

Airedale Trials Performance Report for 01 April 2010 to 27 August 2010

"The YCRN is part of the NIHR and is funded by the Department of Health"

Disease site	Trial title	Screened	Recruited	Cancer Waiting Time (a)		Annual Target	Recruitment % Target
				Screened %	Recruited %		
Breast	BBC-NCRN cohort (b)	4	4	114		35	11%
	BIG 1-98	0	0				
	FH02	0	0			10	0%
	IBIS-II Prevention	9	0				
	NCRN070 (Vinflunine)	1	1			9	11%
	Persephone	2	0			12	0%
	SoFEA	0	1				
	TACT (Long Term)	0	0				
	POETIC	In Setup				12	
	REACT - Randomised EuropeAn C	In Setup				17	
TNT	In Setup		9				
Breast Total		7	6	6.1%	5.3%		
Colorectal	EnROL	0	0	107		20	0%
	NSCCG	92	33			50	66%
	QUASAR 2	5	0			20	0%
	SCOT	11	3			12	25%
Colorectal Cancer Total		108	36	100.9%	33.6%		
Gynaecology	CA125 Doubling Time	1	1	26		5	20%
	NEO-ESCAPE	3	1			11	9%
	NSECG	6	1			20	5%
	NSECG (not count)	0	0				
	ICON 6	In Setup					
Gynaecology Total		10	3	38.5%	11.5%		
Haematology	AML 16	2	0	125		6	0%
	PET Trial in Hodgkin's Disease (Ra	0	0			6	0%
	PT1 (MRC)	0	0				
	SPIRIT 2	In Setup				3	0%
Haematology Total		2	0	1.6%	0.0%		
Lung	LungStar	9	2	79		10	20%
	MALCS	3	2				
	ReSoLuCENT	5	5			20	25%
	ReSoLuCENT (Not Count)	2	3				
	FRAGMATIC	In Setup				10	0%
Lung Total		17	9	21.5%	11.4%		
Melanoma	Melanoma Cohort Study	0	0	64			
Melanoma Total		0	0	0%	0%		
Upper GI	321-GO	1	1	64		7	14%
	REAL 3	2	2			10	20%
	SOCS	0	0			10	0%
Upper GI Total		3	3	5%	5%		
Urology	STAMPEDE	12	3	160		10	30%
	RADICALS (MRC PR10)	In Setup				5	
Urology Total		12	3	8%	2%		
Grand Total (c)		159	60				
Grand Total as % CWT (d)		23.5%	8.9%				

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

(b) - BBC-NCRN cohort study might include patients who have been diagnosed in the past, which is why it's recruitment seems higher than the local CWT data

(c) - Number of grand total does not include the trials that do not count towards NCRN primary target

(d) - Cancer Waiting Times (all disease) for Airedale is 676

Recruitment since last PDO meeting (08.06.2010)

Trial title	Disease Site	Screened	Recruited
BBC-NCRN cohort	Breast	1	0
IBIS-II Prevention	Breast	1	0
NCRN070 (Vinflunine)	Breast	1	1
Persephone	Breast	2	0
NSCCG	Colorectal	43	12
QUASAR 2	Colorectal	1	0
SCOT	Colorectal	5	3
CA125 Doubling Time	Gynaecology	1	1
NSECG	Gynaecology	4	0
AML 16	Haematology	1	0
LungStar	Lung	5	1
MALCS	Lung	1	1
ReSoLuCENT	Lung	3	2
ReSoLuCENT (Not Count)	Lung	1	2
REAL 3	Upper Gastrointestinal	1	1
STAMPEDE	Urology	7	2
Total		76	24

 Do not count towards NCRN Primary Target

Airedale Recruitment within April 10 to date (27 August 2010)

Trial title	Airedale	Harrogate	Bradford	C&H	Leeds	Mid Yokds	York
BBC-NCRN cohort	4	11	6	8		1	
FH02	0				4		
IBIS-II Prevention	0		0		3		
NCRN070 (Vinflunine)	1						
SOFEA	1			1			
Persephone	0		0				
TACT (Long Term)	0		0	0			
EnROL	0						
NSCCG	33	7	5	17	3	10	1
QUASAR 2	0	0	0	0	1	3	
SCOT	3	0	0		3		4
CA125 Doubling Time	1						
NEO-ESCAPE	1		0				
NSECG	1				16		
NSECG (not count)	0						
AML 16	0	0	0		3	3	0
PET Trial in Hodgkin's Disease (R	0				1		0
PT1 (MRC)	0	0	0		0	0	
LungStar	2	0	0	1	2		0
MALCS	2	2		3	3	0	0
ReSoLuCENT	5						
ReSoLuCENT (Not Count)	3						
Melanoma Cohort Study	0	1	2	1	10	2	1
321-GO	1		2	0	4		1
REAL 3	2		2	2	4		
SOCS	0		1	0	0		
STAMPEDE	3		0	5	0		

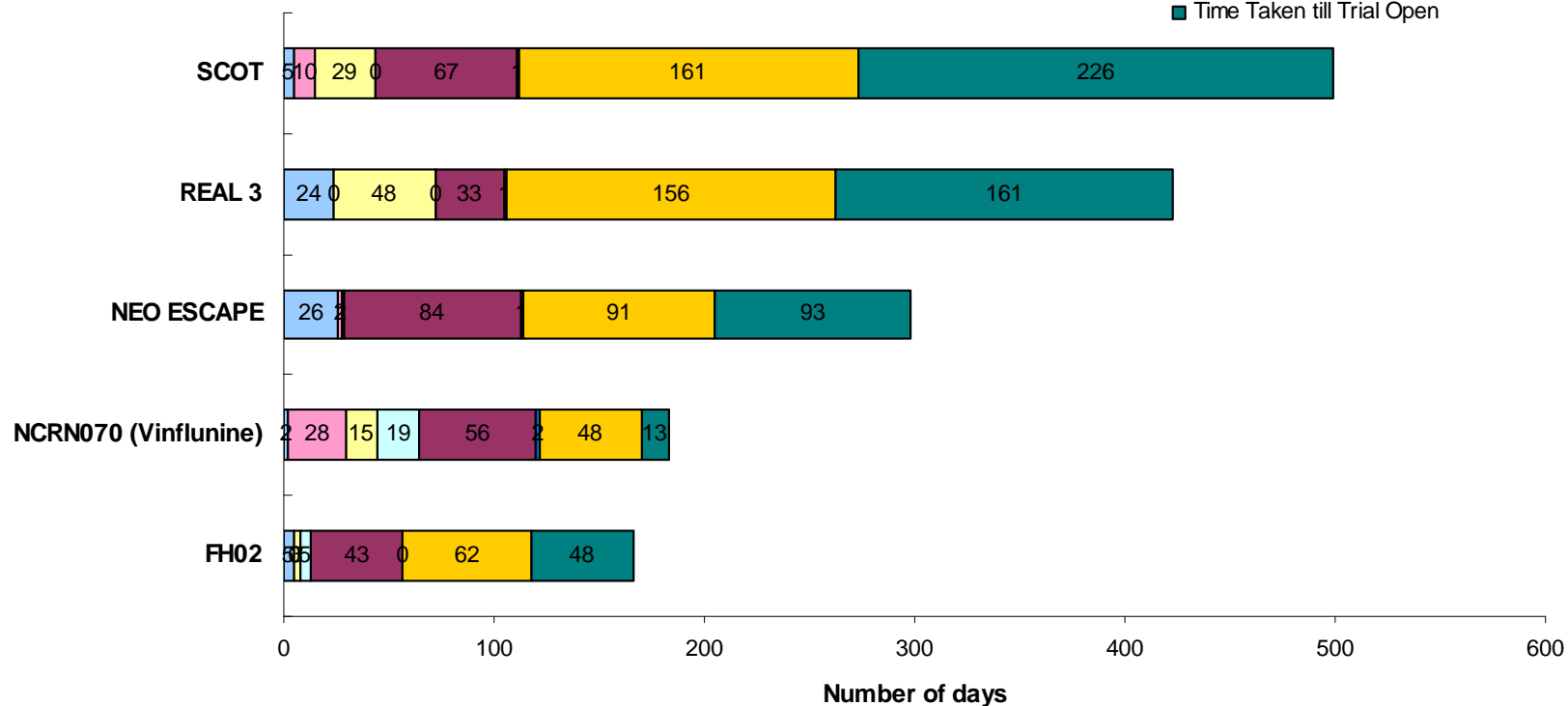
Study has now Closed

Do not count towards NCRN Primary Target

The total recruitment of Airedale to date is 60 (exc. 'not count' studies)

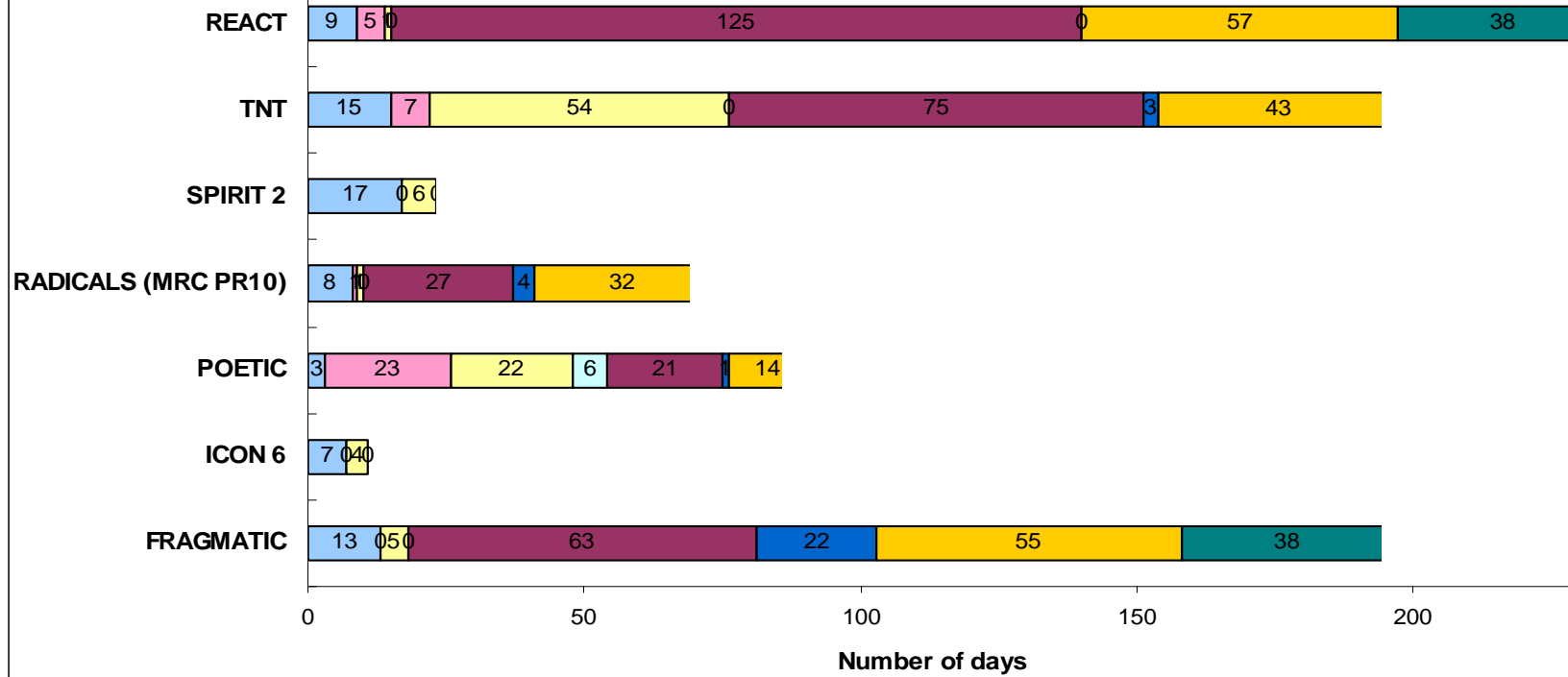
Airedale Trial Setup Process Complete within the last 6 month





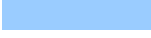




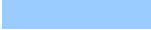
- Period of Information Gathering
- Draft SSI Completion
- Period of SSI Checking
- Amendment Made Period for Final SSI
- Period of Document Signing
- R&D Submission
- R&D Approval
- Time Taken till Trial Open
















Airedale Trial Setup Process On Going Ones

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



TRIALS	Delayed Section	Reason for Delay
SCOT	   	<p>Staff on AL during Christmas and the New Year.</p> <p>Delay in getting all necessary Departmental signatures as outlined above (please see Persephone)</p> <p>R&D submission was sent on 17/3/09. It looks like Pav didn't look at it until the end of May. Then it was with finance for costing for at least a month. Also Pav was off sick for a while.</p> <p>R&D Approval received on 25/08/09. Local team confirmed trial has not opened yet as of 18/11/09 since they only have one CT scanner currently. They have been given the go ahead to open by the trials unit but are not sure if they can start recruiting as the new CT scanner will not be available until April.</p>
REAL 3	    	<p>Initial delay caused as CTU requested completion of forms (site feasibility??) by Airedale, prior to releasing SSI to YCRN.</p> <p>29 January draft SSI sent to Airedale Research Nurse (ARN) to check.</p> <p>Various reminder emails and telephone calls made by YCRN to chase up SSI.</p> <p>18 March Airedale Research Nurse responded with changes to SSI. SSI immediately amended; form agreed and locked; form returned to Airedale to start process of obtaining Departmental signatures. Collection of signatures not completed until 21st April.</p> <p>Trial was with finance for over 3 months.</p> <p>R&D approval received on 24/09/09. Issues re CVs, SOPs etc are still outstanding before it opens.</p>
NEO-ESCAPE		<p>Correct version of SSI received 2 weeks after requested.</p>

	  	<p>28/07/09 - SSI locked and sent for signing. Surgical issue has been arisen one 19/08/09. Surgeons in Leeds didn't have agreement. On hold till 01/10/09 when surgical issues resolved.</p> <p>R&D approval was chased several times but no reason was given. There was a mention of radiology issues on the minutes of the Airedale Trials Portfolio Meeting.</p> <p>Partly due to the wait for the CTA to be signed off, partly due to trial coordinator at the trials unit being on leave and also finding a suitable day for the initiation.</p>
NCRN070	 	<p>Whole Time Equivalent is now required for the SSI forms and this info was not included on the TAF.</p> <p>Radiology were waiting for the IRMER assessment before they would sign the form</p>
REACT	 	<p>No clear reason for the delay in obtaining signatures, despite chasing.</p> <p>Delay in getting costings from Finance.</p>
TNT	  	<p>Local team has not had time to look at it.</p> <p>Delay in getting Radiology to sign off the SSI.</p> <p>R&D application submitted on 15/07/2010 but CTA needs to be amended to show Airedale's new name.</p>
FRAGMATIC	  	<p>Staff was on leave part of the time. This has been chased and she is still obtaining signatures.</p> <p>Delay in getting approval from Finance.</p> <p>Received R&D approval on the 20 July 2010. Set-up initiation meeting has been arranged on 11 August 2010.</p>