

**North East - Tyne & Wear South Research Ethics
Committee**

Annual Report

01 April 2015 - 31 March 2016



Part 1 – Committee Membership and Training

Name of REC:	North East - Tyne & Wear South Research Ethics Committee
Type of REC:	RECs recognised to review CTIMPS in patients - type iii
Type of Flag:	Phase 1 Studies in Patients
Chair:	Mr Paddy Stevenson
Vice-Chair:	Mr Ian Campbell
Alternate Vice-Chair:	Miss Christine Bullmore (up to 31/07/2015) Mrs Debra J Lett (from 01/08/2015)
REC Manager:	Miss Kathryn Murray
REC Assistant:	Miss Sarah Prothero – to September 2015 Miss Kerry Dunbar – from September 2015
Committee Address:	HRA Jarrow Jarrow Business Centre Rolling Mill Road Jarrow NE32 3DT
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Chair's overview of the past year:

Well another year has passed with me at the helm of the good ship Tyne and Wear South. As with every year we have had some valued colleagues leave which was generally down to the increasing workload all of us face away from ethics. I would like to take this opportunity to thank Sophie Barron for her insight into young people's research, Christine Bullmore for her extensive insight into ethical issues and her guidance over the years since I joined the committee. Dr Chris Plummer who's calm methodical views over the last eight years have been invaluable and finally Dr Sunnah Cook and Mr Malcolm Khan who were with us for a short time but I valued their input. With people leaving we were fortunate enough to gain some excellent new members and I look forward to working with Louise Jones and Rachel Smith over the next few years.

Despite the changes to our committee our output has been exemplary; we have increased our workload over the past year from 45 studies being reviewed at full committee in 2013/14 to 55 in 2015/16 as well as increasing our full committee meetings from 9 to 10. With the increase in studies reviewed this has accompanied an increase in complexity with CTIMP reviews increasing from 16 (35.5%) to 22 (40%).

Despite the changes in staffing and the increase in workload it is satisfying to report that our standards have not only remained high but have improved. We had no inquorate meetings in the reporting period and despite the increases in number and complexity we reported no breaches to the timeline targets. I am also proud to report that in June 2015 we were notified by the Health Research Authority that our Tyne and Wear South was one of only 15 Research Ethics Committees to meet the key performance indicators for full REC review, Proportionate review and Substantial amendments over 95% of the time. This along with being classed as excellent in the recent Shared Ethical Debate exercise clearly points out the outstanding work Kathryn and Kerry put in to support of myself and Ian Campbell, Our Vice Chair.

I'm looking forward to another interesting year with the team and I hope you find this an interesting read.

North East - Tyne & Wear South Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Ms Sam Barron	Clinical Lead, Speech and Language Therapist	Expert	01/06/2014	
Ms Sophie Barron	Student	Lay Plus	01/01/2013	19/01/2016
Mr John Blenkinsopp	Clinical Effectiveness Advisor	Lay Plus	14/06/2013	
Miss Christine Bullmore	Emergency Planning Co-ordinator	Expert	27/02/2004	31/07/2015
Mr Ian Campbell	Pharmacy	Expert	12/06/2012	
Dr Dorothy Coe	Senior Research Assistant and Lecturer in Nursing Skills and Staff Nurse (Bank)	Lay	01/05/2014	
Dr Susannah Cook	Service Improvement/Organisational Development Lead	Lay Plus	01/09/2014	11/05/2015
Mr Obi Iwuchukwu	Consultant Surgeon	Expert	07/01/2013	31/03/2016
Mrs Louise Jones	Faculty Research Administrator	Lay Plus	23/09/2015	
Mr Malcolm Khan	Lawyer - Retired	Lay Plus	01/09/2014	06/06/2015
Mrs Debra J Lett	Manager Newcastle Brain Tissue Resource	Lay	19/09/2011	
Dr Helen H Lucraft	Consultant Clinical Oncologist (retired)	Expert	01/07/2013	
Mr Graham McClelland	Research Paramedic	Expert	08/09/2014	
Dr Chris Plummer	Consultant Cardiologist	Expert	18/06/2007	28/09/2015
Miss Rachel Smith	Barrister	Lay Plus	10/08/2015	
Mr Paddy Stevenson	Research Operations Manager	Expert	01/02/2007	
Dr Kate Wilson	Retired - Interim Director of Operations	Lay	08/09/2014	

North East - Tyne & Wear South Research Ethics Committee: Deputy Members

Name	Profession	Status	Meeting date attended
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North East - Tyne & Wear South Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended
Ms Linda Chadd	Library Assistant & Archivist	Lay Plus	27/07/2015
Miss Hannah Stevenson	Data Manager, Clinical Research	Lay	28/09/2015

North East - Tyne & Wear South Research Ethics Committee: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Ms Sam Barron	Works as a Clinical Lead, Speech and Language Therapist through Northumbria Healthcare NHS Foundation Trust.	31/03/2016
Mr John Blenkinsopp	Has involvement in training charities in evidence-based practice but has no active part in research. Member of the Hartlepool NHS Foundation Trust Research Evaluation Committee (Internal Peer Review System).	10/02/2016
Mr Ian Campbell	Member of the Newcastle upon Tyne Hospital NHS Foundation Trust R&D approval Committee and the R&D Trust Executive	10/02/2016
Dr Dorothy Coe	Works as a Senior Research Assistant at Northumbria University. No further interests declared.	01/03/2016
Mrs Louise Jones	Coordinates ethical review process within role; however, due to the nature of the department, these generally do not require NHS review. Involved in the support of the University Ethics Advisory Committee in previous role with Durham University.	29/09/2015
Mrs Louise Jones	Coordinates the ethical review process within the Faculty of Agriculture, Science and Engineering at Newcastle University but has no direct involvement the review.	12/02/2016
Mrs Debra J Lett	Employee of Newcastle University. Manager of Newcastle Brain Tissue Resource, a research tissue bank which supplies samples to approved research projects. Member of management committee approving such projects. Tissue bank receives funding from the Medical Research Council, Alzheimer's Research UK and Alzheimer's Society and the NIHR via the Biomedical Research Centre and Unit.	31/03/2016
Dr Helen H Lucraft	Trustee of St Oswalds Hospice, Gosforth, Newcastle and Public Governor of Newcastle Hospitals	11/02/2016
Mr Graham McClelland	Member of the College of Paramedics. Undertaking a PhD which is based at Newcastle University Stroke Research Group. Research Paramedic for NEAS.	10/02/2016
Miss Rachel Smith	No interests declared.	09/11/2015
Mr Paddy Stevenson	Manager of Newcastle Hospitals Research team however any active involvement had in a research application is declared	10/02/2016
Dr Kate Wilson	None Declared	10/02/2016

Meetings for Full Ethical Review 01 April 2015 - 31 March 2016:

Month	Date	Number of Members Present at Meeting
April	27/04/2015	12
June	22/06/2015	11
July	27/07/2015	10
August	24/08/2015	9
September	28/09/2015	9
October	26/10/2015	10
November	23/11/2015	10
January	25/01/2016	8
February	29/02/2016	11
March	21/03/2016	10

10 full committee meetings were held during the reporting period.

Proportionate Review Sub-Committee Meetings held during 01 April 2015 - 31 March 2016:

Month	Date	Number of Members Present at Meeting
April	01/04/2015	3
April	13/04/2015	3
June	10/06/2015	3
July	10/07/2015	3
August	06/08/2015	3
September	10/09/2015	3
November	09/11/2015	3
December	07/12/2015	3
January	12/01/2016	3
February	10/02/2016	3
March	10/03/2016	3

11 proportionate review sub-committee meetings were held during the reporting period.

Sub-Committee Meetings held during 01 April 2015 - 31 March 2016:

Month	Date	Number of Members Present at Meeting
April	13/04/2015	2
April	27/04/2015	2
May	11/05/2015	2
May	19/05/2015	3
May	25/05/2015	2
June	08/06/2015	2
June	22/06/2015	2
July	06/07/2015	2
July	17/07/2015	4
July	20/07/2015	2
August	03/08/2015	2

August	17/08/2015	2
August	17/08/2015	3
August	24/08/2015	2
September	01/09/2015	2
September	14/09/2015	2
September	25/09/2015	3
September	28/09/2015	2
September	28/09/2015	3
October	08/10/2015	2
October	16/10/2015	3
October	26/10/2015	2
October	30/10/2015	3
November	06/11/2015	2
November	11/11/2015	2
November	24/11/2015	2
December	04/12/2015	2
December	07/12/2015	2
December	21/12/2015	2
January	08/01/2016	2
January	19/01/2016	2
February	05/02/2016	2
February	17/02/2016	2
March	11/03/2016	3
March	18/03/2016	2
March	29/03/2016	2

36 sub-committee meetings were held during the reporting period.

Details of inquorate meeting held: 01 April 2015 - 31 March 2016

Date	Reason	Action taken

Attendance of Members at full committee meetings: 01 April 2015 - 31 March 2016

Name	Number of Meetings Attended
Mr Ian Campbell	10
Dr Dorothy Coe	10
Mr Graham McClelland	10
Mrs Debra J Lett	9
Mr Paddy Stevenson	9
Dr Kate Wilson	9
Mr John Blenkinsopp	8
Dr Helen H Lucraft	8
Ms Sam Barron	7
Ms Sophie Barron	4
Mrs Louise Jones	4
Miss Rachel Smith	4
Dr Chris Plummer	3
Miss Christine Bullmore	2
Mr Malcolm Khan	1

Attendance of Members at proportionate review sub-committee meetings: 01 April 2015 - 31 March 2016

Name	Number of Meetings Attended
Mr Paddy Stevenson	6
Mrs Debra J Lett	5
Mr John Blenkinsopp	4
Mr Ian Campbell	4
Dr Dorothy Coe	3
Ms Sam Barron	2
Dr Helen H Lucraft	2
Mr Graham McClelland	2
Dr Kate Wilson	2
Ms Sophie Barron	1
Miss Christine Bullmore	1
Dr Chris Plummer	1

Attendance of Members at sub-committee meetings: 01 April 2015 - 31 March 2016

Name	Number of Meetings Attended
Mr Paddy Stevenson	33
Mrs Debra J Lett	27
Mr Ian Campbell	7
Ms Sam Barron	3

Dr Dorothy Coe	3
Dr Chris Plummer	3
Mr John Blenkinsopp	2
Dr Kate Wilson	2
Miss Christine Bullmore	1

Training 01 April 2015 - 31 March 2016

Name of Member	Date	Event(s) attended
Ms Sophie Barron	04/06/2015	Regional Members Training Day
Ms Sam Barron	04/06/2015	Regional Members Training Day
Mrs Louise Jones	13/01/2016	Assessing the Consequences (benefits and harms) of Research
Mrs Louise Jones	10/02/2016	New Members Induction
Mrs Louise Jones	11/03/2016	Genetic and Genomic Research - Previously Advanced HTA
Mrs Louise Jones	16/03/2016	National Members Training Day
Mrs Debra J Lett	04/06/2015	Regional Members Training Day
Mr Paddy Stevenson	31/03/2016	Self-Directed Learning Log
Mr John Blenkinsopp	16/03/2016	National Members Training Day
Mr Ian Campbell	31/03/2016	Self-Directed Learning Log
Mr Graham McClelland	31/03/2016	Self-Directed Learning 2015/16
Miss Christine Bullmore	04/06/2015	Regional Members Training Day
Dr Helen H Lucraft	04/06/2015	Regional Members Training Day
Dr Dorothy Coe	04/06/2015	Regional Members Training Day
Dr Kate Wilson	31/03/2016	Self-Directed Learning Log

PART 2: REC WORKLOAD AND ACTIVITY DURING THE REPORTING PERIOD

Table 1: Applications assigned to a full committee meeting held within the reporting period:

Applications for full ethical review – Study Type	Number	%
Clinical Trial of Investigational Medicinal Product	22	40.00
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	1	1.82
Others	32	58.18
Total Applications Reviewed	55	100

Table 2: Breakdown of full applications and other activity during reporting period

Number of applications made invalid by the REC Manager	2
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	10
Number of paediatric applications reviewed	7
Number of device applications reviewed	4
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	0
Number of applications reviewed that are funded by the US DHHS	0
Number of qualitative applications reviewed	2

Table 3: Decisions given at meetings held within the reporting period

Decisions taken at meetings following review of applications	Number	%
Favourable Opinion with Standard Conditions	3	5.45
Favourable Opinion with Additional Conditions	7	12.73
Unfavourable Opinion	1	1.82
Provisional Opinion	44	80.00
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	55	100
Number of studies sent back to full committee meeting for final opinion	0	

Table 4: Summary of current status of applications reviewed during the reporting period

Status of applications at date of generation of report	Number	%
Further Information Favourable Opinion with Standard Conditions	40	72.73
Further Information Favourable Opinion with Additional Conditions	4	7.27
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	3	5.45
Favourable Opinion with Additional Conditions	7	12.73
Unfavourable Opinion	1	1.82
Provisional Opinion	0	0.00
Provisional Opinion Pending Consultation with Referee	0	0.00
Further Information response not complete	0	0.00
No decision entered on system	0	0.00
Number of studies withdrawn after the meeting	0	0.00
Total	55	100

Table 5: Applications assigned to a proportionate review sub-committee within the reporting period

Total Applications Reviewed	31
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Table 6: Breakdown of PRS applications and other activity during reporting period:

Number of applications made invalid by the REC Manager	3
Number of studies withdrawn prior to the meeting	1
Number of student applications reviewed	13
Number of paediatric applications reviewed	4
Number of device applications reviewed	0
Number of qualitative applications reviewed	7

Table 7: Decisions given at proportionate review sub-committee meetings held within the reporting period

Decisions taken at proportionate review sub-committee meetings	Number	%
Favourable Opinion with Standard Conditions	20	64.52
Favourable Opinion with Additional Conditions	5	16.13
No Opinion transfer to full committee for review	2	6.45
Provisional Opinion	3	9.68
Unfavourable Opinion	1	3.23
Total	31	100

Table 8: Other Management Information based on the number of completed applications for the reporting period:

Average number of applications reviewed per full meeting	5.50
Number of completed applications for full ethical review	55
Number of completed applications for full ethical review over 60 days	0
Number of completed applications over 60 days as a % of total	0.00%
Number of completed applications for full ethical review over 40 days	0
Number of completed applications over 40 days as a % of total	0.00%
Number of days taken to final decision – average (mean)	26
Number of completed proportionate review applications for ethical review	29
Number of completed proportionate review applications for ethical review over 14 days	0
Number of completed proportionate review applications over 14 days as a % of total	0.00%
Number of SSAs (non-Phase 1) reviewed	9
Number of completed applications for SSA review over 25 days	0
Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs	0.00%
Number of SSAs (Phase 1) reviewed	0
Number of completed applications for SSA review over 14 days	0
Number of completed applications for SSA review over 14 days as % of all Phase 1 SSAs	0.00%
Number of substantial amendments reviewed	110
Number of completed substantial amendments over 35 days	0
Number of completed substantial amendments over 35 days as a % of total substantial amendments	0.00%
Number of completed substantial amendments over 28 days	2
Number of completed substantial amendments over 28 days as a % of total substantial amendments	1.82%
Number of modified amendments reviewed	0
Number of completed modified amendments over 14 days	0
Number of completed modified amendments over 14 days as a % of total modified amendments	0.00%
Number of minor amendments received	104
Number of substantial amendments received for information	0
Number of substantial amendments received for new sites/Pis	27
Number of annual progress reports received	54
Number of safety reports received	50
Number of Serious Adverse Events received	1
Number of final reports received	17

Table 9.1: Breakdown of current status of all full applications reviewed within the reporting period

Further Information Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
15/NE/0147	Improving Patient's First Point of Contact (Version 001)	18
15/NE/0148	AF219-010 Dose Escalation in Subjects with Refractory Chronic Cough	34
15/NE/0149	Phase 2 study in Patients with Recurrent or Metastatic SCCHN	26
15/NE/0155	Antiplatelet therapy in COPD (APPLE-COPD:ICON 2)	31
15/NE/0190	Physical Activity in Heart Failure	24
15/NE/0199	Molecular Profiling of Primary and Metastatic Penile Cancer	32
15/NE/0212	A Fulranumab study of Osteoarthritis of the hip or knee (3003)	18
15/NE/0213	CASCADE II -Version1	19
15/NE/0216	Alcohol Prevalence in Pregnancy (APP) Study	19
15/NE/0217	Brain maturation and neurodevelopmental outcome in preterm adults	18
15/NE/0243	Investigating a Self-Care Model for Patients with Prostate Cancer	21
15/NE/0251	The utility of feNO in the differential diagnosis of chronic cough	37
15/NE/0252	MK-3475 (Pembrolizumab) in Subjects with Classical Hodgkin Lymphoma	30
15/NE/0274	EORTC 1320	20
15/NE/0277	OPTIMUM	22
15/NE/0278	Efficacy & safety of 2 different aflibercept regimens in nAMD subjects	22
15/NE/0284	PRICKLE follow up	32
15/NE/0307	Does self-compassion positively relate to birth experience?	24
15/NE/0310	The Feasability of Endoscopic Ultrasound-Guided Portal Vein Manometry	25
15/NE/0329	Z7219LO2 Safinamide long-term treatment in fluctuating Parkinson's Dis	30
15/NE/0331	Dabigatran Presence in Breast Milk (DALMATION)	29
15/NE/0358	Phase II HRV16 study examining PrEP-001 in asthmatics	31
15/NE/0360	Effects of an exercise programme on women with breast cancer. v 1.0	24
15/NE/0379	Non-invasive vagus nerve stimulation in Primary Sjogrens Syndrome	28
15/NE/0381	ALTAR	22
15/NE/0382	MASS: Muscle and Ageing Science Study (V.1)	23
15/NE/0390	Myotubular and Centronuclear Patient Registry	24
15/NE/0392	HYPnosis for tastE in Head And Neck CancEr (HYP-EnHANCE)	31
15/NE/0394	A Phase 2a study of multiple doses of BTA-C585 against RSV infection	27
16/NE/0027	B9991009 Phase 3, avelumab for Platinum-Resistant Ovarian Cancer	40
16/NE/0028	SOLAR Study	31
16/NE/0031	Phase 1b study of Foxy5 in Metastatic Breast, Colon or Prostate Cancer	26

16/NE/0049	COSMIC study - A Feasibility study	27
16/NE/0066	D4190C00006 - Ph 1b MEDI4736 in Advanced Non-Small Cell Lung Cancer	30
16/NE/0067	Dose-Ranging Study of Delayed-Release Deferiprone in Parkinson	29
16/NE/0069	Study of UTTR1147A in Healthy Volunteers & Ulcerative Colitis Patients	23
16/NE/0082	Relationship between PA and metabolic control in children with T1DM.	24
16/NE/0089	COG-PBC Study	25
16/NE/0094	Acellular allogeneic peripheral nerves	23
16/NE/0097	Long-term observational study of subjects from Tanezumab studies	33

Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/NE/0119	The effect of whey protein on glycaemia and appetite in T2D	25
15/NE/0312	Residual adrenal function in Addison's disease: PREGENERAD	37
15/NE/0357	SBoCK	23
16/NE/0023	BN29552 A Study of Crenezumab in Patients with Prodromal to Mild AD	36

Further Information Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
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Favourable Opinion with Standard Conditions

REC Reference	Title	Number of Days on Clock
15/NE/0150	EPoS-UK	21
15/NE/0296	Feasibility study for a randomised trial of first-line respiratory support	17
16/NE/0096	Surveillance of emergency canthotomy and cantholysis in the UK	21

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/NE/0227	Knowledge and understanding of cognitive impairment	17
15/NE/0249	ETA305	28
15/NE/0330	ASTEROID in clinical practice	24
15/NE/0349	OSA in Pregnancy: Is STOPBANG Predictive?	22
16/NE/0008	I-KID: Infant Kidney Dialysis and filtration	28

16/NE/0068	MehealthÂ® for Rheumatoid Arthritis	23
16/NE/0083	Viral Challenge Asthma Phenotype (VCAP) Study	22

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
15/NE/0355	Cross-cultural metaphors of pain and pain management	22

Provisional Opinion

REC Reference	Title	Number of Days on Clock
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Provisional Opinion Pending Consultation with Referee

REC Reference	Title	Number of Days on Clock
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Further information response not complete

REC Reference	Title	Number of Days on Clock
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Withdrawn after the meeting

REC Reference	Title	Number of Days on Clock
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Table 9.2: Breakdown of current status of all PRS applications reviewed within the reporting period

Further Information Favourable Opinion with Standard Conditions

REC Reference	Title	Number of Days on Clock
15/NE/0246	PFT after KASS	8
15/NE/0250	Evaluating osteogenic properties of marine-organism derived extracts	8
16/NE/0018	AMR bacteria in diabetic foot ulcers	11

Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
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Further Information Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
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Favourable Opinion with Standard Conditions

REC Reference	Title	Number of Days on Clock
15/NE/0124	Assessing a Measure of Participation Version 1.0	8
15/NE/0132	Physical fitness and appetite before and after bariatric surgery	8
15/NE/0136	Hydrate for Health	8
15/NE/0138	Inflammatory, metabolic, endocrine, immunological pathways in arteries and veins	8
15/NE/0200	Development and Evaluation of a Neurorehabilitation Outcomes Database	10
15/NE/0201	PLACE Qualitative Sub-Study	10
15/NE/0202	Growth in infants with Congenital Diaphragmatic Herniae	13
15/NE/0247	Epidemiology of breast cancer subtypes defined by ER and HER2 status	8
15/NE/0283	Enterovirus D68 in a Regional UK Centre	9
15/NE/0285	Umbilical cord Cell Model of Inflammation and Disease	8
15/NE/0384	AIDE Project	10
15/NE/0387	Olympus Lucera vs Olympus Elite - an observational study	9
15/NE/0422	A Survey of patient education in atopic eczema	14
15/NE/0424	Sleep and Psoriasis Qualitative Study	13
16/NE/0026	Morbidity and Mortality in Tetralogy of Fallot	9
16/NE/0055	ROUGE V1	11
16/NE/0058	Post-traumatic stress & growth in childhood cancer survivors / parents	10
16/NE/0059	Derivation of human ear stem cells from fetal tissues	10
16/NE/0090	Psychiatric Genetic Counselling: A Pilot Study	12
16/NE/0092	Impulsivity and Executive Function Following Traumatic Brain Injury	13

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/NE/0326	NEURONAL AUTOANTIBODIES IN IRRITABLE BOWEL SYNDROME	8
15/NE/0421	Incidence of Malignancy in Patients with Lysosomal Storage Disorders	13
16/NE/0019	Asthma medication adherence in young people	10

16/NE/0056	Patient Discharge from acute medicine: Observation of practice	13
16/NE/0088	Study assessing patient perception and adherence to medicine	12

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
16/NE/0091	Exploring the psychosocial needs of amputee patients during recovery	14

Provisional Opinion

REC Reference	Title	Number of Days on Clock
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Further information response not complete

REC Reference	Title	Number of Days on Clock
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Withdrawn after the meeting

REC Reference	Title	Number of Days on Clock
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Table 10.1: Breakdown of current status of all substantial amendments reviewed within the reporting period

Favourable opinion				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
06/Q0904/78/AM39	Peri-operative Chemotherapy & Bevacizumab in Gastric Cancer (ST03)	Substantial Amendment 10, 25/0	08/07/2015	15
06/Q0904/78/AM43	Peri-operative Chemotherapy & Bevacizumab in Gastric Cancer (ST03)	Substantial Amendment 11 - 7/1	07/12/2015	8
07/H0904/77/AM19	Study of INT-747 in Primary Biliary Cirrhosis- Version 1	SA-201 IB v13 Addendum 8 PIS_I	16/06/2015	18
07/H0904/77/AM20	Study of INT-747 in Primary Biliary Cirrhosis- Version 1	Substantial Amendment 17 - SA2	09/10/2015	21
10/H0904/49/AM20	CFTY720D2399 a possible treatment for MS extension study	Substantial Amendment 9 - 9/9/	09/09/2015	22
11/NE/0039/AM11	Open Label Brivaracetam Study in Patients with Partial Onset Seizures	Substantial Amendment 8, 28/07	28/07/2015	9
11/NE/0039/AM12	Open Label Brivaracetam Study in Patients with Partial Onset Seizures	Substantial Amendment 9 - 22/1	22/12/2015	28
11/NE/0334/AM05	Extension Study of rhuMAb BETA7 in patients with Ulcerative Colitis	Substantial Amendment 4, 27/06	29/07/2015	23
12/NE/0018/AM03	Virtual reality intervention for anxiety in children with ASD version1	Substantial Amendment 3, 23/07	24/07/2015	13
12/NE/0160/AM03	ICON 1	Substantial Amendment 3, 02/04	13/04/2015	15
12/NE/0225/AM06	Fatigue fingerprints	Substantial Amendment 3, 27/04	29/04/2015	14
12/NE/0234/AM04	RCT of CPAP in patients with diabetic retinopathy and OSA (ROSA Trial)	Amendment 4	13/03/2015	23

12/NE/0235/AM08	Paediatric Liver Transplant study with Everolimus	Substantial Amendment 7, 30/04	30/04/2015	26
12/NE/0323/AM17	First in Human Study of VX-970 in Advanced Solid Tumors VX12-970-001	Substantial Amendment 12, 07/0	12/05/2015	12
12/NE/0323/AM18	First in Human Study of VX-970 in Advanced Solid Tumors VX12-970-001	Substantial Amendment 13, 10/0	24/07/2015	13
12/NE/0323/AM22	First in Human Study of VX-970 in Advanced Solid Tumors VX12-970-001	Substantial Amendment 15, 02/0	02/09/2015	19
12/NE/0323/AM24	First in Human Study of VX-970 in Advanced Solid Tumors VX12-970-001	Substantial Amendment 17 - 18/	18/01/2016	1
12/NE/0333/AM10	Tasquinimod in patients with advanced/ metastatic HCC,GC,OAC and RCC	Substantial Amendment 6, 08/06	08/06/2015	8
12/NE/0355/AM03	129Xe/3He MRI in idiopathic pulmonary fibrosis patients. Version 1.0	Substantial Amendment 3, 17/03	27/04/2015	15
12/NE/0355/AM04	129Xe/3He MRI in idiopathic pulmonary fibrosis patients. Version 1.0	Substantial Amendment 4 - 20/1	20/10/2015	20
13/NE/0049/AM12	BAY 94-9027 pediatric pharmacokinetics, safety, and efficacy trial	Substantial Amendmetnt 7 - 18/	18/09/2015	10
13/NE/0095/AM03	Objective movement assessment in preterm infants (Version 1.0)	Substantial Amendment 1, 16/04	19/04/2015	20
13/NE/0196/AM15	Antibiotic prophylaxis for clean intermittent catheterisation v1.0	Substantial Amendment 11	13/03/2015	23
13/NE/0196/AM17	Antibiotic prophylaxis for clean intermittent catheterisation v1.0	Substantial Amendment 12, 20/0	21/05/2015	18
13/NE/0196/AM22	Antibiotic prophylaxis for clean intermittent catheterisation v1.0	Substantial Amendment 15, 28/0	25/08/2015	26

13/NE/0196/AM24	Antibiotic prophylaxis for clean intermittent catheterisation v1.0	Substantial Amendment 16 - 29/	29/01/2016	14
13/NE/0259/AM01	THALAMOSS	Substantial Amendment 1, 04/03	02/07/2015	13
13/NE/0269/AM06	Maintenance Study of Niraparib/Placebo in Patients with Ovarian Cancer	Substantial Amendment 3 - 11/9	11/09/2015	13
13/NE/0270/AM03	CD64 as a marker of prosthetic joint infection	Substantial Amendment 4 - 5/12	05/12/2015	22
13/NE/0280/AM06	AZ: D0816C00005 - Ph. 1 Study Hepatic Function/Impairment	Substantial Amendment 4 - 23/9	23/09/2015	15
13/NE/0293/AM04	PK study of Carfilzomib in Patients with Hepatic Impairment	Substantial Amendment 7 - 11/1	19/11/2015	28
13/NE/0336/AM04	Trial of Proton Pump Inhibitors in Throat Symptoms	Substantial Amendment 2 - 9/9/	09/09/2015	20
13/NE/0336/AM05	Trial of Proton Pump Inhibitors in Throat Symptoms	Substantial Amendment 3 - 7/1	07/12/2015	13
13/NE/0342/AM06	OPTIMISTIC	Substantial Amendment 6, 04/06	02/07/2015	20
13/NE/0344/AM13	A monotherapy study of ertugliflozin in participants with T2DM	Substantial Amendment 8, 13/05	14/05/2015	20
13/NE/0344/AM14	A monotherapy study of ertugliflozin in participants with T2DM	Substantial Amendment 9, 31/07	31/07/2015	14
13/NE/0344/AM15	A monotherapy study of ertugliflozin in participants with T2DM	Substantial Amendment 10 - 23/	23/11/2015	25
13/NE/0355/AM04	AMG145 vs Ezetimibe in Statin Intolerant Hypercholesterolemic Subjects	Substantial Amendment 3 - 13/8	13/08/2015	27

14/NE/0010/AM02	Phase I study of PM01183 with cisplatin in advanced solid tumors.	Substantial Amendment 3, 24/04	24/04/2015	12
14/NE/0016/AM07	Ibodontant for relief of irritable bowel syndrome (Nak-06)	Substantial Amendment 5 - 16/9	16/09/2015	15
14/NE/0017/AM08	Ibodontant for relief of irritable bowel syndrome (Nak-07)	Substantial Amendment 5 - Chan	20/07/2015	13
14/NE/0073/AM04	BI836845 in women with Breast Cancer.	Substantial Amendment 2	01/06/2015	16
14/NE/0073/AM06	BI836845 in women with Breast Cancer.	Substantial Amendment 3 - 8/9/	08/09/2015	21
14/NE/0073/AM07	BI836845 in women with Breast Cancer.	Substantial Amendment 4 - 14/1	14/10/2015	21
14/NE/0073/AM08	BI836845 in women with Breast Cancer.	Substantial Amendment 5 - 4/12	04/12/2015	18
14/NE/0127/AM03	Validation of a palliative needs assessment tool in ILD (NA-ILD study)	Substantial Amendment 3 - 24/1	23/11/2015	19
14/NE/0147/AM02	D081CC00001, PK study Olaparib in combination with Endocrine therapy	Substantial Amendment 1 - 23/6	23/06/2015	15
14/NE/0151/AM04	THYRoxine in Acute Myocardial Infarction (ThyrAMI)	Substantial Amendment 3, 17/03	27/03/2015	18
14/NE/0151/AM05	THYRoxine in Acute Myocardial Infarction (ThyrAMI)	Substantial Amendment 4, 08/05	05/06/2015	16
14/NE/1040/AM02	Pfizer A3921092 - Phase 3 Tofacitinib (Active PsA) Extension Study	Substantial Amendment 2, 30/03	31/03/2015	19
14/NE/1040/AM03	Pfizer A3921092 - Phase 3 Tofacitinib (Active PsA) Extension Study	Substantial Amendment 3, 23/01	13/05/2015	12

14/NE/1040/AM04	Pfizer A3921092 - Phase 3 Tofacitinib (Active PsA) Extension Study	Substantial Amendment 4 - June	21/08/2015	19
14/NE/1041/AM07	A Phase II randomized study of OligoG in subjects with cystic fibrosis	Substantial Amendment 4 UK, 12	12/03/2015	24
14/NE/1041/AM08	A Phase II randomized study of OligoG in subjects with cystic fibrosis	Substantial Amendment 5 UK, 07	07/05/2015	18
14/NE/1041/AM10	A Phase II randomized study of OligoG in subjects with cystic fibrosis	Substantial Amendment 7, 27/08	02/09/2015	17
14/NE/1041/AM12	A Phase II randomized study of OligoG in subjects with cystic fibrosis	Substantial Amendment 8 - 26/10/15	26/10/2015	12
14/NE/1041/AM14	A Phase II randomized study of OligoG in subjects with cystic fibrosis	Substantial Amendment 9 - 18/1	18/11/2015	21
14/NE/1042/AM05	Biomarkers of Remission in Rheumatoid Arthritis (BioRRA)	Substantial Amendment 2, 05/06	22/07/2015	14
14/NE/1046/AM01	The Humanising Care Project.	Substantial Amendment 1, 26/08	28/10/2015	14
14/NE/1075/AM03	TRAFIC	Substantial Amendment 2, 10/03	08/04/2015	19
14/NE/1075/AM05	TRAFIC	Substantial Amendment 3 - 23/1	23/10/2015	12
14/NE/1080/AM04	Tropomyosin Receptor kinase Antagonism in Cylindromatosis (TRAC)	Substantial Amendment 2, 22/06	24/06/2015	20
14/NE/1098/AM04	D5160C00012 - Phase I, Open Label, EGFRm positive NSCLC (Inhibitor)	Substantial Amendment 4	20/03/2015	22
14/NE/1098/AM06	D5160C00012 - Phase I, Open Label, EGFRm positive NSCLC (Inhibitor)	Substantial Amendment 5,	03/06/2015	20

		01/06		
14/NE/1123/AM01	Tobacco and older people: A mixed methods exploration	Amendment 1	09/03/2015	22
14/NE/1143/AM04	ACCURE-UK Feasibility Study	Substantial Amendment 3, 09/04	23/04/2015	20
14/NE/1143/AM05	ACCURE-UK Feasibility Study	Substantial Amendment 4 - 21/5	21/05/2015	12
14/NE/1144/AM11	The NAational Trial of Tonsillectomy IN Adults (NATTINA)	Substantial Amendment 3 - 3/12	03/12/2015	28
14/NE/1145/AM05	A Study of Ruxolitinib in advanced HER-2 negative breast cancer	Substantial Amendment 4, 30/04	01/05/2015	25
14/NE/1145/AM06	A Study of Ruxolitinib in advanced HER-2 negative breast cancer	Substantial Amendment 5 - 18/1	18/12/2015	26
14/NE/1148/AM01	Endothelial cell culture in pulmonary hypertension	Substantial Amendment 1, 22/05	22/05/2015	17
14/NE/1150/AM02	Microvascular monitoring during liver resection surgery - pilot study	Substantial Amendment 1 - 4/2/	04/02/2016	13
14/NE/1179/AM01	ECASS - Evaluation of a Computer Aid for assessing Stomach Symptoms	Substantial Amendment 1 – 13/8	13/08/2015	21
14/NE/1190/AM02	MS Fine	Substantial Amendment 1, 06/07	10/07/2015	10
14/NE/1214/AM11	A Phase 2 Veliparib plus Chemotherapy Study in Non-Squamous NSCLC	Substantial Amendment 3 - 17/7	17/07/2015	29
14/NE/1214/AM12	A Phase 2 Veliparib plus Chemotherapy Study in Non-Squamous NSCLC	Substantial Amendment 6, 14/10	20/10/2015	13
14/NE/1221/AM03	EPOS Trial	Substantial Amendment 2 - 15/1	15/10/2015	18

14/NE/1253/AM06	D5160C00019 - Phase I, Open Label, PK, EGFRm+ NSCLC (Rosuvastatin)	Substantial Amendment 5	20/03/2015	23
14/NE/1253/AM08	D5160C00019 - Phase I, Open Label, PK, EGFRm+ NSCLC (Rosuvastatin)	Substantial Amendment 6, 01/06	02/06/2015	23
15/NE/0025/AM01	Performance of HE4 in ovarian cancer screening	Substantial Amendment 1, 29/04	29/04/2015	7
15/NE/0025/AM02	Performance of HE4 in ovarian cancer screening	Substantial Amendment 2 - 1/12	01/12/2015	15
15/NE/0058/AM01	The Genome Diversity in Africa Project (GDAP)	Substantial Amendment 1, 01/10	02/10/2015	6
15/NE/0058/AM02	The Genome Diversity in Africa Project (GDAP)	Substantial Amendment 2, 16/10	22/10/2015	20
15/NE/0058/AM03	The Genome Diversity in Africa Project (GDAP)	Substantial Amendment 3 - 23/1	23/11/2015	25
15/NE/0058/AM04	The Genome Diversity in Africa Project (GDAP)	Substantial Amendment 4, 01/02	01/02/2016	16
15/NE/0070/AM01	A Phase 1b study in patients with B-Cell Chronic Lymphocytic Leukemia	Substantial Amendment 1	25/03/2015	23
15/NE/0070/AM02	A Phase 1b study in patients with B-Cell Chronic Lymphocytic Leukemia	Substantial Amendment 2, 01/06	04/06/2015	19
15/NE/0070/AM03	A Phase 1b study in patients with B-Cell Chronic Lymphocytic Leukemia	Substantial Amendment 3 - 3/11	03/11/2015	22
15/NE/0070/AM04	A Phase 1b study in patients with B-Cell Chronic Lymphocytic Leukemia	Substantial Amendment 4, 01/02	01/02/2016	16
15/NE/0072/AM03	CICERO Version 1	Substantial Amendment 3, 17/08	27/08/2015	18

15/NE/0119/AM01	The effect of whey protein on glycaemia and appetite in T2D	Substantial Amendment 1, 08/07	08/07/2015	14
15/NE/0124/AM03	Assessing a Measure of Participation Version 1.0	Substantial Amendment 1 - 21/9	21/09/2015	17
15/NE/0138/AM01	Inflammatory, metabolic, endocrine, immunological pathways in arteries and veins	Substantial Amendment 1 - 7/10	07/10/2015	23
15/NE/0149/AM04	Phase 2 study in Patients with Recurrent or Metastatic SCCHN	Substantial Amendment 2 - 14/9	14/09/2015	15
15/NE/0149/AM07	Phase 2 study in Patients with Recurrent or Metastatic SCCHN	Substantial Amendment 4 - 19/1	19/11/2015	28
15/NE/0150/AM02	EPoS-UK	Substantial Amendment 1 - 23/1	23/12/2015	8
15/NE/0155/AM03	Antiplatelet therapy in COPD (APPLE-COPD:ICON 2)	Substantial Amendment 1 - 8/12	08/12/2015	19
15/NE/0201/AM01	PLACE Qualitative Sub-Study	Substantial Amendment 1, 14/09	23/09/2015	7
15/NE/0212/AM01	A Fulranumab study of Osteoarthritis of the hip or knee (3003)	Substantial Amendment 1, 19/10	19/10/2015	23
15/NE/0212/AM02	A Fulranumab study of Osteoarthritis of the hip or knee (3003)	Substantial Amendment 2 - 17/1	17/12/2015	27
15/NE/0212/AM03	A Fulranumab study of Osteoarthritis of the hip or knee (3003)	Substantial Amendment 3 - 11/1	11/01/2016	8
15/NE/0249/AM01	ETA305	Substantial Amendment 1 - 13/7	13/08/2015	21
15/NE/0252/AM02	MK-3475 (Pembrolizumab) in Subjects with Classical Hodgkin	Substantial	05/11/2015	25

	Lymphoma	Amendment 01 - 05/		
15/NE/0252/AM03	MK-3475 (Pembrolizumab) in Subjects with Classical Hodgkin Lymphoma	Substantial Amendment 3 - 21/1	21/01/2016	19
15/NE/0277/AM02	OPTIMUM	Substantial Amendment 2 - 11/1	11/12/2015	28
15/NE/0277/AM03	OPTIMUM	Substantial Amendment 3 - 10/3	10/03/2016	20
15/NE/0278/AM03	Efficacy & safety of 2 different aflibercept regimens in nAMD subjects	Substantial Amendment 2 - 10/1	10/12/2015	16
15/NE/0296/AM02	Feasibility study for a randomised trial of first-line respiratory support	Substantial Amendment 1 - 22/1	22/01/2016	8
15/NE/0387/AM01	Olympus Lucera vs Olympus Elite - an observational study	Substantial Amendment 1 - 4/12	04/12/2015	14

Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
13/NE/0344/AM16	A monotherapy study of ertugliflozin in participants with T2DM	Substantial Amendment 11 - 24/	24/02/2016	35

Table 10.2: Breakdown of current status of all modified amendments reviewed within the reporting period

Favourable opinion timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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Unfavourable opinion timeline				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock

Table 11: Items exceeding timelines

Full applications for ethical review over 60 day timeline

REC Reference	Title	Number of Days on Clock
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Proportionate review applications for ethical review over 14 day timeline

REC Reference	Title	Number of Days on Clock
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SSAs (non Phase 1) over 25 day timeline

REC Reference	Title	Number of Days on Clock
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SSAs (Phase 1) over 14 day timeline

REC Reference	Title	Number of Days on Clock
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Substantial Amendments over 35 day timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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Modified Amendments over 14 day timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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