

**North East - Newcastle & North Tyneside 2
Research Ethics Committee**

Annual Report

01 April 2015 - 31 March 2016



Part 1 – Committee Membership and Training

Name of REC:	North East - Newcastle & North Tyneside 2 Research Ethics Committee
Type of REC:	REC recognised to review CTIMPs in Patients – Type III
Type of Flag:	Research Involving Adults Lacking Capacity
Chair:	Dr Alasdair MacSween
Vice-Chair:	Dr Sarah Bartlett from May 2015 – March 2016 (resigned) Position currently vacant.
Alternate Vice-Chair:	Dr Jared Thornton
REC Manager:	Mrs Helen Wilson (July 2014 – February 2016) Mrs Hayley Henderson (February 2016 – Current)
REC Assistant:	Donna Bennett (July 2014 – February 2016)
Committee Address:	HRA Jarrow Jarrow Business Centre Rolling Mill Road Jarrow NE32 3DT
Telephone:	
Email:	nrescommittee.northeast-newcastleandnorthtyneside2@nhs.net

Chair's overview of the past year:

The Committee has continued to function very well over this year giving (in my opinion) well judged, defensible and precise ethical opinions which are consistent with the current mores, standards and expectations of UK Society and the REC community in general. We have continued to enjoy exemplary administrative support (from Helen, Kerry and Hayley) and we are very grateful for their hard work and assistance. Members have shown respect for all applicants and have conducted themselves in a professional and courteous way in all their interactions with applicants.

There has been some turnaround of membership with some long standing members leaving, but, appropriate new members have replaced them and the committee is well constituted. Our Alternate Vice Chair is currently on sabbatical for a year and we are also looking to appoint a Vice Chair for the Committee.

North East - Newcastle & North Tyneside 2 Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Mr Chris Barron	ECMC & CTU Manager	Expert	16/07/2007	
Dr Sarah Bartlett	Child and Adolescent Psychiatrist	Expert	11/05/2015	07/03/2016
Mrs Ann Boardman	Retired Educationalist	Lay Plus	01/02/2010	
Mr Andrew Brenikov	Historian	Lay Plus	01/04/2008	
Mrs Jane Curry	Head of Cardiac and Respiratory Services	Expert	01/10/2013	
Dr Sumeet Gupta	Consultant Psychiatrist	Expert	09/07/2014	
Dr Alasdair MacSween	Principal Lecturer in Research Governance	Expert	01/04/2013	
Mrs Gaynor Mitchell	Part-time Biology Lecturer (Retired)	Lay Plus	01/06/2011	
Mrs Susan P Phillips	Clinical Lead Pharmacist	Expert	13/10/2003	
Dr Meiyi Pu	Consultant	Expert	01/05/2014	
Ms Vicky Ryan	Statistician	Expert	15/07/2011	
Miss Hannah Stevenson	Data Manager, Clinical Research	Lay	07/07/2014	
Ms Emma Thompson	Research Radiographer	Expert	10/04/2015	
Dr Jared Thornton	Clinical Trials Co-ordinator	Lay	12/07/2011	
Mr Richard Tomlin	Consultant in Research Management (Retired)	Lay Plus	01/05/2015	

North East - Newcastle & North Tyneside 2 Research Ethics Committee: Deputy Members

Name	Profession	Status	Meeting date attended
Mrs Nermine Basta	Research Assistant/Statistician	Expert	21/10/2015
Mrs Nermine Basta	Research Assistant/Statistician	Expert	19/08/2015
Mrs Nermine Basta	Research Assistant/Statistician	Expert	15/04/2015

North East - Newcastle & North Tyneside 2 Research Ethics Committee: Co-opted

Name	Profession	Status	Meeting date attended
N/A			

North East - Newcastle & North Tyneside 2 Research Ethics Committee: Members'

Name	Declaration of Interest	Date
Mr Chris Barron	Manager the late phase Oncology Trials Team at Sir Bobby Robson Cancer Trials Research Centre, Freeman Hospital, Newcastle Hospitals Trust.	09/02/2016
Mrs Nermine Basta	None.	24/04/2015
Mrs Ann Boardman	None	09/02/2016
Mr Andrew Brenikov	None.	22/01/2016
Mrs Jane Curry	Sit on County Durham and Darlington NHS Foundation Trust Research and Development Committee	18/01/2016
Dr Sumeet Gupta	I am a member of Research Leaders Group of Tees, Esk & Wear Valleys NHS Foundation Trust	17/02/2016
Dr Alasdair MacSween	None	09/02/2016
Mrs Gaynor Mitchell	Member of Carers' Management Board (Sunderland Care and Support Ltd).	03/03/2016
Mrs Susan P Phillips	None	17/02/2016
Dr Meiyi Pu	None	13/01/2016
Ms Vicky Ryan	My employment by the Newcastle Clinical Trials Unit at Newcastle University has the potential to conflict with the purpose role or remit of this NHS REC. Should such a conflict arise as a result of my being involved with an application to the REC during the course of my employment I undertake to inform the REC coordinator of the specific conflict of interest at the earliest opportunity.	10/02/2016
Miss Hannah Stevenson	I work as an Assistant Clinical Trials Co-ordinator for Newcastle University at the Clinical Research Facility, Royal Victoria Infirmary, Newcastle upon Tyne Hospitals NHS Foundation Trust. I am involved in the set-up and running of many research studies that run through the Clinical Research Facility.	13/01/2016
Ms Emma Thompson	None	10/02/2016
Mr Richard Tomlin	Wife is an active member of the Multiple Sclerosis Society. She acts as a lay referee for research proposals, as a reviewer of on-going projects, and is a member of a national task group on integration of health and social care. Lead Governor of Northumberland Tyne and Wear NHS FT. Member of Selection Panel for NIHR Postdoctoral Awards. Members of NIHR HTA Panel for Mental Psychological and Occupational Health. My wife is a Governor of the North East Ambulance Service NHS FT.	02/05/2015

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

Month	Date	Number of Members Present at Meeting
April	15/04/2015	9
May	20/05/2015	9
June	17/06/2015	13
August	19/08/2015	8
September	16/09/2015	11
October	21/10/2015	10
December	16/12/2015	7
January	20/01/2016	11
February	17/02/2016	8

9 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	15/04/2015	3
June	23/06/2015	3
July	28/07/2015	3
August	26/08/2015	3
September	23/09/2015	3
October	27/10/2015	3
November	25/11/2015	3
February	01/02/2016	3
February	29/02/2016	3
March	28/03/2016	3

10 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	16/04/2015	2
April	27/04/2015	2
May	12/05/2015	2
May	18/05/2015	2
May	26/05/2015	3
June	02/06/2015	2
June	11/06/2015	2
June	29/06/2015	2
July	02/07/2015	2
July	13/07/2015	2
July	22/07/2015	2
August	10/08/2015	2

August	24/08/2015	2
September	08/09/2015	2
September	10/09/2015	2
September	21/09/2015	2
October	06/10/2015	2
October	06/10/2015	2
October	12/10/2015	4
October	19/10/2015	2
November	02/11/2015	2
November	23/11/2015	3
December	14/12/2015	3
December	21/12/2015	2
January	11/01/2016	3
January	15/01/2016	2
January	29/01/2016	2
February	12/02/2016	2
February	26/02/2016	2
February	29/02/2016	3
March	10/03/2016	3
March	11/03/2016	2
March	25/03/2016	2

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

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

None Attendance of Members at full committee meetings:01 April 2015 - 31 March 2016

Name	Number of Meetings Attended
Mr Chris Barron	4
Dr Sarah Bartlett	4
Mrs Nermine Basta	3
Mrs Ann Boardman	4
Mr Andrew Brenikov	9
Mrs Jane Curry	7
Dr Sumeet Gupta	5
Dr Alasdair MacSween	8
Mrs Gaynor Mitchell	4
Mrs Susan P Phillips	8
Dr Meiyi Pu	5
Ms Vicky Ryan	4
Miss Hannah Stevenson	5
Ms Emma Thompson	7
Dr Jared Thornton	3
Mr Richard Tomlin	6

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

Name	Number of Meetings Attended
Mr Chris Barron	1
Dr Sarah Bartlett	2
Mrs Ann Boardman	3
Mr Andrew Brenikov	2
Mrs Jane Curry	1
Dr Sumeet Gupta	3
Dr Alasdair MacSween	5
Mrs Gaynor Mitchell	4
Mrs Susan P Phillips	2
Ms Vicky Ryan	1
Ms Emma Thompson	1
Dr Jared Thornton	4
Mr Richard Tomlin	1

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

Name	Number of Meetings Attended
Mr Chris Barron	5
Dr Sarah Bartlett	1
Mrs Ann Boardman	2
Mr Andrew Brenikov	5
Mrs Jane Curry	3
Dr Sumeet Gupta	4
Dr Alasdair MacSween	21
Mrs Gaynor Mitchell	4
Mrs Susan P Phillips	8
Dr Meiyi Pu	2
Ms Vicky Ryan	3
Miss Hannah Stevenson	2
Ms Emma Thompson	1
Dr Jared Thornton	10
Mr Chris Turnock	2

Training 01 April 2015 - 31 March 2016

Name of Member	Date	Event(s) attended
Mr Chris Barron	16/03/2016	National Members Training Day
Mr Andrew Brenikov	03/12/2015	HRA Workshop: Pragmatic or Point of Care trials
Mr Andrew Brenikov	11/03/2016	Genetic and Genomic Research (previously HTA Advanced)
Dr Alasdair MacSween	06/04/2015	NREAP Chairs Network meeting
Dr Alasdair MacSween	27/11/2015	HRA CTIMP Training
Dr Alasdair MacSween	09/12/2015	HRA Chairs meeting
Mrs Gaynor Mitchell	11/03/2016	Centre for Life 'Genetic and Genomic Research (Advanced)
Mrs Susan P Phillips	04/06/2015	Regional Members Training Day
Dr Meiyi Pu	08/04/2015	Ethics & GCP Forum ICR
Dr Meiyi Pu	12/10/2015	Complex Cases
Dr Meiyi Pu	19/11/2015	Personal Data in Research - A Workshop
Dr Meiyi Pu	03/12/2015	Pragmatic or Point of Care Trials
Dr Meiyi Pu	03/02/2016	Handling Health-Related Findings in Research
Dr Meiyi Pu	11/03/2016	Genetic and Genomic Research (prev HTA)
Ms Vicky Ryan	11/03/2016	Genetic and Genomic Research (previously HTA Advanced)
Miss Hannah Stevenson	23/07/2015	Research Involving the Disadvantaged and Vulnerable: a Workshop for Researchers and Reviewers
Ms Emma Thompson	04/11/2015	Induction
Ms Emma Thompson	05/11/2015	Equality and Diversity
Mr Richard Tomlin	06/10/2015	Quantitative Research Methods and Statistics: A Health Research Authority Workshop
Mr Richard Tomlin	04/11/2015	Induction
Mr Richard Tomlin	04/11/2015	Equality and Diversity Certificate
Mr Richard Tomlin	19/11/2015	Personal Data in Research - A Workshop
Mr Richard Tomlin	04/02/2016	Researcher Training Day
Mr Richard Tomlin	05/02/2016	Local Training Day - Social Care

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	16	34.04
Phase 1	1	2.13
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	0	0.00
Others	30	63.83
Total Applications Reviewed	47	100

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

Number of applications made invalid by the REC Manager	1
Number of applications withdrawn prior to the meeting	1
Number of student applications reviewed	13
Number of paediatric applications reviewed	5
Number of device applications reviewed	1
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	4
Number of applications reviewed that are funded by the US DHHS	0
Number of qualitative applications reviewed	3

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	1	2.13
Favourable Opinion with Additional Conditions	12	25.53
Unfavourable Opinion	3	6.38
Provisional Opinion	30	63.83
Provisional Opinion Pending Consultation with Referee	1	2.13
Total	47	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	29	60.42
Further Information Favourable Opinion with Additional Conditions	3	6.25
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	1	2.08
Favourable Opinion with Additional Conditions	12	25.00
Unfavourable Opinion	3	6.25
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	48	100

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

Total Applications Reviewed	22
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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	8
Number of studies withdrawn prior to the meeting	3
Number of student applications reviewed	9
Number of paediatric applications reviewed	4
Number of device applications reviewed	0
Number of qualitative applications reviewed	4

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	11	50.00
Favourable Opinion with Additional Conditions	2	9.09
No Opinion transfer to full committee for review	2	9.09
Provisional Opinion	7	31.82
Unfavourable Opinion	0	0.00
Total	22	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	5.22
Number of completed applications for full ethical review	48
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	5
Number of completed applications over 40 days as a % of total	10.64%
Number of days taken to final decision – average (mean)	31
Number of completed proportionate review applications for ethical review	19
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	5
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	100
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	1
Number of completed substantial amendments over 28 days as a % of total substantial amendments	1.00%
Number of modified amendments reviewed	2
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	75
Number of substantial amendments received for information	0
Number of substantial amendments received for new sites/PIs	18
Number of annual progress reports received	61
Number of safety reports received	23
Number of Serious Adverse Events received	27
Number of final reports received	19

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/0097	A qualitative account of pain enactment with persons in chronic pain	20
15/NE/0131	Indocyanine green near-infrared laparoscopy in surgery	31
15/NE/0143	GA29144 Phase III ETRO IN MODERATE TO SEVERE ACTIVE CROHNS DISEASE	32
15/NE/0144	GA29145 – Open label extension & safety monitoring study	32
15/NE/0159	NASH-EX-1114	34
15/NE/0194	Clinical Study to Assess Markers of Disease Activity in Patients with PBC	40
15/NE/0208	Biomarkers of methotrexate response in atopic eczema	28
15/NE/0210	20140128 GLAGOV Extension study	37
15/NE/0211	Strike	30
15/NE/0257	Feasibility of high intensity interval training in people with IPD	32
15/NE/0269	A Long Term Safety Trial of MK-8931 in AD (EPOCH)	30
15/NE/0270	D5136C00008 HESTIA2, Phase IIB, Sickle Cell Disease (Ticagrelor)	37
15/NE/0279	SERINE PROTEASES AND SERPINS IN DUCHENNE MUSCULAR DYSTROPHY	40
15/NE/0321	Understanding Adaptive Challenges Assoc with Male factor Infertility	33
15/NE/0323	Subglottic study - ICU	35
15/NE/0324	Simvastatin as a neuroprotective treatment for moderate PD (PD STAT)	30
15/NE/0352	BUL1/EEA	37
15/NE/0353	DECIDE	32
15/NE/0354	The development of an orthodontic patient satisfaction questionnaire	28
15/NE/0406	Safety and Tolerability of MTL-CEBPA in Advanced Liver Cancer	28
15/NE/0415	CHRONOS-4	22
15/NE/0419	PRE-OP BIRDS - Feasibility Study	21
15/NE/0420	SUPERB version 1.0	34
16/NE/0011	Developing an Intervention for Fall Related Injury in Dementia	26
16/NE/0015	AlgiFood	34
16/NE/0021	Asthma and Obstructive Sleep Apnoea. IRAS Version 5.2.0	44
16/NE/0024	Dexketoprofen Analgesic eVolution with tramaDol- DAVID Study	52
16/NE/0050	Efficacy & Safety of TANEZUMAB in subjects Osteoarthritis of Hip/Knee	39
16/NE/0057	Safety & Efficacy of Tideglusib in Type 1 Myotonic Dystrophy	52

Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/NE/0103	ME Research UK severe ME/CFS	47
15/NE/0126	Psoriasis Clinic Quality Index	29
15/NE/0333	EXERCISE CAPACITY IN PRIMARY SJÄ-GREN'S SYNDROME	29

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/0396	BUL2/EER	41

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/NE/0118	The lived experience of using social media by young self-harmers?	26
15/NE/0129	It's not dementia: the experience of receiving a diagnosis of MCI	26
15/NE/0146	Maternal stress in children with autism and/or learning disability1	27
15/NE/0192	Early Diagnosis of Inherited Immune Deficiency	27
15/NE/0275	Phase II, Influenza A, study examining PrEP-001 in healthy subjects	35
15/NE/0276	IMPACT OF CHEMOTHERAPY ON CARDIORESPIRATORY RESERVE	22
15/NE/0297	Drooling in Parkinson's Disease: a case for divided attention	26
15/NE/0308	Evaluating non-drug therapies in older people with OH	26
15/NE/0350	PneumRX registry	27
15/NE/0399	Expression of m.3243 A>G	21
16/NE/0016	My Health Guide: A trial of a tablet app to support people with LD	26
16/NE/0025	Association of capecitabine pharmacokinetics and toxicity with aging	22

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
15/NE/0173	A Long Term Safety Trial of MK-8931 in AD (EPOCH)	27
15/NE/0191	NIR light as a treatment for age-related intellectual impairment	27
16/NE/0051	Reducing hallucination-related distress in Parkinson's Disease	23

Provisional Opinion		
REC Reference	Title	Number of Days on Clock

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

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

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

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/0139	Patients' views of discussing weight management with knee OA V1.15.1.15	12
15/NE/0225	Biofilms study in chronic otitis media with effusion and adenoids	12
15/NE/0271	Temporomandibular disorders, diet & nutrition: a mixed-methods study	13
15/NE/0272	Validity of a renal inpatient nutrition screening tool (iNUT)	14
15/NE/0335	Body image analysis following treatment for thyrotoxicosis	16
15/NE/0368	SuTURE	11
16/NE/0047	Steroid Induction Regimen for Juvenile Idiopathic Arthritis (JIA)	13

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock

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

Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
15/NE/0140	Patient-reported measures of quality of life in bariatric surgery v1.0	10
15/NE/0306	Complete arterial versus conventional coronary artery bypass grafting	7
15/NE/0338	Microvascular Endothelial Function in Pulmonary Arterial Hypertension	12
15/NE/0371	Handgrip strength and exercise capacity in heart failure	8
15/NE/0408	Renal Ischaemia reperfusion injury	9
15/NE/0409	PODDS	9
15/NE/0410	Impact of rotavirus vaccination on paediatric hospital pressures, v1	11
15/NE/0411	Physical activity communication in inflammatory arthritis (version 1)	11
16/NE/0081	Retrospective PROMs	14
16/NE/0107	Studying islet of Langerhans dysfunction during health and disease	9
16/NE/0108	Leeds Observational Cohort Ultrasound Study (LOCUS)	9

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
15/NE/0142	RLS-NMS Quest	10
16/NE/0043	Building Resilience In young people with Skin Conditions (BRISC)	14

Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock

Provisional Opinion		
REC Reference	Title	Number of Days on Clock

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

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

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
10/H0907/47/AM01	Long-term risks of paediatric fluoroscopic cardiology v1.0	Substantial Amendment 1 - 2/4/	02/04/2015	3
10/H0908/39/AM12	Supporting Enhanced Research in Vulnerable Infants (SERVIS)	Substantial Amendment 11 - 13/	13/05/2015	24
11/NE/0256/AM01	Collection of clinical remnant samples (version 1)	Substantial Amendment 1 - 11/6	11/06/2015	14
11/NE/0312/AM08	MelResist Version 1.0	Substantial Amendment 6 - 8/5/	08/05/2015	21
11/NE/0348/AM02	Role of prion protein in neurodegenerative disease	Substantial amendment 1.0, 1st September 2015	01/09/2015	8
11/NE/0374/AM10	BSRBR-AS	Substantial Amendment 7	01/05/2015	21
11/NE/0374/AM12	BSRBR-AS	Substantial Amendment 8, 22/12	07/01/2016	5
12/NE/0142/AM04	Open-Label Study for Previously Treated PTC124 patients with nmDBMD V1	Substantial Amendment 3 - 11/8	11/08/2015	16
12/NE/0196/AM03	LPS to characterise cellular immune responses & alveolar leak in ALI	Substantial Amendment 2, 12/08	04/09/2015	13
12/NE/0251/AM01	Northeast Early Arthritis Cohort	Substantial Amendment 1	07/04/2015	21
12/NE/0301/AM07	DAPPA	Substantial Amendment 2	01/06/2015	24
12/NE/0315/AM11	Pragmatic Ischaemic Stroke Thrombectomy Evaluation: PISTE	Substantial Amendment 1 - 27/4	27/04/2015	17
12/NE/0345/AM05	A Phase I trial of AZD3965 in patients with advanced cancer.	Substantial	17/04/2015	23

		Amendment 4 (CTA A		
12/NE/0361/AM08	aHUS Registry	Substantial Amendment 3	21/05/2015	18
12/NE/0361/AM09	aHUS Registry	Substantial Amendment 4, 21/09	20/10/2015	23
12/NE/0410/AM14	An Efficacy and Safety Trial of MK-8931 in Mild to Moderate AD(EPOCH)	Substantial Amendment 10	11/05/2015	27
12/NE/0410/AM15	An Efficacy and Safety Trial of MK-8931 in Mild to Moderate AD(EPOCH)	Substantial Amendment 11	26/10/2015	22
13/NE/0011/AM10	BMS-936558 versus investigator's choice in advanced melanoma	Substantial Amendment 9 - 10/4	10/04/2015	24
13/NE/0011/AM11	BMS-936558 versus investigator's choice in advanced melanoma	Substantial Amendment 10	10/06/2015	22
13/NE/0011/AM12	BMS-936558 versus investigator's choice in advanced melanoma	Substantial Amendment 11 (EC),	19/08/2015	17
13/NE/0026/AM02	Stem cells in Endocrine Surgical Disease	Substantial Amendment 1 - 22/4	22/04/2015	22
13/NE/0064/AM06	The AMPLE study, version 1.0	Substantial Amendment 2 - 27/4	27/04/2015	14
13/NE/0106/AM05	ASPIRE	Substantial Amendment 4	24/03/2015	21
13/NE/0115/AM12	Ciprofloxacin in subjects with Non-Cystic Fibrosis Bronchiectasis	Substantial Amendment 10 - tem	17/03/2015	17
13/NE/0115/AM14	Ciprofloxacin in subjects with Non-Cystic Fibrosis Bronchiectasis	Substantial Amendment 11, 24/0	09/10/2015	6
13/NE/0115/AM15	Ciprofloxacin in subjects with Non-Cystic Fibrosis Bronchiectasis	Substantial Amendment 6, 16/12	08/01/2016	12
13/NE/0238/AM04	Effects of AMG 145 Treatment on Atherosclerotic Disease	Substantial	09/11/2015	15

	GLAGOV	Amendment 2, 30/10		
13/NE/0299/AM02	EuroHyp-1	Substantial Amendment 2, 02/11	03/11/2015	19
13/NE/0327/AM05	Apomorphine s.c. infusion in Parkinson's to control motor symptoms.	Substantial Amendment 4	18/05/2015	18
13/NE/0327/AM06	Apomorphine s.c. infusion in Parkinson's to control motor symptoms.	Substantial Amendment 5 - 19/6	19/06/2015	28
13/NE/0339/AM07	Glycerine Trinitrate for Retained Placenta (GOT-IT Trial)	Substantial Amendment 4	06/05/2015	19
13/NE/0339/AM09	Glycerine Trinitrate for Retained Placenta (GOT-IT Trial)	Substantial Amendment 5 - 19/5	19/05/2015	29
13/NE/0339/AM11	Glycerine Trinitrate for Retained Placenta (GOT-IT Trial)	Substantial Amendment 7, 28/09	30/09/2015	7
13/NE/0360/AM09	4080 DEVOTE Degludec CV Outcome Study	Substantial Amendment 6	22/05/2015	20
13/NE/0360/AM11	4080 DEVOTE Degludec CV Outcome Study	Substantial Amendment 7 - 11/6	11/06/2015	27
13/NE/0360/AM14	4080 DEVOTE Degludec CV Outcome Study	Substantial Amendment 8, versi	08/10/2015	19
13/NE/0360/AM17	4080 DEVOTE Degludec CV Outcome Study	Substantial amendment 10, V1, 8th March 2016	08/03/2016	20
14/NE/0011/AM05	STRIDER	Substantial Amendment 5, 01.12.15	01/12/2015	13
14/NE/0043/AM03	Textured insoles for gait and balance impairment in MS	Substantial Amendment V4, 07/0	21/08/2015	17
14/NE/0045/AM08	TUBE Trial	Substantial Amendment 2	12/11/2015	22

14/NE/0059/AM01	Understanding adhesion formation, version 1	Substantial Amendment 1, Septe	06/10/2015	21
14/NE/0091/AM03	Clinical trial investigating seromas following mastectomy	Substantial Amendment 2, 28/12	23/12/2015	15
14/NE/0103/AM07	CaPP3	Substantial amendment 2 - new documentation	01/03/2016	12
14/NE/0144/AM01	Reproductive Decision Making in Mitochondrial Patients:	Substantial Amendment 1	28/03/2015	27
14/NE/0155/AM05	SURAB	Substantial amendment 4, 12th February 2016	12/02/2016	24
14/NE/1019/AM06	Phase 2a Study Evaluating ABT-981 in Patients with Knee Osteoarthritis	Substantial Amendment 5 - 24/3	24/03/2015	6
14/NE/1019/AM08	Phase 2a Study Evaluating ABT-981 in Patients with Knee Osteoarthritis	Substantial Amendment 7	14/09/2015	4
14/NE/1036/AM01	Metabonomic and Microbiomic profile of Pruritus and Fatigue in PBC	Substantial Amendment 1 - 15/6	15/06/2015	26
14/NE/1057/AM03	RIOPRED	Substantial Amendment 1	10/03/2015	28
14/NE/1057/AM05	RIOPRED	Substantial Amendment 2 - 1/12	01/12/2015	13
14/NE/1062/AM02	The PHOTO Trial	Substantial Amendment 1 - 1/7/	01/07/2015	18
14/NE/1063/AM04	GA28950 PHASE III TRIAL OF ETROLIZUMAB IN MODERATE TO SEVERE ACTIVE UC	Substantial Amendment 3 - 19/8	19/08/2015	26
14/NE/1063/AM05	GA28950 PHASE III TRIAL OF ETROLIZUMAB IN MODERATE TO SEVERE ACTIVE UC	Substantial Amendment 4	13/10/2015	22
14/NE/1063/AM06	GA28950 PHASE III TRIAL OF ETROLIZUMAB IN MODERATE TO SEVERE ACTIVE UC	Substantial Amendment 5	16/12/2015	6
14/NE/1070/AM02	Ciclosporin to reduce reperfusion injury in primary PCI (CAPRI)	Substantial	14/01/2016	24

		Amendment 2 - 14/1		
14/NE/1085/AM01	Dietary Intervention for the Treatment of Gestational Diabetes	Substantial Amendment 1 - 22/4	22/04/2015	18
14/NE/1119/AM02	Lenvatinib in Children With Refractory or Relapsed Solid Malignancies	Substantial Amendment 1 - 9/7/	09/07/2015	19
14/NE/1119/AM03	Lenvatinib in Children With Refractory or Relapsed Solid Malignancies	Substantial Amendment 2 - 30/07/2015 2	30/07/2015	14
14/NE/1119/AM04	Lenvatinib in Children With Refractory or Relapsed Solid Malignancies	Substantial Amendment 3	11/11/2015	18
14/NE/1131/AM02	Stratification of patellofemoral pain (StrOPP)	Substantial Amendment 2, 02/11	05/11/2015	19
14/NE/1135/AM02	MRC-BLISS	Substantial Amendment 2 - 30/3	30/03/2015	12
14/NE/1135/AM04	MRC-BLISS	Substantial Amendment 3 - 02/1	04/12/2015	19
14/NE/1163/AM01	Evaluation of pelvic position in total hip replacement	Substantial Amendment 1 - 30/6	30/06/2015	16
14/NE/1163/AM02	Evaluation of pelvic position in total hip replacement	Amendment 2, 16.11.15	16/11/2015	10
14/NE/1181/AM03	ADAPTeR	Substantial Amendment 2 - 03/12/2015	03/12/2015	15
14/NE/1235/AM01	Peptest in patients with suspected gastro-oesophageal reflux disease	Substantial Amendment 1	13/04/2015	13
14/NE/1235/AM02	Peptest in patients with suspected gastro-oesophageal reflux disease	Substantial Amendment 2, 13/10	15/10/2015	20
15/NE/0021/AM01	Children's immunisations in the London Charedi Jewish community	Substantial Amendment 1 - 8/8/	08/08/2015	28
15/NE/0023/AM01	Identification of Novel Psychoactive Substances (IONA)	Substantial	06/01/2016	18

		Amendment 1 - 6/1/		
15/NE/0057/AM03	Falls Prevention in the Visually Impaired (Violet Study)	Substantial Amendment 1, 11/12	15/12/2015	26
15/NE/0088/AM01	GX29633 - PROXIMA Study A	Substantial Amendment 1 - 2/7/	02/07/2015	20
15/NE/0088/AM02	GX29633 - PROXIMA Study A	Substantial Amendment 2 - 28/01/2016	28/01/2016	17
15/NE/0089/AM01	GX29639 - PROXIMA Study B	Substantial Amendment 2, 11/08	07/09/2015	14
15/NE/0089/AM02	GX29639 - PROXIMA Study B	Substantial Amendment 3 - 28/01/2016	28/01/2016	17
15/NE/0094/AM01	BI-010 as a diagnostic biomarker for cholangiocarcinoma Version 1.0	Substantial Amendment 1	20/05/2015	13
15/NE/0096/AM01	adjustment to hand injury version 3	Substantial Amendment version 4, 28/09/2015	09/10/2015	23
15/NE/0103/AM01	ME Research UK severe ME/CFS	Substantial Amendment 1 - 12/8	12/08/2015	22
15/NE/0103/AM03	ME Research UK severe ME/CFS	Substantial Amendment 2, 11/12	06/01/2016	5
15/NE/0129/AM01	It's not dementia: the experience of receiving a diagnosis of MCI	Substantial Amendment 1, 07/10	30/10/2015	25
15/NE/0139/AM01	Patients' views of discussing weight management with knee OA V1.15.1.15	Substantial Amendment 1, 09.02.16	09/02/2016	14
15/NE/0140/AM01	Patient-reported measures of quality of life in bariatric surgery v1.0	Substantial Amendment 1 - 4/6/	04/06/2015	20
15/NE/0142/AM02	RLS-NMS Quest	Substantial amendment 2,	10/03/2016	8

		10.03.16		
15/NE/0143/AM02	GA29144 Phase III ETRO IN MODERATE TO SEVERE ACTIVE CROHNS DISEASE	Substantial Amendment 1 - 12/8	12/08/2015	22
15/NE/0143/AM03	GA29144 Phase III ETRO IN MODERATE TO SEVERE ACTIVE CROHNS DISEASE	Substantial Amendment 2 - 19/8	19/08/2015	26
15/NE/0143/AM04	GA29144 Phase III ETRO IN MODERATE TO SEVERE ACTIVE CROHNS DISEASE	Substantial Amendment 3	16/10/2015	28
15/NE/0144/AM01	GA29145 – Open label extension & safety monitoring study	Substantial Amendment 1 - 12/8	12/08/2015	26
15/NE/0194/AM01	Clinical Study to Assess Markers of Disease Activity in Patients with PBC	Substantial Amendment 1 - 23/1	23/11/2015	18
15/NE/0257/AM01	Feasibility of high intensity interval training in people with IPD	Substantial Amendment 1, 12/10	13/10/2015	28
15/NE/0269/AM01	A Long Term Safety Trial of MK-8931 in AD (EPOCH)	Substantial amendment 1, 24.02.16	24/02/2016	12
15/NE/0270/AM02	D5136C00008 HESTIA2, Phase IIB, Sickle Cell Disease (Ticagrelor)	Substantial Amendment 2	18/12/2015	25
15/NE/0271/AM01	Temporomandibular disorders, diet & nutrition: a mixed-methods study	Substantial Amendment 3, 01/12	31/12/2015	8
15/NE/0297/AM01	Drooling in Parkinson's Disease: a case for divided attention	Substantial Amendment 1, 04/11	05/11/2015	15
15/NE/0324/AM02	Simvastatin as a neuroprotective treatment for moderate PD (PD STAT)	Substantial Amendment 2	17/11/2015	22
15/NE/0338/AM01	Microvascular Endothelial Function in Pulmonary Arterial Hypertension	Amendment version 3.0, February 2016	01/02/2016	16

Unfavourable opinion

Amendment REC	Title	Version	Date	Number of Days on
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Reference				Clock
06/Q1003/51/AM10	Role of gap junctions in human cortical epilepsy (version 1)	Substantial Amendment 6, 01/12	12/01/2016	27
11/NE/0281/AM01	Patient reported outcome measure in orthodontic patients	Substantial Amendment 1	07/04/2015	6
11/NE/0366/AM02	The Development of an orthodontic questionnaire	Substantial Amendment 3, 05/08	07/09/2015	12
12/NE/0251/AM02	Northeast Early Arthritis Cohort	Amendment 2, 30th August 2015	30/08/2015	17
13/NE/0360/AM15	4080 DEVOTE Degludec CV Outcome Study	Substantial Amendment 9	20/11/2015	25
15/NE/0097/AM01	A qualitative account of pain enactment with persons in chronic pain	Substantial Amendment 1 - 29/5	29/05/2015	9

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
12/NE/0251/AM02/1	Northeast Early Arthritis Cohort	Modified Substantial Amendment 2, 21/09/2015	22/09/2015	13
15/NE/0097/AM01/1	A qualitative account of pain enactment with persons in chronic pain	Modified Amendment 1 - 12/6/15	12/06/2015	2

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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