

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

Annual Report

01 April 2016 - 31 March 2017



Part 1 – Committee Membership and Training

Name of REC:	North East - Tyne & Wear South Research Ethics Committee
Type of REC:	Recognised, CTIMP in Patients Type III
Type of Flag:	Phase 1 studies in Patients
Chair:	Mr Paddy Stevenson
Vice-Chair:	Mr Ian Campbell
Alternate Vice-Chair:	Mrs Debra J Lett
REC Manager:	Ms Gillian Mayer (17.10.16 to date) Miss Kathryn Murray (until 14.10.16)
REC Assistant:	Miss Rheanneon Fuller/Miss Kirstie Penman (3.1.17 to date) Miss Sarah Prothero (17.10.16 – 2.1.17) Miss Kerry Dunbar (1.4.16 -1.10.16)
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Chair's overview of the past year:

2016/17 has been one of the most challenging years for the research ethics service with the introduction of the HRA assessments and the continued financial challenges faced by the NHS. The HRA assessment process has led to a number of problems including delays in final approvals, confusion and overlapping of HRA assessment and ethical reviews of studies, however I can say that Tyne and Wear South have worked with a number of other ethics committees and HRA senior management to see how we can overcome these; hopefully in next year's report I will be able to advise on improvements. The continued financial pressure the HNHS is facing has led to a number of members (who are NHS employees) to reflect on whether they can continue to offer their time as members and this has led to some colleagues leaving committees. The HRA changes have also led to a number of experienced NRES officers moving to fill new posts within the HRA and that has had a significant impact on our Jarrow office including our previous REC manager Kathryn Murray and Kerry Dunbar moving to pastures new; thank you all for your outstanding support. With such moves however, we have been fortunate in welcoming Ms Gillian Mayer as our REC Manager and new REC Assistant Rheanneon Fuller with support from Kirstie Penman to our committee (with interim support from Sarah Prothero). That said I am pleased to say our committee has performed outstandingly well as will be explained below which is a resounding endorsement of the new team.

I would firstly like to take this opportunity to thank Dr Helen Lucraft who resigned this year after 3 years of membership, Helen was an asset using her extensive knowledge and experience of cancer treatment and research as a retired Clinical Oncologist and I'm sure Newcastle Hospitals will benefit from this experience in her role of hospital governor. Finally could I thank Mr Obi Iwuchukwu for his 3 years' service.

We have been extremely fortunate in recruiting a number of new members who bring a wealth of experience; Chris Barron had been a member for a number of years on NNT2 committee as well as a therapeutic radiographer and clinical trials' department manager. David Hill brings along years of experience in technical engineering and device development. Hannah Stevenson came to us again from NNT2 with expertise in trial management and equality and diversity / communication expertise as well as supporting our newest and youngest member Jack Bissett who has helped advise on research applications in children, especially keeping us 'older folks' up to date with social media and communications.

Looking at our performance I would like to highlight the following:

Of the 10 full meetings all were quorate with an average attendance of 11 members up from last year's figures of 10 members, We reviewed the same amount of studies as last year although there was a slight change in Full REC (FR) and Proportionate Review (PR) 2015/16 = 55 FR and 31 PR, 2016/17 = 54 FR and 32 PR. I can also state we had no breaches in the reporting period. Finally we have continued our innovative program of encouraging researchers to attend meetings as observers so they can see how we work and gain insights into improving their applications.

I am looking forward to another year at the helm of Tyne and Wear South Committee and I remain proud of the fantastic team that supports us as well as the excellent and dedicated membership. I hope you enjoy reading this report.

North East - Tyne & Wear South Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Mr Chris Barron	ECMC & CTU Manager	Expert	07/04/2016	
Ms Sam Barron	Clinical Lead, Speech and Language Therapist	Expert	01/06/2014	
Mr Jack Bissett	Student	Lay Plus	16/08/2016	
Mr John Blenkinsopp	Clinical Effectiveness Manager	Lay Plus	14/06/2013	
Mr Ian Campbell	Pharmacy	Expert	12/06/2012	
Dr Dorothy Coe	Senior Research Assistant and Lecturer in Nursing Skills	Lay	01/05/2014	
Mr David Hill	Retired Technical Director	Lay	01/06/2016	
Mr Obi Iwuchukwu	Consultant Surgeon	Expert	07/01/2013	31/03/2016
Mrs Louise Jones	Faculty Research Administrator	Lay Plus	23/09/2015	
Mrs Debra J Lett	Manager Newcastle Brain Tissue Resource	Lay	19/09/2011	
Dr Helen Lucraft	Retired Consultant Clinical Oncologist	Expert	01/07/2013	07/04/2016
Mr Graham McClelland	Research Paramedic	Expert	08/09/2014	
Miss Rachel Smith	Barrister	Lay Plus	10/08/2015	
Mr Paddy Stevenson	Research Operations Manager	Expert	01/02/2007	
Ms Hannah Stevenson	Trial Co-ordinator	Lay	15/06/2016	
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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N/A

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

Name	Profession	Status	Meeting date attended
Ms Heather McGrath	School Research Administrator	Lay Plus	24/04/2016

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

Name	Declaration of Interest	Date
Ms Sam Barron	No interests declared.	15/08/2016
Mr Chris Barron	Manager of the Sir Bobby Robson Cancer Trials Research Centre at the Newcastle upon Tyne Hospitals NHS Foundation Trust	20/04/2016
Mr Jack Bissett	No interests declared.	06/09/2016
Mr John Blenkinsopp	Clinical effectiveness Advisor and Deputy Clinical Audit Manager - North Tees and Hartlepool Foundation Trust. Kings Fund Critical Appraisal Trainer 2016. NECS Embedding Evidence in Commissioning Trainer 2016. BMA Critical Appraisal Trainer (from 2002 onwards). Regularly trains and is in contact with colleagues at Prostate Cancer UK Member of Trust Research Evaluation Board Reviewer for NICE Accreditation Programme.	12/08/2016
Mr Ian Campbell	Member of Newcastle upon Tyne Hospitals R&D Approval Committee and R&D Executive Committee, which review and approve new studies and look at the Trust strategy in research. Specialist referee in Pharmacy.	12/08/2016
Dr Dorothy Coe	No interests declared.	17/02/2017
Mrs Debra 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.	31/03/2017
Mr David Hill	Involved with the following organisations who may be involved in research: Ronin Solutions (Ownership also), Amdel Medical Ltd, Medical Device Creations Ltd, Newcastle University Medical School.	09/06/2016
Mrs Louise Jones	Co-ordinate the ethical review process in the Faculty of Science, Agriculture and Engineering at Newcastle University. Although some of Academics in the department are involved in inter-disciplinary research such as biomedical engineering, the vast majority of ethics applications reviewed by the Committee are not related to healthcare research. Under the University's ethics framework, duplicate reviews of applications which require external ethical approval from an NHS REC are not undertaken.	18/08/2016
Mr Graham McClelland	Member of College of Paramedics. Specialist referee for Pre-Hospital Care.	17/08/2016
Miss Rachel Smith	No interests declared.	15/08/2016
Mr Paddy Stevenson	Manages the research departments and research staff at Newcastle Hospitals; however, always makes a personal declaration of interest when appropriate.	12/08/2016
Ms Hannah Stevenson	Hepatology Research Study Co-ordinator working	28/07/2016

	for Newcastle upon Tyne Hospitals NHS Foundation Trust. This role involves the co-ordination of a large portfolio Hepatology research studies running in NUTH Trust from feasibility to close out.	
Dr Kate Wilson	No interests declared.	11/08/2016

Meetings for Full Ethical Review 01 April 2016 - 31 March 2017:

Month	Date	Number of Members Present at Meeting
April	25/04/2016	9
June	27/06/2016	10
July	25/07/2016	11
August	22/08/2016	10
September	26/09/2016	11
October	24/10/2016	11
November	28/11/2016	10
January	23/01/2017	13
February	27/02/2017	13
March	27/03/2017	11

10 full committee meetings were held during the reporting period.

Proportionate Review Sub-Committee Meetings held during 01 April 2016 - 31 March 2017:

Month	Date	Number of Members Present at Meeting
April	07/04/2016	3
June	09/06/2016	3
July	07/07/2016	3
August	08/08/2016	3
September	08/09/2016	3
October	14/10/2016	3
November	07/11/2016	3
December	08/12/2016	3
January	20/01/2017	3
February	07/02/2017	3
March	15/03/2017	3

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

Sub-Committee Meetings held during 01 April 2016 - 31 March 2017:

Month	Date	Number of Members Present at Meeting
April	01/04/2016	2
April	15/04/2016	3
April	15/04/2016	2
April	27/04/2016	2
April	28/04/2016	2
May	10/05/2016	3
May	13/05/2016	2
May	27/05/2016	2
June	10/06/2016	2
June	22/06/2016	2

June	23/06/2016	2
July	07/07/2016	2
July	18/07/2016	2
July	19/07/2016	3
July	22/07/2016	2
August	05/08/2016	2
August	12/08/2016	2
August	19/08/2016	2
September	02/09/2016	2
September	21/09/2016	2
September	30/09/2016	2
October	14/10/2016	2
October	28/10/2016	2
November	11/11/2016	2
November	17/11/2016	3
November	23/11/2016	3
November	25/11/2016	2
December	09/12/2016	2
December	23/12/2016	2
December	23/12/2016	3
January	06/01/2017	2
January	09/01/2017	2
January	18/01/2017	2
January	20/01/2017	2
January	20/01/2017	3
February	03/02/2017	2
February	17/02/2017	2
March	03/03/2017	2
March	17/03/2017	2
March	27/03/2017	2
March	28/03/2017	3
March	31/03/2017	2

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

Details of inquorate meeting held: 01 April 2016 - 31 March 2017

Date	Reason	Action taken

N/A

Attendance of Members at full committee meetings: 01 April 2016 - 31 March 2017

Name	Number of Meetings Attended
Ms Sam Barron	6
Mr Chris Barron	5
Mr Jack Bissett	6
Mr John Blenkinsopp	8
Mr Ian Campbell	9
Dr Dorothy Coe	10
Mr David Hill	9
Mrs Louise Jones	8
Mrs Debra J Lett	6
Mr Graham McClelland	8
Miss Rachel Smith	6
Ms Hannah Stevenson	8
Mr Paddy Stevenson	10
Dr Kate Wilson	9

Attendance of Members at proportionate review sub-committee meetings: 01 April 2016 - 31 March 2017

Name	Number of Meetings Attended
Mr Chris Barron	1
Ms Sam Barron	3
Mr John Blenkinsopp	1
Mr Ian Campbell	4
Dr Dorothy Coe	2
Mrs Louise Jones	2
Mrs Debra J Lett	3
Dr Helen H Lucraft	1
Mr Graham McClelland	3
Ms Hannah Stevenson	3
Mr Paddy Stevenson	7
Dr Kate Wilson	3

Attendance of Members at sub-committee meetings: 01 April 2016 - 31 March 2017

Name	Number of Meetings Attended
Ms Sam Barron	2
Mr John Blenkinsopp	1
Mr Ian Campbell	6
Dr Dorothy Coe	8
Mr David Hill	1
Mrs Debra J Lett	30
Ms Hannah Stevenson	2
Mr Paddy Stevenson	40

Training 01 April 2016 - 31 March 2017

Name of Member	Date	Event(s) attended
Mr Jack Bissett	10/09/2016	Members' Induction
Mr John Blenkinsopp	22/03/2017	National Members' Training Day
Dr Dorothy Coe	22/03/2017	National Members' Training Day
Mr David Hill	01/09/2016	Members' Induction (On-line Module)
Mr David Hill	23/11/2016	Equality & Diversity (On-line Module)
Mr David Hill	10/01/2017	Members' Induction
Mr David Hill	22/03/2017	National Members' Training Day
Mrs Louise Jones	22/05/2016	Equality & Diversity (On-line Module)
Mrs Louise Jones	06/07/2016	Regional Members' Training Day
Mrs Louise Jones	14/07/2016	Personal Data in Research - A Workshop
Mrs Debra J Lett	06/07/2016	Regional Members' Training Day
Mrs Debra J Lett	22/03/2017	National Members' Training Day
Mr Graham McClelland	14/07/2016	Personal Data in Research - A Workshop
Miss Rachel Smith	08/06/2016	Members' Induction
Ms Hannah Stevenson	09/09/2016	Researcher Training Day
Mr Paddy Stevenson	01/12/2016	National Chairs' Training Day
Dr Kate Wilson	06/07/2016	Regional Members' Training Day
Ms Sam Barron	03/02/2017	GCP Training
Mr Ian Campbell	15/03/2017	SDL – Equality and Diversity, Information Governance & Lecturing staff on ethical issues from a pharmacy aspect.

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	29.63
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	0	0.00
Others	38	70.37
Total Applications Reviewed	54	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	0
Number of student applications reviewed	9
Number of paediatric applications reviewed	3
Number of device applications reviewed	3
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	4

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	4	7.41
Favourable Opinion with Additional Conditions	11	20.37
Unfavourable Opinion	1	1.85
Provisional Opinion	38	70.37
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	54	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	30	55.56
Further Information Favourable Opinion with Additional Conditions	6	11.11
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	4	7.41
Favourable Opinion with Additional Conditions	11	20.37
Unfavourable Opinion	1	1.85
Provisional Opinion	1	1.85
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	1	1.85
Total	54	100

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

Total Applications Reviewed	32
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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	6
Number of studies withdrawn prior to the meeting	1
Number of student applications reviewed	17
Number of paediatric applications reviewed	5
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	26	81.25
Favourable Opinion with Additional Conditions	1	3.13
No Opinion transfer to full committee for review	2	6.25
Provisional Opinion	3	9.38
Unfavourable Opinion	0	0.00
Total	32	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	5.40
Number of completed applications for full ethical review	53
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	1
Number of completed applications over 40 days as a % of total	1.85%
Number of days taken to final decision – average (mean)	26
Number of completed proportionate review applications for ethical review	30
Number of completed proportionate review applications for ethical review over 14 days (<i>Please note, the timeline for the review of PR applications was extended from 14 to 21 calendar days in December 2016</i>)	4
Number of completed proportionate review applications for ethical review over 21 days	0
Number of completed proportionate review applications over 21 days as a % of total	0.00%
Number of SSAs (non-Phase 1) reviewed	6
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	140
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	0.71%
Number of modified amendments reviewed	1
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 non-substantial amendments received	108
Number of substantial amendments received for information	1
Number of substantial amendments received for new sites/PIs	37
Number of annual progress reports received	108
Number of safety reports received	40
Number of Serious Adverse Events received	2
Number of final reports received	34

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
16/NE/0147	RESOLVE-IT: A Study of Elafibranor in Patients with NASH and fibrosis	23
16/NE/0148	Prevalence and trends in UK ambulance service staff suicides	22
16/NE/0192	C-peptide and exercise in T1D	24
16/NE/0200	FAIRPARK II	27
16/NE/0216	Impact of masculinity upon psychosis	35
16/NE/0219	Feasibility study of e-cigarettes in periodontitis.0.6	19
16/NE/0241	Significance of disseminated cancer cells in oesophagogastric cancer	22
16/NE/0252	Patient involvement in improving patient safety in primary care v1	20
16/NE/0268	Health Status and Quality of Life in Congenital Agammaglob	28
16/NE/0274	Effectiveness of knee braces for knee osteoarthritis	27
16/NE/0279	TIDaL	25
16/NE/0287	Non-invasive assessment of cardiac function to identify heart failure	39
16/NE/0306	Fatigue, autonomic dysfunction and immune dysregulation	26
16/NE/0322	Fun with Feelings: Parent group for children with ASD and anxiety	24
16/NE/0342	A Phase 1 Study of ADCT-402 in Patients with Non-Hodgkin Lymphoma	33
16/NE/0343	Life threatening bronchopulmonary dysplasia in infants	24
16/NE/0344	First-in-Human, Phase 1/2 study, JNJ-63723283 in Advanced Cancers	25
16/NE/0353	ARASENS	38
16/NE/0374	RCT - Platelet Rich Plasma vs Placebo in GTPS V1.0	28
16/NE/0396	The psychosocial impact of diabetes & severe mental illness: DAWN-SMI	25
17/NE/0024	Phase IIa study of Anti-IL-7 receptor-1 \pm Mab GSK2618960 in pSS treatment	28
17/NE/0031	Effects of dietary nutrients on liver and adipose tissue metabolism	29
17/NE/0032	Mixed methods evaluation of a novel apnoea event detection monitor	23
17/NE/0043	Exploring RATS for lung cancer V1	37
17/NE/0045	ROSETREES: Personalised ultraviolet B (UVB) treatment of psoriasis	29
17/NE/0056	The TRIAL-STIM Study	37
17/NE/0062	The effects of BAY 1193397 on skin capillary blood flow	41
17/NE/0085	Influence of the Vitabreath device on exercise tolerance in COPD	23
17/NE/0093	PRE-OP BIRDS - Pilot RCT	23
17/NE/0096	Safety and efficacy study of patients with primary Sjögren's Syndrome	26

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
16/NE/0146	2WW v1	21
16/NE/0253	Rituximab in Graves' Disease (RIGD)	20
16/NE/0323	A Phase 2 Study to Evaluate Weekly RG012 Injections in Alport Syndrome	38
16/NE/0329	Family members' experiences of home alcohol detox.	34
17/NE/0025	Clinical & biological factors associated with relapsed neuroblastoma	34
17/NE/0035	Balance training for fall reduction in individuals with COPD	37

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
16/NE/0212	Radiotherapy vs Surgery in the treatment of Bladder Cancer Patients	23
16/NE/0326	Pancreatic Acinar Cell Cancer Registry	21
17/NE/0027	CRest2	23
17/NE/0095	ImPROve	22

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
16/NE/0142	B9991010 Phase 3, avelumab for Untreated Epithelial Ovarian Cancer	22
16/NE/0144	Lifestyle Intervention For Liver Transplantation	17
16/NE/0213	NIV outcomes study	23
16/NE/0239	ENHANCE	25
16/NE/0273	Forensic carers in England	22
16/NE/0281	Experiences of people with psychosis being detained under the MHA	22
16/NE/0321	A Phase 2 Study of RSLV-132 in Subjects with Sjogren's Syndrome	17
16/NE/0324	MyxofibroSarcoma staging using PET-MRI: comparison to standard MRI	16
16/NE/0384	ARNI versus ACE inhibition to reduce Heart Failure events after an MI	15
17/NE/0026	LCZ696 versus enalapril on daily physical activity	23
17/NE/0091	Transcutaneous vagal nerve stimulation & postoperative bowel function	22

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
16/NE/0217	What matters to older breast cancer patients?	23

Provisional Opinion

REC Reference	Title	Number of Days on Clock
17/NE/0097	A MDT foot intervention in people with diabetes on dialysis	n/a

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
16/NE/0231	RO7034067 in Type 2 and 3 SMA Patients	18

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
16/NE/0310	Appetite and Body Composition Changes in CKD (ABC study)	14
16/NE/0311	A study to describe the impact of AbbVie Care	14
17/NE/0081	Empowerment in intellectual disabilities.	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

Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
16/NE/0118	Systemo Twin Study	8
16/NE/0119	Patient perspectives on HIV Care into the future	15
16/NE/0130	Biomarkers for duodenal cancers	5
16/NE/0203	Measuring risk preferences in the health domain	12
16/NE/0210	Can microbiome data improve the NHS Bowel Cancer Screening Programme?	13
16/NE/0211	Exploring young people's preferences for STI screening	12
16/NE/0247	Advanced glycation end products as a biomarker for accelerated ageing	14
16/NE/0248	The Optimisation of Human Steatotic Livers for Transplantation	13
16/NE/0250	MAP (Muscle Assessment in Peripheral nerve injury)	13
16/NE/0275	Seqirus EPSS 2016	13
16/NE/0276	The surprise question and heart failure	13
16/NE/0277	Links between successful IVF treatment and daily light-dark cycles	12
16/NE/0314	Neonatal Ventilation Follow-up Post Puberty	11
16/NE/0349	The economic and QOL impact of acute urinary stone disease	14
16/NE/0350	Implementing assays for Direct Oral Anticoagulants	13
16/NE/0352	Therapeutic needs of recent SCI individuals: interview study	14
16/NE/0375	Returning to sport following ankle sprain Version 2.0	14
16/NE/0376	MS in Asian and Afro-Caribbean patients in the UK	14
16/NE/0378	An adaptive orthosis for hand osteoarthritis; a patient focus group v1	14
16/NE/0410	Landmark accuracy in spinal anaesthesia in obese obstetric patients V1	14
17/NE/0016	Liaison psychiatry ACT groups: Grounded theory analysis	18
17/NE/0018	Data and sample collection from Rotherham Institute for Obesity	14
17/NE/0021	Driving simulation in patients with heart failure	17
17/NE/0038	Medication Adherence in the Elderly	14
17/NE/0040	The Future of Healthcare: Automation in General Practice Services	18
17/NE/0080	Optimising neonatal service provision for preterm babies (27-31 weeks)	11

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/NE/0202	Patient expectations for the outcome of anti-reflux surgery	13

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
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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
07/H0904/77/AM24	INT 747 Monotherapy Study in Patients with Primary Biliary Cirrhosis	SA18	03/03/2017	22
08/H0904/3/AM12	Treatment of Parkinson's Disease Psychosis with ACP-103	Substantial Amendment - IB Ed.	31/10/2016	15
08/H0904/3/AM13	Treatment of Parkinson's Disease Psychosis with ACP-103	AM13	06/02/2017	9
10/H0904/49/AM21	CFTY720D2399 a possible treatment for MS extension study	Substantial Amendment 10 - 12/	12/05/2016	19
11/NE/0039/AM14	Open Label Brivaracetam Study in Patients with Partial Onset Seizures	Substantial Amendment 10, 22/0	17/10/2016	12
11/NE/0118/AM01	Biomarkers in oral cancer version 1	Substantial Amendment 1 - 4/6/	04/06/2016	16
12/NE/0323/AM26	First in Human Study of VX-970 in Advanced Solid Tumors VX12-970-001	Substantial Amendment 18 - 11/	11/03/2016	20
12/NE/0323/AM27	First in Human Study of VX-970 in Advanced Solid Tumors VX12-970-001	Substantial Amendment 19 - 5-1	05/10/2016	21
12/NE/0323/AM28	First in Human Study of VX-970 in Advanced Solid Tumors VX12-970-001	Substantial Amendment 20, 02/1	02/11/2016	20
12/NE/0355/AM05	¹²⁹ Xe/ ³ He MRI in idiopathic pulmonary fibrosis patients. Version 1.0	SA5	10/02/2017	24
12/NE/0412/AM08	Phase II study to evaluate safety, tolerability and efficacy of OPN305	Substantial Amendment 7 - 9/3/	09/03/2016	8
13/NE/0049/AM14	BAY 94-9027 paediatric pharmacokinetics, safety, and efficacy trial	Substantial Amendment 8 - 5/5/	05/05/2016	21
13/NE/0049/AM15	BAY 94-9027 paediatric pharmacokinetics, safety, and efficacy trial	Substantial Amendment 9	22/08/2016	23

13/NE/0125/AM08	PRESTO Neo.1.C/E	Substantial Amendment 3 - 9/3/	09/03/2016	8
13/NE/0125/AM09	PRESTO Neo.1.C/E	Substantial Amendment 4 - 11/7	11/07/2016	16
13/NE/0196/AM26	Antibiotic prophylaxis for clean intermittent catheterisation v1.0	Substantial Amendment 18	17/08/2016	28
13/NE/0269/AM08	Maintenance Study of Niraparib/Placebo in Patients with Ovarian Cancer	Substantial Amendment 6 - 9/3/	09/03/2016	12
13/NE/0269/AM10	Maintenance Study of Niraparib/Placebo in Patients with Ovarian Cancer	SA8	20/02/2017	13
13/NE/0274/AM02	Robot Assisted Training for the Upper Limb after Stroke	Substantial Amendment 2 - 2/8/	02/08/2016	10
13/NE/0280/AM07	AZ: D0816C00005 - Ph. 1 Study Hepatic Function/Impairment	Substantial Amendment 5 - 11/	06/04/2016	9
13/NE/0336/AM08	Trial of Proton Pump Inhibitors in Throat Symptoms	Substantial Amendment 5 - 7/12	07/12/2015	22
13/NE/0342/AM07	OPTIMISTIC	Substantial Amendment 7 - 3/6/	03/06/2016	15
13/NE/0355/AM05	AMG145 vs Ezetimibe in Statin Intolerant Hypercholesterolemic Subjects	Substantial Amendment 4 - 25/5	25/05/2016	14
14/NE/0073/AM09	BI836845 in women with Breast Cancer.	Substantial Amendment 6 - 28/4	28/04/2016	18
14/NE/0073/AM10	BI836845 in women with Breast Cancer.	Substantial Amendment 7 - 21/7	21/07/2016	21
14/NE/0073/AM12	BI836845 in women with Breast Cancer.	Substantial Amendment 8 - 26/9	26/09/2016	17
14/NE/0073/AM13	BI836845 in women with Breast Cancer.	Substantial Amendment 9 - Urge	28/10/2016	19
14/NE/0073/AM14	BI836845 in women with Breast Cancer.	SA10	16/01/2017	16

14/NE/0121/AM09	Ibrutinib in Subjects with Relapsed/Refractory Marginal Zone Lymphoma	Substantial Amendment 4 - 13/4	13/04/2016	14
14/NE/0121/AM10	Ibrutinib in Subjects with Relapsed/Refractory Marginal Zone Lymphoma	SA5	16/01/2017	18
14/NE/0151/AM08	THYROxine in Acute Myocardial Infarction (ThyrAMI)	Substantial Amendment 6 - 13/1	13/01/2016	18
14/NE/1040/AM05	Pfizer A3921092 - Phase 3 Tofacitinib (Active PsA) Extension Study	Substantial Amendment 5 - March 2016	21/04/2016	15
14/NE/1040/AM06	Pfizer A3921092 - Phase 3 Tofacitinib (Active PsA) Extension Study	Substantial Amendment 6, 02/08	02/08/2016	15
14/NE/1040/AM08	Pfizer A3921092 - Phase 3 Tofacitinib (Active PsA) Extension Study	SA8	16/02/2017	19
14/NE/1041/AM17	A Phase II randomized study of OligoG in subjects with cystic fibrosis	Substantial Amendment 10 - 14/	14/09/2016	13
14/NE/1042/AM06	Biomarkers of Remission in Rheumatoid Arthritis (BioRRA)	SA3	29/07/2016	18
14/NE/1045/AM02	Cognitive Behavioural-Enhanced Swallowing Therapy (CB-EST)	Substantial Amendment 1 - 19/8	19/08/2016	17
14/NE/1075/AM06	TRAFIC	Substantial Amendment 4 - 10/3	10/03/2016	16
14/NE/1075/AM08	TRAFIC	Substantial Amendment 5 - 2/6/	02/06/2016	13
14/NE/1075/AM10	TRAFIC	Substantial Amendment 6, 04/10	17/10/2016	12
14/NE/1075/AM11	TRAFIC	SA7	11/01/2017	18
14/NE/1080/AM06	Tropomyosin Receptor kinase Antagonism in Cyndromatosis (TRAC)	Substantial Amendment 3 - 24/3	24/03/2016	8
14/NE/1098/AM07	D5160C00012 - Phase I, Open Label, EGFRm positive NSCLC (Inhibitor)	Substantial Amendment 6 -	22/04/2016	24

		22/4		
14/NE/1098/AM08	D5160C00012 - Phase I, Open Label, EGFRm positive NSCLC (Inhibitor)	SA7	22/02/2017	10
14/NE/1144/AM13	The NATional Trial of Tonsillectomy IN Adults (NATTINA)	Substantial Amendment 4, 19/10	19/10/2016	11
14/NE/1144/AM15	The NATional Trial of Tonsillectomy IN Adults (NATTINA)	SA5	16/03/2017	14
14/NE/1149/AM03	Engaging stakeholders to enable personalised stroke care	Substantial Amendment 1 - 17/6	17/06/2016	9
14/NE/1179/AM05	ECASS - Evaluation of a Computer Aid for assessing Stomach Symptoms	Substantial Amendment 2 - 7/7/16	07/07/2016	17
14/NE/1214/AM14	A Phase 3 Veliparib plus Chemotherapy Study in Non-Squamous NSCLC	Substantial Amendment 8 - 18/7	18/07/2016	10
14/NE/1221/AM04	EPOS Trial	Substantial Amendment 3 - 6/4/	06/04/2016	9
14/NE/1242/AM04	Digital self-monitoring of health in primary care	Substantial Amendment 2	11/04/2016	21
14/NE/1253/AM09	D5160C00019 - Phase I, Open Label, PK, EGFRm+ NSCLC (Rosuvastatin)	Substantial Amendment 7 - 6/5/	06/05/2016	21
14/NE/1253/AM11	D5160C00019 - Phase I, Open Label, PK, EGFRm+ NSCLC (Rosuvastatin)	SA9	22/02/2017	10
15/NE/0058/AM05	The Genome Diversity in Africa Project (GDAP)	Substantial Amendment 5 - Sept	13/09/2016	13
15/NE/0070/AM05	A Phase 1b study in patients with B-Cell Chronic Lymphocytic Leukemia	Substantial Amendment 5 - 30/6	30/06/2016	8
15/NE/0070/AM06	A Phase 1b study in patients with B-Cell Chronic Lymphocytic Leukemia	Substantial Amendment 6, 01/09	19/12/2016	17
15/NE/0149/AM08	Phase 2 study in Patients with Recurrent or Metastatic SCCHN	Substantial Amendment 5 - 13/	13/04/2016	14
15/NE/0149/AM10	Phase 2 study in Patients with Recurrent or Metastatic SCCHN	Substantial	17/05/2016	10

		Amendment 7 - 17/5		
15/NE/0149/AM11	Phase 2 study in Patients with Recurrent or Metastatic SCCHN	SA08	23/08/2016	13
15/NE/0150/AM03	EPoS-UK	Substantial Amendment 2 - 14/9	14/09/2016	13
15/NE/0155/AM05	Antiplatelet therapy in COPD (APPLE-COPD:ICON 2)	Substantial Amendment 2 - 23/6	23/06/2016	10
15/NE/0155/AM08	Antiplatelet therapy in COPD (APPLE-COPD:ICON 2)	Substantial Amendment 3, 16/11	17/11/2016	13
15/NE/0190/AM01	Physical Activity in Heart Failure	Substantial Amendment 1 - 4/4/	04/04/2016	19
15/NE/0212/AM04	A Fulranumab study of Osteoarthritis of the hip or knee (3003)	Substantial Amendment 4 - 10/6	10/06/2016	15
15/NE/0212/AM05	A Fulranumab study of Osteoarthritis of the hip or knee (3003)	Substantial Amendment 5 - 3/10	03/10/2016	11
15/NE/0213/AM03	CASCADE II -Version1	SA1	16/08/2016	13
15/NE/0216/AM01	Alcohol Prevalence in Pregnancy (APP) Study	Substantial Amendment 1 - 7/3/	07/03/2016	9
15/NE/0216/AM02	Alcohol Prevalence in Pregnancy (APP) Study	Substantial Amendment 2 - 1/6/	01/06/2016	14
15/NE/0249/AM04	ETA305	Substantial Amendment 2, 31/10	31/10/2016	15
15/NE/0251/AM02	The utility of feNO in the differential diagnosis of chronic cough	Substantial Amendment 1 - 12/4	12/04/2016	8
15/NE/0252/AM04	MK-3475 (Pembrolizumab) in Subjects with Classical Hodgkin Lymphoma	Substantial Amendment 4 - 5/8/	05/08/2016	10
15/NE/0252/AM07	MK-3475 (Pembrolizumab) in Subjects with Classical Hodgkin Lymphoma	Substantial Amendment 6, 20/12	20/12/2016	11

15/NE/0252/AM09	MK-3475 (Pembrolizumab) in Subjects with Classical Hodgkin Lymphoma	SA08/09	22/03/2017	14
15/NE/0277/AM04	OPTIMUM	Substantial Amendment 4 - 29/6	29/06/2016	8
15/NE/0277/AM05	OPTIMUM	Substantial Amendment 5 - 11/8	11/08/2016	18
15/NE/0277/AM08	OPTIMUM	Substantial Amendment 7, 07/12	07/12/2016	28
15/NE/0278/AM04	Efficacy & safety of 2 different aflibercept regimens in nAMD subjects	Substantial Amendment 3 - 21/3	21/03/2016	6
15/NE/0278/AM05	Efficacy & safety of 2 different aflibercept regimens in nAMD subjects	Substantial Amendment 4 - 6/2/	02/06/2016	7
15/NE/0278/AM08	Efficacy & safety of 2 different aflibercept regimens in nAMD subjects	Substantial Amendment 5, 07/11	07/11/2016	12
15/NE/0296/AM03	Feasibility study for a randomised trial of first-line respiratory support	Substantial Amendment 2 - 17/3/	22/03/2016	9
15/NE/0310/AM01	The Feasibility of Endoscopic Ultrasound-Guided Portal Vein Manometry	Substantial Amendment 1 - 18/4	18/04/2016	21
15/NE/0331/AM01	Dabigatran Presence in Breast Milk (DALMATION)	Substantial Amendment 2 - update	22/02/2016	15
15/NE/0331/AM02	Dabigatran Presence in Breast Milk (DALMATION)	Substantial Amendment 4 - 17/5	17/05/2016	12
15/NE/0331/AM04	Dabigatran Presence in Breast Milk (DALMATION)	Substantial Amendment 5 - 7/7/	07/07/2016	14
15/NE/0331/AM05	Dabigatran Presence in Breast Milk (DALMATION)	Substantial Amendment 6 - 21/7	21/07/2016	21
15/NE/0349/AM01	OSA in Pregnancy: Is STOPBANG Predictive?	Substantial	01/04/2016	14

		Amendment 1 - 1/4/		
15/NE/0357/AM01	SBoCK	Substantial Amendment 1 - 4/5/	04/05/2016	17
15/NE/0358/AM01	Phase II HRV16 study examining PrEP-001 in asthmatics	Substantial Amendment 1 - 25/4	25/04/2016	19
15/NE/0381/AM01	ALTAR	Substantial Amendment 1 - 8/4/	08/04/2016	24
15/NE/0381/AM02	ALTAR	SA2	11/08/2016	15
15/NE/0381/AM04	ALTAR	SA4	03/03/2017	11
15/NE/0382/AM01	MASS: Muscle and Ageing Science Study (V.1)	Substantial Amendment 1 - 3/6/	03/06/2016	6
15/NE/0384/AM01	AIDE Project	SA1	20/02/2017	23
15/NE/0390/AM01	Myotubular and Centronuclear Patient Registry	Substantial Amendment 1, 09/12	09/12/2016	15
15/NE/0394/AM03	A Phase 2a study of multiple doses of BTA-C585 against RSV infection	Substantial Amendment 1 - temp	06/06/2016	16
15/NE/0394/AM04	A Phase 2a study of multiple doses of BTA-C585 against RSV infection	Substantial Amendment 2 - 13/6	13/06/2016	21
16/NE/0023/AM02	BN29552 A Study of Crenezumab in Patients with Prodromal to Mild AD	Substantial Amendment 2 - 23/5	23/05/2016	23
16/NE/0023/AM03	BN29552 A Study of Crenezumab in Patients with Prodromal to Mild AD	Substantial Amendment 3 - 8/7/	08/07/2016	12
16/NE/0023/AM06	BN29552 A Study of Crenezumab in Patients with Prodromal to Mild AD	Substantial Amendment 6, 05/12	05/12/2016	28
16/NE/0023/AM08	BN29552 A Study of Crenezumab in Patients with Prodromal to Mild AD	SA7	15/03/2017	17
16/NE/0027/AM02	B9991009 Phase 3, avelumab for Platinum-Resistant Ovarian Cancer	Substantial Amendment 1 - 17/3	17/03/2016	14
16/NE/0027/AM07	B9991009 Phase 3, avelumab for Platinum-Resistant Ovarian	Substantial	09/06/2016	12

	Cancer	Amendment 5 - 9/6/		
16/NE/0027/AM12	B9991009 Phase 3, avelumab for Platinum-Resistant Ovarian Cancer	SA7	10/03/2017	22
16/NE/0028/AM01	SOLAR Study	Substantial Amendment 1 - 28/4	28/04/2016	18
16/NE/0028/AM02	SOLAR Study	Substantial Amendment 2 - 16/5	16/05/2016	6
16/NE/0028/AM03	SOLAR Study	SA3	15/12/2016	13
16/NE/0031/AM01	Phase 1b study of Foxy5 in Metastatic Breast, Colon or Prostate Cancer	Substantial Amendment 1 - 18/4	18/04/2016	21
16/NE/0031/AM02	Phase 1b study of Foxy5 in Metastatic Breast, Colon or Prostate Cancer	Substantial Amendment 2 - 8/6/	08/06/2016	7
16/NE/0031/AM03	Phase 1b study of Foxy5 in Metastatic Breast, Colon or Prostate Cancer	Substantial Amendment 3, 27/10	27/10/2016	19
16/NE/0031/AM04	Phase 1b study of Foxy5 in Metastatic Breast, Colon or Prostate Cancer	Substantial Amendment 4, 05/12	06/12/2016	30
16/NE/0031/AM05	Phase 1b study of Foxy5 in Metastatic Breast, Colon or Prostate Cancer	SA5	23/01/2017	8
16/NE/0066/AM02	D4190C00006 - Ph 1b MEDI4736 in Advanced Non-Small Cell Lung Cancer	Substantial Amendment 1 - 12/5	12/05/2016	9
16/NE/0066/AM03	D4190C00006 - Ph 1b MEDI4736 in Advanced Non-Small Cell Lung Cancer	Substantial Amendment 2 - 7/6/	07/06/2016	18
16/NE/0066/AM04	D4190C00006 - Ph 1b MEDI4736 in Advanced Non-Small Cell Lung Cancer	SA3	10/03/2017	19
16/NE/0067/AM01	Dose-Ranging Study of Delayed-Release Deferiprone in Parkinson	Substantial Amendment 1 - 6/4/	06/04/2016	16
16/NE/0067/AM03	Dose-Ranging Study of Delayed-Release Deferiprone in Parkinson	Substantial Amendment 2 - 11/5	11/05/2016	9
16/NE/0067/AM04	Dose-Ranging Study of Delayed-Release Deferiprone in	Substantial	11/11/2016	22

	Parkinson	Amendment 3, 08/11		
16/NE/0069/AM01	Study of UTTR1147A in Healthy Volunteers & Ulcerative Colitis Patients	Substantial Amendment 1 - 22/8	22/08/2016	14
16/NE/0082/AM01	Relationship between PA and metabolic control in children with T1DM.	SA1	05/01/2017	22
16/NE/0083/AM01	Viral Challenge Asthma Phenotype (VCAP) Study	Substantial Amendment 1 - 26/5	26/05/2016	9
16/NE/0083/AM02	Viral Challenge Asthma Phenotype (VCAP) Study	SA2	01/08/2016	17
16/NE/0083/AM03	Viral Challenge Asthma Phenotype (VCAP) Study	Substantial Amendment 3, 07/10	11/10/2016	21
16/NE/0097/AM05	Long-term observational study of subjects from Tanezumab studies	Substantial Amendment 2, 21/12	22/12/2016	15
16/NE/0142/AM01	B9991010 Phase 3, avelumab for Untreated Epithelial Ovarian Cancer	Substantial Amendment 1 - 10/6	10/06/2016	13
16/NE/0142/AM02	B9991010 Phase 3, avelumab for Untreated Epithelial Ovarian Cancer	Substantial Amendment 2 - 4/7/	04/07/2016	17
16/NE/0142/AM06	B9991010 Phase 3, avelumab for Untreated Epithelial Ovarian Cancer	SA3	14/02/2017	19
16/NE/0146/AM04	2WW v1	Substantial Amendment 2, 13/10	13/10/2016	17
16/NE/0147/AM02	RESOLVE-IT: A Study of Elafibranor in Patients with NASH and fibrosis	Substantial Amendment 2 - 28/9	28/09/2016	16
16/NE/0147/AM03	RESOLVE-IT: A Study of Elafibranor in Patients with NASH and fibrosis	SA3	24/01/2017	8
16/NE/0247/AM01	Advanced glycation end products as a biomarker for accelerated ageing	Substantial Amendment 1, 21/11	21/11/2016	22
16/NE/0248/AM01	The Optimisation of Human Steatotic Livers for Transplantation	SA1	03/01/2017	13

16/NE/0252/AM03	Patient involvement in improving patient safety in primary care v1	SA1	25/01/2017	14
16/NE/0253/AM02	Rituximab in Graves' Disease (RIGD)	SA1	09/03/2017	15
16/NE/0279/AM01	TIDaL	Substantial Amendment 1, 06/10	10/11/2016	20
16/NE/0279/AM04	TIDaL	AM4	02/02/2017	9
16/NE/0281/AM02	Experiences of people with psychosis being detained under the MHA	Substantial Amendment 1, 27/10	04/11/2016	24
16/NE/0322/AM01	Fun with Feelings: Parent group for children with ASD and anxiety	Substantial Amendment 1, 07/11	07/11/2016	14
16/NE/0353/AM01	ARASENS	SA1	23/01/2017	11

Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
16/NE/0092/AM05	Impulsivity and Executive Function Following Traumatic Brain Injury	SA1	25/01/2017	9
16/NE/0146/AM06	2WW v1	Substantial Amendment 3, 23/11	05/12/2016	25

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
13/NE/0344/AM16/1	A monotherapy study of ertugliflozin in participants with T2DM	Modified Amendment 1 - (Sub Am	14/06/2016	8

Unfavourable opinion timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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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 21 day timeline

REC Reference	Title	Number of Days on Clock

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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