

## Bradford Trials Performance Report for 01 April 2010 to 15 July 2010

Disease site	Trial title	Screened	Recruited	Cancer Waiting Time (a)		Annual Target	Recruitment % Target
				Screened %	Recruited %		
Breast	BBC-NCRN cohort	0	0	292		52	0%
	IBIS-II DCIS	2	0				
	IBIS-II Prevention	0	0				
	IMPORT-LOW	2	2			10	20%
	Persephone	0	0			35	0%
	TACT (Long Term)	0	0				
	TNT	0	0			25	0%
	LATTE	In Setup				19	0%
	POETIC	In Setup				20	0%
<b>Breast Total</b>		<b>4</b>	<b>2</b>	<b>1.4%</b>	<b>0.7%</b>		
Colorectal	CReST	1	1	149			
	COIN-B / CR11	0	0			4	0%
	FOXROT	1	0				
	NSCCG	9	4			100	4%
	PICCOLO	0	1				
	QUASAR 2	1	0				
	SCOT	3	0				
<b>Colorectal Total</b>		<b>15</b>	<b>6</b>	<b>10.1%</b>	<b>4.0%</b>		
Gynaecology	NEO-ESCAPE	1	0	44		4	0%
<b>Gynaecology Total</b>		<b>0</b>	<b>0</b>	<b>0.0%</b>	<b>0.0%</b>		
Haematology	AML 16	1	0	100		6	0%
	AML 17	0	0			10	0%
	Bortezomib Study (aka 'CHOP Velcade' or CMML201)	0	0			1	0%
		1	1			8	13%
	EBV associated NK/T cell malignancies	0	0			5	0%
	FCLL (Sample Study Familial CLL)	1	1			8	13%
	Hospital water supplies and gram negative	3	3			2	150%
	Mantle Cell PHASE 3 (LY05)	0	0			1	0%
	MRD feasibility study	0	0			2	0%
	Myeloma X Relapse	0	0			2	0%
	MYELOMA XI	0	0			8	0%
	NCRN016 - INDUSTRY STUDY	0	0			15	0%
	NCRN042	0	0			5	0%
	NCRN043	0	0			5	0%
	NSHLG - National Study of Hodgkin's Lymphoma	0	0			10	0%
	PT1 (MRC)	0	0			2	0%
	R-GCVP	0	0			10	0%
	SPIRIT 2	0	0			5	0%
	AML LEN5	In Setup					
	PACIFICO	In Setup				6	0%
R-CODOX-M/IVAC	In Setup		4	0%			
UKALL 14	In Setup		2	0%			
<b>Haematology Total</b>		<b>3</b>	<b>2</b>	<b>3.0%</b>	<b>2.0%</b>		
Head & Neck	Determination of Quality of Life Instrument	13	13	82			
	HopOn	0	0				
	PET-NECK	3	0				
<b>Head &amp; Neck Total</b>		<b>16</b>	<b>13</b>	<b>19.5%</b>	<b>15.9%</b>		
Lung	CONVERT	0	0	144		6	0%
	LungStar	0	0			6	0%
	FRAGMATIC	In Setup				2	0%
<b>Lung Total</b>		<b>0</b>	<b>0</b>	<b>0.0%</b>	<b>0.0%</b>		

Melanoma	Melanoma Cohort Study	0	0	210				
	Melanoma Lifestyle Study	1	1					
<b>Melanoma Total</b>		<b>1</b>	<b>1</b>	<b>0%</b>	<b>0%</b>			
Thyroid	TCUK IN	In Setup		NA		20		
<b>Thyroid Total</b>		<b>0</b>	<b>0</b>					
Upper GI	321-GO	2	2	151		7	29%	
	ESPAC-4	0	0				2	
	OE05	3	3				25	12%
	REAL 3	1	1				20	5%
	SOCS	3	1				12	8%
	ST03	1	0					
	BOSS	In Setup						
<b>Upper GI Total</b>		<b>10</b>	<b>7</b>	<b>7%</b>	<b>5%</b>			
Urology	CHHiP	4	4	381		3	133%	
	RADICALS (MRC PR10)	3	2				10	20%
	STAMPEDE	1	0				13	0%
	TRAPEZE (PIII)	0	0				8	0%
	UKGPCS	2	0				5	0%
<b>Urology Total</b>		<b>10</b>	<b>6</b>	<b>3%</b>	<b>2%</b>			
<b>Grand Total (b)</b>		<b>44</b>	<b>37</b>					
<b>Grand Total as % CWT (c)</b>		<b>2.8%</b>	<b>2.4%</b>					

(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' and non-cancer studies

(c) - Cancer Waiting Times (all disease) for Bradford is 1571

	Do not count towards NCRN Primary Target
	Trial is under set up
	Study has now closed to recruitment
	Non-cancer topic study

## Recruitment since last PDO meeting (14.05.2010)

Trial title	Disease Site	Screened	Recruited
IMPORT-LOW	Breast	2	2
FOxTROT	Colorectal	1	0
NSCCG	Colorectal	9	4
QUASAR 2	Colorectal	1	0
SCOT	Colorectal	3	0
CMML201	Haematology	1	1
<b>DETERMIN (Determination of Quality of Life Instrument)</b>	Head & Neck	3	5
<b>PET-NECK</b>	Head & Neck	1	0
<b>321-GO</b>	Upper GI	2	2
<b>OE05</b>	Upper GI	2	2
<b>REAL 3</b>	Upper GI	1	1
<b>SOCS</b>	Upper GI	2	1
<b>ST03</b>	Upper GI	1	0
<b>CHHiP</b>	Urology	2	2
<b>STAMPEDE</b>	Urology	1	0
<b>UK Genetic Prostate Cancer Study</b>	Urology	2	0
<b>Total</b>		<b>34</b>	<b>20</b>

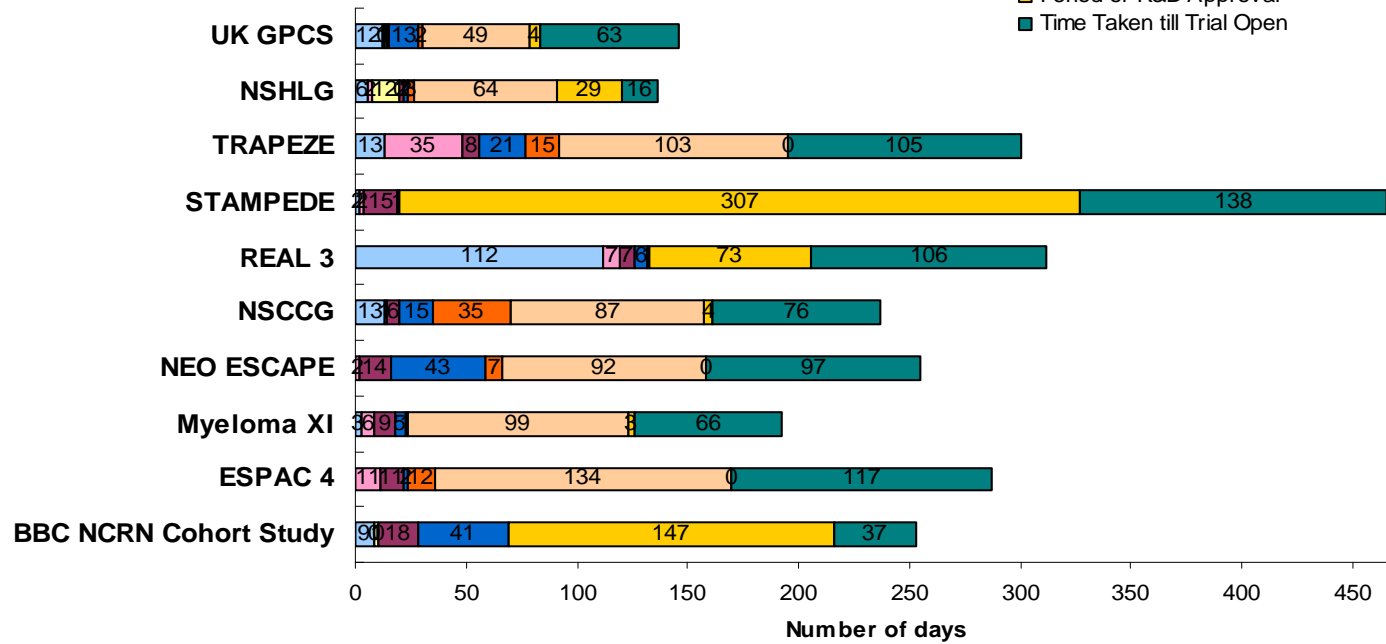
## Bradford Recruitment within April 10 to 15 JULY 2010

Trial title	Bradford	Airedale	C&H	Harrogate	Leeds	Mid Yorks	York
BBC-NCRN cohort	0	4	7	7		1	
IBIS-II DCIS	0		2		0	0	0
IBIS-II Prevention	0	0			3		
IMPORT-LOW	2				5	2	
Persephone	0	0					
TACT (Long Term)	0	0	0				
TNT	0				1		
COIN-B / CR11	0						
CReST	1			0	2	0	
FOxTROT	0		0	0	2		
NSCCG	4	25	7	2	0	7	1
PICCOLO	1	0	2		4		
QUASAR 2	0	0	0	0	1	3	
SCOT	0	2		0	1		4
NEO-ESCAPE	0	1					
AML 16	0	0		0	3	2	0
AML 17	0				1	2	0
Bortezomib Study (aka 'CHOP Velcade' or 'Relapsed	0			0	0		
CMML201	1				1		
EBV associated NK/T cell malignancies	0				0		
FCLL (Sample Study Familial CLL)	1		0		0	15	18
Hospital water supplies and gram negative infections	3						
Mantle Cell PHASE 3 (LY05)	0			0	0	0	0
MRD feasibility study	0				0		
Myeloma X Relapse	0				1	0	
MYELOMA XI	0		2				
NCRN016 - INDUSTRY STUDY	0						
NCRN042	0						
NCRN043 (GSK OMB 110911)	0				0		
NSHLG National Study of Hodgkin's Lymphoma Gene	0						
PT1 (MRC)	0	0		0	0	0	
R-GCVP	0			0	0		0
SPIRIT 2	0			1	1	1	0
DETERMIN (Determination of Quality of Life Instrume	13				0		
HopOn	0				0		
PET-NECK	0				0		
CONVERT	0		0		2		
LungStar	0	1	0	0	1		0
Melanoma Cohort Study	0	0	0	0	0	0	0
Melanoma Lifestyle Study	1			0	1	0	0
321-GO	2	1	0		2		0
ESPAC-4	0				3		
OE05	3		2		3		0
REAL 3	1	1	1		2		
SOCS	1	0	0		0		
ST03	0		1		0		
CHHiP	4				4	4	
RADICALS (MRC PR10)	2				2	1	0
STAMPEDE	0	3	3		0		
TRAPEZE (PIII)	0		0		4		
UK Genetic Prostate Cancer Study	0			0	0	1	0

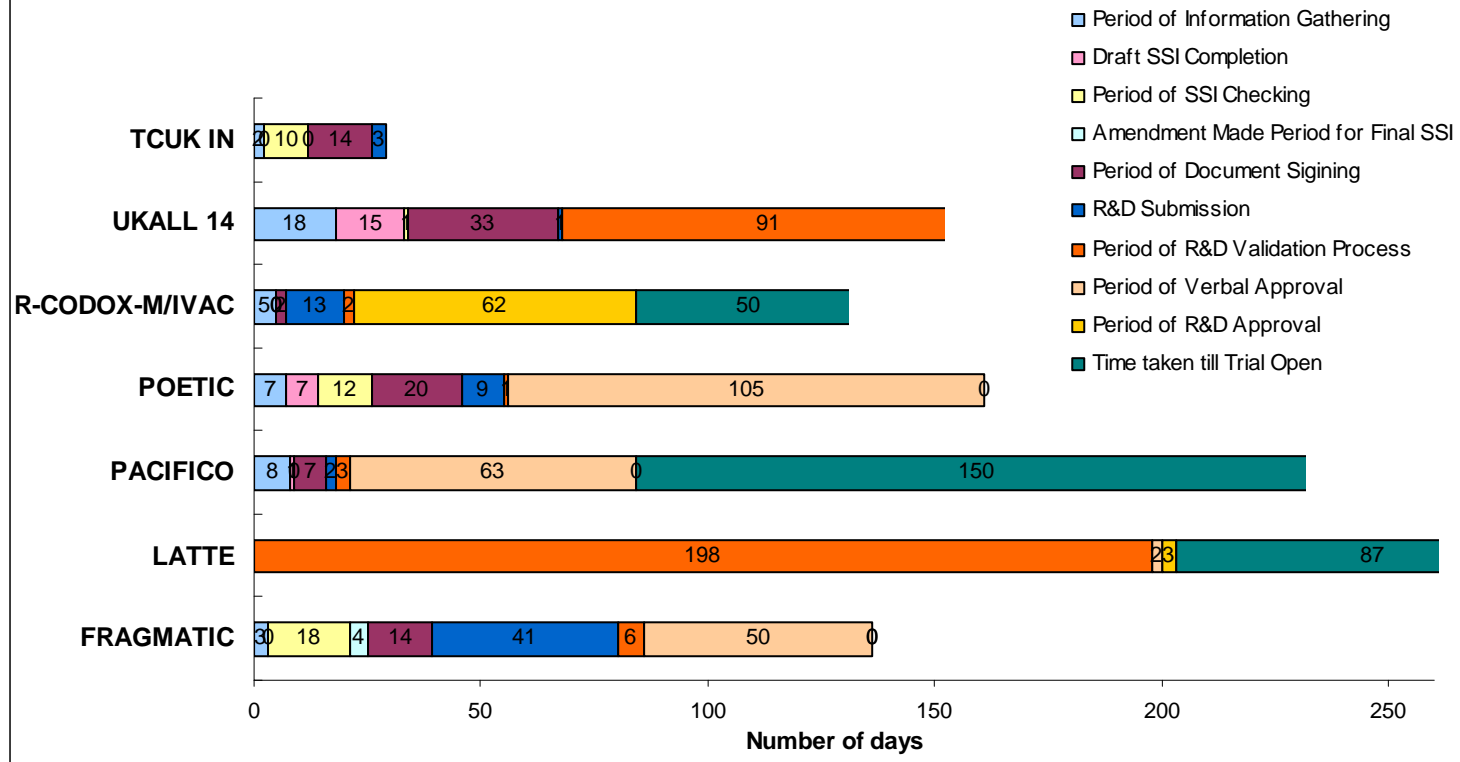
## Bradford Trial Setup Process

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
- R&D Submission
- Period of R&D Validation Process
- Period of Verbal Approval
- Period of R&D Approval
- Time Taken till Trial Open






















## Bradford Trial Setup Process On Going Ones



Received R&D Verbal approval for POETIC and FRAGMATIC as of today (15 July 2010)

<b>TRIALS</b>	<b>Delayed Section</b>	<b>Reason for Delay</b>
<b>UKALL 14</b>	 	Vicki was on leave.  R&D submitted on 15/04/10, received verbal approval on 26/05/10 but amendment is pending. No 'Valid application received' date in record.
<b>R-CODOX-M/IVAC</b>		Clarification re data protection issue requested.
<b>POETIC</b>		Verbal approval process was put off by pathology signing off.
<b>PACIFICO</b>	 	IRMER approval not granted until 8/2/10.  The agreement was not reviewed with the R&D application, although it is available on CSP. It has now been sent for review. Chased up signature log and GCP certificates.
<b>LATTE</b>	 	YCRN has been chasing the supply agreement since R&D submission on 28/09/09. All the documents listed on the approval letter and the data agreement has been sent to R&D as requested. Verbal approval was given on 16/4/10.  Waiting to resolve the IT purchasing issue.
<b>FRAGMATIC</b>	  	The SSI form was agreed and locked but then some further amendments had to be made.  Chased up missing MoU, CI CV, signed REC form and in xml before submitted to R&D.  Awaiting signature log returned to R&D,
<b>UK GPCS</b>		Delay due to queries raised by Caldicott Guardian.

		Delay in Signature collecting.
<b>NSHLG</b>		Reason for delay unknown as it has not been chased yet.
<b>TRAPEZE</b>	   	<p>20/07/09 - Time taken to obtain info re funding from CTU. Once locked it took a while for the form to be agreed due to holidays. Once the form was locked it had to be unlocked to make changes due to change from giving Strontium in Bradford to giving it in Leeds.</p> <p>Delay in getting Radiology signing off.</p> <p>08/10/10 Valid R&amp;D application confirmed.</p> <p>17/11/09 R&amp;D chased outstanding signature sheets. Needs to find out 'how much Bradford will be recharged for the strontium'.</p> <p>04/01/10 Chased sponsor's signature.</p> <p>19/01/10 Verbal approval given.</p> <p>The CTA went missing in the post at the sponsor end. Further copies have been signed and forwarded for the sponsor signature.</p>
<b>STAMPEDE</b>	 	<p>19/03/09 - Due to delay in IRMER sign off because of "radiology issues"</p> <p>R&amp;D approval received on 20/01/10.</p>
<b>REAL 3</b>	 	<p>Awaiting CTU re confirmation of Site feasibility check.</p> <p>No specific reason indicated for the delay. There was a query regarding a question on the SSI saying that there was no ionising radiation involved. Which is incorrect.</p>

		Delay in opening the trial due to the CTA and this was signed off incorrectly and had missing signatures so had to be returned to Bradford R&D.
<b>NSCCG</b>	  	16/10/09 R&D application valid. R&D stated one signature needs to be chased others are fine on 18/11/09.  04/01/10 Queried from R&D re if the relatives use the separate PIS and consent form, sorted on 06/01/09.  11/01/10 Verbal approval given.  Did not receive a copy of the R&D approval letter until 25/2. Unclear what the reason for the delay has been since then.
<b>NEO ESCAPE</b>	   	23/07/09 - Needed to check if Bradford would be doing the Abdo xray at baseline in case changes were needed to SSI.  Study was on hold during 26/08/09 to 01/10/09 during to surgical issue.  14/10/09 R&D application valid.  24/11/09 R&D queried the research bloods and should there be a separate consent for this.  14/01/10 Verbal R&D approval granted.  Delays in getting the CTA signed and organising an initiation.
<b>Myeloma XI</b>		Issues rose regarding the funding of the drugs which needs to be checked with YCN Lead Pharmacist for advice. IRMER approval not granted until 16/2/10.
<b>ESPAC 4</b>		Not all signature sheets have been received back from the departments involved. R&D approved 20/1/10.

		There was a delay in CTA sign off and also some problems organising an initiation meeting.
<b>BBC NCRN</b>		14/07/09 - R&D application first sent on 16/7/09, informed invalid on 6/8/09. Obtained missing documents and resent on 14/8/09  Not all signature sheets have been received back from the departments involved.