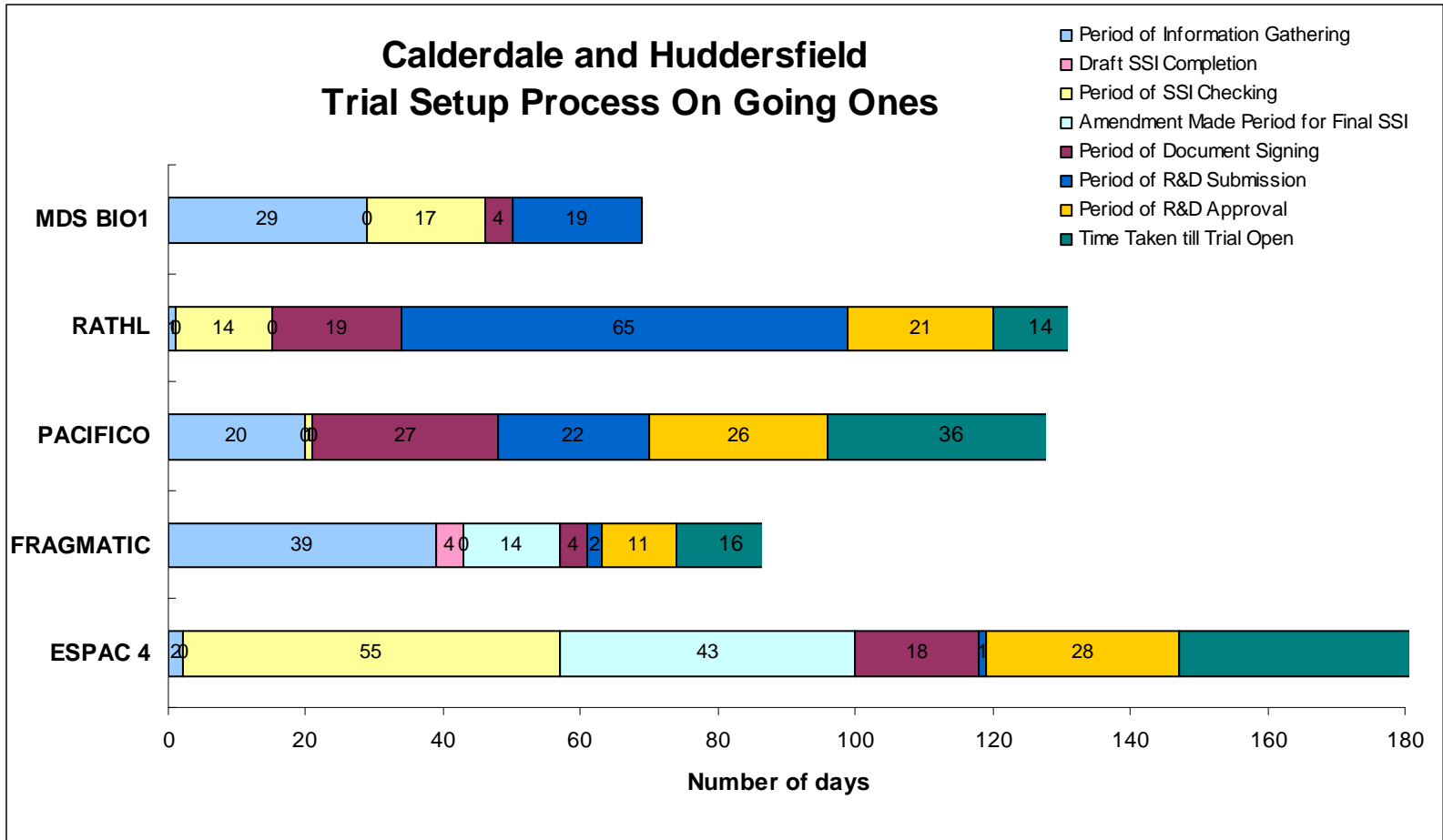
The accrual is as accurate as of 07 July 2010





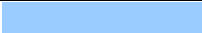

Calderdale and Huddersfield Trial Setup Process Complete within the last 6 month





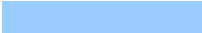


- Period of Information Gathering
- Draft SSI Completion
- Period of SSI Checking
- Amendment Made Period for Final SSI
- Period of Document Signing
- Period of R&D Submission
- Period of R&D Approval
- Time Taken till Trial Open



Calderdale and Huddersfield Trial Setup Process On Going Ones



TRIAL	Delayed Section	Reason for Delay
REAL 3	  	<p>04/02/09 - Local trial Information requested. Received on 14/04/09</p> <p>16/03/09 - SSI form received from CTU.</p> <p>21/04/09 - CVs for Nitesh Rohatgi & Elaine Dunwoodie requested to enable completion of SSI.</p> <p>05/05/9 - It was later identified NR and ED were leaving the Trust.</p> <p>15/9/09 - Clinical Trial Agreement awaiting sign-off from pharmacy department. Collecting delegation log as well.</p>
NSCCG		<p>16/12/09 - R&D application was submitted</p> <p>25/02/2010 - R&D approval granted - R&D office very busy in between dates in terms of being able to process the paperwork & issue the approval.</p>
Myeloma XI	 	<p>11/01/10 Amendments made to draft SSI.</p> <p>21/01/10 Chasing WTE for the pharmacist, IRMER approval and ARSAC.</p> <p>04/02/10 A few more amendment has been done as request by RN.</p> <p>08/02/10 Signed SSI received.</p> <p>17/02/10 applied to R&D for approval. Chased IRMER on 04/03/2010</p> <p>22/03/10 Not heard any updates from R&D.</p> <p>29/03/10 IRMER assessment received and ask for an update on the progress of the R&D approval.</p> <p>31/03/10 new amendment to add sites - documents sent to R&D</p> <p>16/4 R&D confirmed they will review the agreement and should be able to issue the approval today.</p>

LATTE		23/09/09 R&D approval granted. Awaiting for national study launch.
FOCUS 3	 	22/06/09 - locked the SSI form and emailed for signing by PI, Dr Dent. Received back on 18/08/09 27/08/09 - R&D application sent. 09/09/09 - Received the signed and completed pharmacy agreement and lab ranges from RN 16/10/09 - Emailed R&D for update 11/11/09 - Received protocol amendment from v1.0 to v3.0. Emailed R&D with the amendment. 03/12/09 - Received more amendment docs for v3.0 of protocol and v2.0 of all PIS, Consent Forms and GP Letter. Emailed R&D for amendment approval. 15/12/09 - R&D Approval received.
ET Trial		12/11 R&D confirmed need copy of PI CV+GCP, pharmacy drug destruction policy, site registration form and completed delegation log. 01/12 Chased R&D app, to be reviewed tomorrow no problems anticipated 04/12 Last page of the reg form could be redone with pathologist details not secretaries and for a signature log to be done. 15/12/09 R&D approval granted.
MDS Bio1	  	29/4/10 - Email from RN keen to start this trial at C&H. 30/4/10 - Faxed TAF received by RN 24/5/10 - Received IRAS SSI form from CTU in order to be able to complete the SSI with the TAF. 28/5/10 - Draft SSI emailed to RN. 14/6/10 - RN agreed SSI is accurate, and final SSI form able to be locked and sent for PI sign-off. 14/6/10 - SSI form agreed with RN. 18/6/10 - Received back a signed PI copy of the SSI form, from RN at Huddersfield.

		- Currently collecting final R&D documents for submission & awaiting confirmation from CTU there is no CTA involved in the study.
RATHL		29/3/10 - Received signed SSI form. 8/4/10 - Emailed through IRMER information to IRS contact + frequent chasing thereafter 27/5/10 - Received IRMER approval for the trial 02/6/10 - R&D application submitted in full 10/3/10 - SSI sent to site for signing 29/3/10 - Received back signed SSI from site
PACIFICO		18/03/10 SSI sent to site for signing. 14/4/10 - Received back signed SSI from site
FRAGMATIC		21/5/10 - Draft SSI sent to RN at site 03/6/10 - Email from RN requesting further info to be added to SSI form, regarding sub-study. Info added and sent back to RN on same day. 04/6/10 - RN confirmed SSI accurate, ok to lock and send for PI sign-off.
ESPAC 4		Draft SSI sent on 04/12/09 delay due to Christmas and New Year Holidays. 28/01/10 - received confirmation of IRMER approval. Amended SSI and forwarded to RN. 12/02/10 - received amended draft SSI back from Hayley.