

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

**Annual Report**

**01 April 2017 - 31 March 2018**



## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	North East - Newcastle & North Tyneside 2 Research Ethics Committee
<b>Type of REC:</b>	REC recognised to review CTIMPS in patients - type iii
<b>Type of Flag:</b>	Research Involving Adults Lacking Capacity
<b>Chair:</b>	Dr Alasdair MacSween
<b>Vice-Chair:</b>	Vacancy
<b>Alternate Vice-Chair:</b>	Vacancy
<b>REC Manager:</b>	Miss Kerry Dunbar – 26 March 2018 Miss Kirstie Penman (2017 until 25 March 2018)
<b>REC Assistant:</b>	Donna Bennett
<b>Committee Address:</b>	NHS BT Blood Donor Centre Holland Drive Newcastle upon Tyne Tyne and Wear NE2 4NQ
<b>Telephone:</b>	0207 104 8082
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## Chair's overview of the past year:

Despite some changes to membership over the period, including the departure of some long standing members, the committee continued to engage in healthy debate and give developed and well founded opinions.

Some members are particularly concerned at our no longer having a statistician as a standing member, but, are (hopefully) re-assured that, if members feel it is needed, for any application, statistical advice can be sought from an external advisor through the REC manager and HRA.

The change of venue has been well received (to my knowledge) and the availability of free parking is particularly appreciated by all.

We continue to struggle to always keep to the set time and this is an ongoing issue which members are aware of and consider on a regular basis. The conflict between members enjoying a wide ranging and open debate, yet, keeping to the set half an hour per application, is difficult to resolve - but - we work on it together and discuss it often.

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

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Mrs Ann Boardman	Retired Educationalist	Lay Plus	01/02/2010	
Mr Andrew Brenikov	Historian	Lay Plus	01/04/2008	
Professor Andrew Hall	Former Associate Associate Dean for Bioresources	Expert	04/08/2017	
Miss Phillipa Hearty	Research Assistant	Lay	02/01/2018	
Dr Alasdair MacSween	Principal Lecturer in Research Governance	Expert	01/04/2013	
Mr Ben Morrison	PhD Student	Lay	07/09/2016	
Dr Tony Newton	Director	Expert	04/08/2017	
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	
Ms Emma Thompson	Research Radiographer	Expert	10/04/2015	
Mr Richard Tomlin	Consultant in Research Management (Retired)	Lay Plus	01/05/2015	08/08/2017
Dr Elizabeth Walsh-Heggie	General Practitioner	Expert	14/07/2016	23/10/2017
Mrs Susan Webster	Head of Psychology	Lay Plus	29/03/2017	

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

Name	Profession	Status	Meeting date attended
Mr Martin Edmunds	Editor	Lay Plus	12/04/2017 (Full Mtg)
Dr Rhona Bratt	Retired Multimedia Project Manager	Lay Plus	20/2/2018 (SC)
M Heidi Chandler	Deputy Research Delivery Manager	Lay	06/03/2018 (SC)

**North East - Newcastle & North Tyneside 2 Research Ethics Committee: Members' Declarations of Interest:**

<b>Name</b>	<b>Declaration of Interest</b>	<b>Date</b>
Mrs Ann Boardman	None	30/03/2018
Mr Andrew Brenikov	None	30/03/2018
Professor Andrew Hall	Member of the Human Tissue Authority Founder and Trustee, givemysample.org Member, scientific advisory board, Bone Cancer Research Trust and GIST support UKAs an emeritus professor at Newcastle University I provide advice on an ad hoc basis regarding research grant applications Specialist advice = Use of tissues in research; Biobanks; Haematology research (especially laboratory based); Cancer research (especially laboratory based)	30/03/2018
Miss Phillipa Hearty	Researcher at spectrum CIC - company involved in conduct of research. PHD Student at University of Leeds. Specialist advice in research being conducted in prisons.	30/03/2018
Dr Alasdair MacSween	None	30/03/2018
Dr Tony Newton	Shareholding in Glaxo Smith Kline Public Governor, Northumbria Healthcare NHS Foundation Trust	21/11/2017
Mrs Susan P Phillips	None	30/03/2018
Dr Meiyi Pu	None	30/03/2018
Ms Emma Thompson	None	30/03/2018
Mrs Susan Webster	None	17/05/2017

### Meetings for Full Ethical Review 01 April 2017 - 31 March 2018:

Month	Date	Number of Members Present at Meeting
April	12/04/2017	9
May	17/05/2017	8
June	14/06/2017	7
July	12/07/2017	8
September	13/09/2017	8
January	31/01/2018	8
February	21/02/2018	7
March	14/03/2018	9

8 full committee meetings were held during the reporting period.

### Proportionate Review Sub-Committee Meetings held during 01 April 2017 - 31 March 2018:

Month	Date	Number of Members Present at Meeting
April	05/04/2017	3
May	03/05/2017	3
June	06/06/2017	3
August	03/08/2017	3
September	07/09/2017	3
October	05/10/2017	3
November	02/11/2017	3
December	13/12/2017	10
January	10/01/2018	3

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

### Sub-Committee Meetings held during 01 April 2017 - 31 March 2018:

Month	Date	Number of Members Present at Meeting
April	07/04/2017	2
April	21/04/2017	2
May	05/05/2017	2
May	23/05/2017	2
May	31/05/2017	3
June	01/06/2017	3
June	16/06/2017	2
June	29/06/2017	3
June	30/06/2017	2
July	14/07/2017	2
July	31/07/2017	3
August	10/08/2017	3
August	11/08/2017	2
August	14/08/2017	3

August	25/08/2017	2
September	05/09/2017	2
September	08/09/2017	3
September	22/09/2017	5
October	06/10/2017	2
October	20/10/2017	2
November	03/11/2017	2
November	17/11/2017	3
December	01/12/2017	3
December	15/12/2017	2
January	05/01/2018	3
January	09/01/2018	3
January	23/01/2018	3
January	23/01/2018	2
February	06/02/2018	2
February	14/02/2018	3
February	20/02/2018	2
March	06/03/2018	2
March	20/03/2018	2

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

**Details of inquorate meeting held: 01 April 2017 - 31 March 2018**

None.

**Attendance of Members at full committee meetings:01 April 2017 - 31 March 2018**

<b>Name</b>	<b>Number of Meetings Attended</b>
Mrs Ann Boardman	6
Mr Andrew Brenikov	7
Professor Andrew Hall	2
Miss Phillipa Hearty	2
Dr Alasdair MacSween	7
Mr Ben Morrison	7
Dr Tony Newton	3
Mrs Susan P Phillips	6
Dr Meiyi Pu	4
Ms Vicky Ryan	5
Ms Emma Thompson	6
Mr Richard Tomlin	1
Dr Elizabeth Walsh-Heggie	1
Mrs Susan Webster	6

**Attendance of Members at proportionate review sub-committee meetings: 01 April 2017 - 31 March 2018**

<b>Name</b>	<b>Number of Meetings Attended</b>
Mrs Ann Boardman	4
Mr Andrew Brenikov	5
Professor Andrew Hall	1
Dr Alasdair MacSween	4
Mr Ben Morrison	6
Dr Tony Newton	1
Mrs Susan P Phillips	5
Dr Meiyi Pu	1
Ms Vicky Ryan	1
Ms Emma Thompson	4
Mr Richard Tomlin	1
Mrs Susan Webster	1

**Attendance of Members at sub-committee meetings: 01 April 2017 - 31 March 2018**

<b>Name</b>	<b>Number of Meetings Attended</b>
Mrs Ann Boardman	4
Mr Andrew Brenikov	7
Professor Andrew Hall	1



Dr Alasdair MacSween	16
Mr Ben Morrison	13
Dr Tony Newton	2
Mrs Susan P Phillips	16
Dr Meiyi Pu	2
Ms Vicky Ryan	5
Ms Emma Thompson	7
Mr Richard Tomlin	3
Dr Elizabeth Walsh Heggie	1
Mrs Susan Webster	1

**Training 01 April 2017 - 31 March 2018**

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Mrs Ann Boardman	14/06/2017	PPI Training
Mrs Ann Boardman	14/09/2017	Health Related Findings
Mrs Ann Boardman	14/09/2017	Handling Health Related Findings in Research
Mrs Ann Boardman	09/02/2018	Complex Cases
Mr Andrew Brenikov	06/06/2017	Webinar - HARP portal
Mr Andrew Brenikov	18/06/2017	Equality and Diversity
Mr Andrew Brenikov	18/06/2017	Equality and Diversity
Mr Andrew Brenikov	06/07/2017	Local Training day - York
Mr Andrew Brenikov	14/09/2017	Handling Health Related Findings in Research
Mr Andrew Brenikov	29/11/2017	Regional Members Training Day
Mr Andrew Brenikov	09/02/2018	Complex Cases
Professor Andrew Hall	29/11/2017	Regional Members Training Day
Professor Andrew Hall	12/12/2017	National Members' Training Day
Professor Andrew Hall	11/01/2018	Committee Members Induction
Dr Alasdair MacSween	14/06/2017	PPI Training
Dr Alasdair MacSween	29/11/2017	Regional Members Training Day
Mr Ben Morrison	14/06/2017	PPI Training
Mr Ben Morrison	24/11/2017	HRA National Chairs' Day and Policy Event
Dr Tony Newton	29/11/2017	Regional Members Training Day
Dr Tony Newton	11/01/2018	Committee Members Induction
Mrs Susan P Phillips	14/06/2017	PPI Training
Mrs Susan P Phillips	23/06/2017	Equality and Diversity Course
Mrs Susan P Phillips	05/10/2017	Introduction to Phase 1 Research - Trials & Regulation
Mrs Susan P Phillips	05/10/2017	Introduction to Phase 1 Research - Trials & Regulation
Mrs Susan P Phillips	23/10/2017	Ethical Issues in Phase One Research: An Advanced Training Course
Ms Emma Thompson	01/04/2017	SDL Covering April 17 - May 2017
Ms Emma Thompson	14/06/2017	PPI Training
Ms Emma Thompson	29/11/2017	Regional Members Training Day
Mr Richard Tomlin	12/09/2017	Genetic and Genomic Research
Mrs Susan Webster	09/04/2017	Induction for new Research Ethics Service Committee members
Mrs Susan Webster	09/04/2017	Equality and Diversity Training
Mrs Susan Webster	02/05/2017	Induction Training
Mrs Susan Webster	14/06/2017	PPI Training
Mrs Susan Webster	09/02/2018	Complex Cases

## PART 2: REC WORKLOAD AND ACTIVITY DURING THE REPORTING PERIOD

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

<b>Applications for full ethical review – Study Type</b>	<b>Number</b>	<b>%</b>
Clinical Trial of Investigational Medicinal Product	11	31.43
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	24	68.57
<b>Total Applications Reviewed</b>	<b>35</b>	<b>100</b>

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

Number of applications made invalid by the REC Manager	0
Number of applications withdrawn prior to the meeting	1
Number of student applications reviewed	12
Number of paediatric applications reviewed	1
Number of device applications reviewed	3
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	6
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**

<b>Decisions taken at meetings following review of applications</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	3	8.57
Unfavourable Opinion	2	5.71
Provisional Opinion	30	85.71
Provisional Opinion Pending Consultation with Referee	0	0.00
<b>Total</b>	<b>35</b>	<b>100</b>
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**

<b>Status of applications at date of generation of report</b>	<b>Number</b>	<b>%</b>
Further Information Favourable Opinion with Standard Conditions	23	65.71
Further Information Favourable Opinion with Additional Conditions	2	5.71
Further Information Unfavourable Opinion	1	2.86
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	3	8.57
Unfavourable Opinion	2	5.71
Provisional Opinion	1	2.86
Provisional Opinion Pending Consultation with Referee	0	0.00
Further Information response not complete	3	8.57
No decision entered on system	0	0.00
Number of studies withdrawn after the meeting	0	0.00
<b>Total</b>	<b>35</b>	<b>100</b>

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

<b>Total Applications Reviewed</b>	<b>18</b>
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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	2
Number of student applications reviewed	9
Number of paediatric applications reviewed	5
Number of device applications reviewed	2
Number of qualitative applications reviewed	2

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

<b>Decisions taken at proportionate review sub-committee meetings</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	7	38.89
Favourable Opinion with Additional Conditions	2	11.11
No Opinion transfer to full committee for review	4	22.22
Provisional Opinion	5	27.78
Unfavourable Opinion	0	0.00
<b>Total</b>	<b>18</b>	<b>100</b>

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

<b>Average number of applications reviewed per full meeting</b>	4.38
<b>Number of completed applications for full ethical review</b>	35
<b>Number of completed applications for full ethical review over 60 days</b>	0
<b>Number of completed applications over 60 days as a % of total</b>	0.00%
<b>Number of days taken to final decision – average (mean)</b>	37
<b>Number of completed proportionate review applications for ethical review</b>	13
<b>Number of completed proportionate review applications for ethical review over 21 days</b>	1
<b>Number of completed proportionate review applications over 21 days as a % of total</b>	7.69%
<b>Number of SSAs (non-Phase 1) reviewed</b>	15
<b>Number of completed applications for SSA review over 25 days</b>	0
<b>Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs</b>	0.00%
<b>Number of SSAs (Phase 1) reviewed</b>	0
<b>Number of completed applications for SSA review over 14 days</b>	0
<b>Number of completed applications for SSA review over 14 days as % of all Phase 1 SSAs</b>	0.00%
<b>Number of substantial amendments reviewed</b>	105
<b>Number of completed substantial amendments over 35 days</b>	1
<b>Number of completed substantial amendments over 35 days as a % of total substantial amendments</b>	0.95%
<b>Number of modified amendments reviewed</b>	2
<b>Number of completed modified amendments over 14 days</b>	0
<b>Number of completed modified amendments over 14 days as a % of total modified amendments</b>	0.00%
<b>Number of non substantial amendments received</b>	129
<b>Number of substantial amendments received for information</b>	0
<b>Number of substantial amendments received for new sites/PIs</b>	27
<b>Number of annual progress reports received</b>	54
<b>Number of safety reports received</b>	38
<b>Number of Serious Adverse Events received</b>	3
<b>Number of final reports received</b>	26

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

<b>Further Information Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
17/NE/0117	Phase 2b Dose Finding Study in Adult Patients Osteogenesis Imperfecta	43
17/NE/0118	SUGAR-DM-HF	55
17/NE/0120	Pilot Study of Patient Directed Monitoring of Crohn's Disease	31
17/NE/0121	EPOS 2	48
17/NE/0149	ROVA-T Maintenance in SCLC (MERU)	33
17/NE/0153	Investigating body image in young adults who have cancer	31
17/NE/0159	POLARIS Retreatment	31
17/NE/0161	LIVERHOPE - simvastatin & rifaximin safety in decompensated cirrhosis	36
17/NE/0183	Modifiable risk factors for postoperative delirium in older adults.	23
17/NE/0200	SMART Registry_Boston Scientific_(0393-0026)	40
17/NE/0232	Evaluation of Tear Characteristics Following TrueTear <sup>®</sup> Use	41
17/NE/0236	Glutamate Dysfunction in Gliomas, V1.0	32
17/NE/0239	NAIROS	29
17/NE/0242	Anomia in People with Relapsing-Remitting Multiple Sclerosis	49
17/NE/0294	Value of CEUS as a surrogate for CTA for EVAR surveillance (Ver 1.1)	36
17/NE/0297	Developing an intervention for Falls in Dementia WP4	43
17/NE/0300	UM203	31
17/NE/0301	IN-UK-311-3956: TAF Switch Study in HBV/HIV	35
18/NE/0035	LJPC-401 for Iron Overload in Adults with Hereditary Hemochromatosis	48
18/NE/0036	Effects of Critical Illness on the Innate Immune System	36
18/NE/0041	Usual dementia care: an observation study	54
18/NE/0075	IU and strain in the caregivers of people with dementia	58
18/NE/0092	ELAN	26

<b>Further Information Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
18/NE/0037	Feasibility of respiratory muscle training in ILD	42
18/NE/0076	Feasibility study:EULOv01	42

**Further Information Unfavourable Opinion**

REC Reference	Title	Number of Days on Clock
17/NE/0206	BHiRCH Pilot cluster randomised trial	30

#### Favourable Opinion with Standard Conditions

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

REC Reference	Title	Number of Days on Clock
17/NE/0282	Chest x-ray interpretation in intensive care units	27
18/NE/0033	CLP-AF-004_Visualise Etiology of Recurrent AF after failed AF ablation	28
18/NE/0073	The HOT 2 Trial	27

#### Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
17/NE/0119	Evaluation of grommets and hearing aids in children with otitis media	30
18/NE/0095	A study aspirin pharmacokinetics in women at high risk of preeclampsia	22

#### Provisional Opinion

REC Reference	Title	Number of Days on Clock
18/NE/0074	Transfer of babies from multiple pregnancies for Intensive Care V.1	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
17/NE/0283	ATTUNE: Understanding Pathways to Stimulant Use	n/a
18/NE/0064	Recovery from Trauma Research Study (RTRS)	n/a
18/NE/0072	A Study of INCB050465 in Relapsed or Refractory (MCL)	n/a



<b>Withdrawn after the meeting</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>

**Table 9.2: Breakdown of current status of all PRS applications reviewed within the reporting period**

<b>Further Information Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
17/NE/0180	High intensity inspiratory muscle training for lung resection surgery	18
17/NE/0389	Med Rec Study	20

<b>Further Information Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>

<b>Further Information Unfavourable Opinion</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
18/NE/0088	An exploration of self management physiotherapy programmes (SMPP)	27

<b>Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
17/NE/0140	qSOFA, SIRS, and NEWS for predicting mortality in sepsis	5
17/NE/0144	MULTIVARIATE ANALYSIS OF PATIENTS WITH OCCUPATIONAL ASTHMA	6
17/NE/0182	Image overlay for robot assisted partial nephrectomy - a Pilot study	15
17/NE/0185	Bioprocessing of UCT-MS	14
17/NE/0317	AI-COPD: Acceptability to patients & clinicians of COPD APP	15
17/NE/0349	Willingness to Pay (WTP) for adult orthodontic treatment	15
18/NE/0028	Development of a PROM for anaemia symptoms during pregnancy.	21

<b>Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
17/NE/0350	Molecular Basis of Congenital Heart Disease	15

18/NE/0027	Tangible toys (TATO) with sensors and biofeedback mechanism	21
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#### Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
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#### Provisional Opinion

REC Reference	Title	Number of Days on Clock
17/NE/0390	IgA Vasculitis study, version 1	n/a

#### 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
17/NE/0107	SleepSoundly v2	7

**Table 10.1: Breakdown of current status of all substantial amendments reviewed within the reporting period**

<b>Favourable opinion</b>				
<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>
09/H0905/41/AM03	The assessment of failed hip resurfacing components	Substantial Amendment 3 - 15/06/2017	15/06/2017	29
11/NE/0312/AM11	MelResist Version 1.0	Substantial Amendment 8 - 31/05/2017	31/05/2017	27
11/NE/0312/AM12	MelResist Version 1.0	Substantial Amendment 9 - 22/08/2017	22/08/2017	33
11/NE/0348/AM04	Role of prion protein in neurodegenerative disease	Substantial Amendment 3, 15/09/17	23/11/2017	16
11/NE/0360/AM09	A natural history study of dysferlinopathy	Substantial Amendment 6 - 30/3/17	30/03/2017	26
12/NE/0251/AM05	Northeast Early Arthritis Cohort	Substantial Amendment 4, 13/12/17	31/01/2018	20
12/NE/0345/AM06	A Phase I trial of AZD3965 in patients with advanced cancer.	Substantial Amendment 5 - CTA Amend 09/PA 06 - 7/2/17	07/02/2017	27
12/NE/0345/AM08	A Phase I trial of AZD3965 in patients with advanced cancer.	Substantial Amendment 7 (CTA Amendment 11 / PA 07) - 24/8/17	24/08/2017	29
13/NE/0011/AM16	BMS-936558 versus investigator's choice in advanced melanoma	Substantial Amendment 14 - 17/03/17	17/03/2017	37
13/NE/0011/AM18	BMS-936558 versus investigator's choice in advanced melanoma	Substantial Amendment 16 -	08/09/2017	32

		8/9/17		
13/NE/0011/AM19	BMS-936558 versus investigator's choice in advanced melanoma	Substantial Amendment 17	30/11/2017	28
13/NE/0011/AM20	BMS-936558 versus investigator's choice in advanced melanoma	Substantial Amendment 18	12/02/2018	8
13/NE/0299/AM04	EuroHyp-1	Substantial Amendment 3, 14/06/17	15/09/2017	20
13/NE/0326/AM03	MitoCohort	Substantial Amendment 2, 18/12/17	04/01/2018	28
13/NE/0361/AM13	OPTIMAL - Optimising Renal outcome in Myeloma renal failure	Substantial Amendment 11 - 1/8/17	01/08/2017	13
14/NE/0100/AM13	CPP-1X and SULINDAC in patients with FAP	Substantial Amendment 5 - 21/7/17	21/07/2017	14
14/NE/1062/AM08	The PHOTO Trial	SA2	27/11/2017	27
14/NE/1062/AM09	The PHOTO Trial	Substantial amendment 3, 08/02/18	09/02/2018	11
14/NE/1063/AM11	GA28950 PHASE III TRIAL OF ETROLIZUMAB IN MODERATE TO SEVERE ACTIVE UC	SA9 Protocol 7	30/10/2017	21
14/NE/1135/AM07	MRC-BLISS	Substantial Amendment 4, 04/04/17	16/04/2017	28
14/NE/1161/AM02	DBT Group for Bulimia Nervosa and Binge Eating Disorder	Substantial Amendment 1, 12/07/17	12/07/2017	22
14/NE/1181/AM05	ADAPTeR	3	21/03/2017	35
15/NE/0013/AM11	Radiation versus Observation following surgery for Atypical Meningioma	Substantial Amendment 5 (overall 13) - 20/7/17	20/07/2017	13
15/NE/0142/AM03	RLS-NMS Quest	Substantial Amendment 3 - 29/3/17	29/03/2017	21

15/NE/0143/AM14	GA29144 Phase III ETRO IN MODERATE TO SEVERE ACTIVE CROHNS DISEASE	Substantial Amendment 10, Protocol v6, ICF and patient materials, 05/10/2017	06/10/2017	20
15/NE/0144/AM05	GA29145 – Open label extension & safety monitoring study	Substantial Amendment 5 - 10/4/17	10/04/2017	15
15/NE/0144/AM11	GA29145 – Open label extension & safety monitoring study	Substantial Amendment 8	27/10/2017	28
15/NE/0210/AM04	20140128 GLAGOV Extension study	Substantial Amendment 3 - 3/8/17	03/08/2017	22
15/NE/0211/AM08	Strike	SA1	25/01/2018	15
15/NE/0308/AM01	Evaluating non-drug therapies in older people with OH	Substantial Amendment 1 – 12/6/17	12/06/2017	35
15/NE/0324/AM13	Simvastatin as a neuroprotective treatment for moderate PD (PD STAT)	Substantial Amendment 8, 27/04/17	27/04/2017	28
15/NE/0396/AM01	BUL2/EER	Substantial Amendment 1, 26/07/17	11/10/2017	13
15/NE/0396/AM02	BUL2/EER	Substantial Amendment 2, 11/12/17	23/01/2018	27
15/NE/0406/AM09	Safety and Tolerability of MTL-CEBPA in Advanced Liver Cancer	Substantial Amendment 6 - 21/3/17	21/03/2017	24
15/NE/0406/AM10	Safety and Tolerability of MTL-CEBPA in Advanced Liver Cancer	Substantial Amendment 7, 04/10/17	05/10/2017	16
15/NE/0406/AM12	Safety and Tolerability of MTL-CEBPA in Advanced Liver Cancer	SA09	05/12/2017	16
15/NE/0406/AM13	Safety and Tolerability of MTL-CEBPA in Advanced Liver Cancer	Substantial Amendment 10	26/01/2018	11

15/NE/0415/AM07	CHRONOS-4	SA7	13/04/2017	29
15/NE/0415/AM08	CHRONOS-4	SA8	19/04/2017	32
15/NE/0415/AM10	CHRONOS-4	Substantial Amendment10 - 26/6/17	26/06/2017	25
15/NE/0415/AM11	CHRONOS-4	Substantial Amendment 11	25/10/2017	9
15/NE/0415/AM14	CHRONOS-4	Substantial Amendment 12, 05/02/18	08/02/2018	13
15/NE/0415/AM15	CHRONOS-4	Substantial Amendment 13	15/02/2018	14
15/NE/0420/AM04	SUPERB version 1.0	Substantial Amendment 4.0, 29/09/17	20/10/2017	9
16/NE/0047/AM02	Steroid Induction Regimen for Juvenile Idiopathic Arthritis (JIA)	Substantial Amendment 1 - 7/2/17	07/02/2017	25
16/NE/0047/AM04	Steroid Induction Regimen for Juvenile Idiopathic Arthritis (JIA)	Substantial Amendment 2, 30/01/17	12/02/2018	15
16/NE/0050/AM10	Efficacy & Safety of TANEZUMAB in subjects Osteoarthritis of Hip/Knee	Substantial Amendment 6 - 4/4/17	04/04/2017	24
16/NE/0057/AM03	Safety & Efficacy of Tideglusib in Type 1 Myotonic Dystrophy	Substantial Amendment 3, 15/01/18	19/01/2018	15
16/NE/0108/AM04	Leeds Observational Cohort Ultrasound Study (LOCUS)	SA3	09/10/2017	11
16/NE/0138/AM09	177Lu-OPS201 phase I/II study for the therapy of NETs, version 5	Substantial Amendment 6 - 29/7/17	29/07/2017	14
16/NE/0138/AM10	177Lu-OPS201 phase I/II study for the therapy of NETs, version 5	SA7	22/12/2017	8
16/NE/0140/AM01	EMT2: EPA for Metastasis Trial 2	Substantial Amendment 1 - 21/4/17	21/04/2017	13
16/NE/0140/AM03	EMT2: EPA for Metastasis Trial 2	Substantial	13/03/2018	21

		Amendment 2, 13/03/18		
16/NE/0169/AM03	Phase II/III of MOR00208 with BEN versus Ritux with BEN in R/R DLBCL	Substantial Amendment 2 - 7/12/16	07/12/2016	19
16/NE/0169/AM04	Phase II/III of MOR00208 with BEN versus Ritux with BEN in R/R DLBCL	Substantial Amendment 6, 21/07/2017	18/10/2017	25
16/NE/0169/AM05	Phase II/III of MOR00208 with BEN versus Ritux with BEN in R/R DLBCL	Substantial Amendment 4, 20/02/2018	20/02/2018	29
16/NE/0170/AM07	UX007-CL202	SA7	02/10/2017	26
16/NE/0175/AM04	A Study of Gilteritinib in Acute Myeloid Leukaemia with FLT3 Mutation	Substantial Amendment 4 - 1/6/17	01/06/2017	14
16/NE/0175/AM05	A Study of Gilteritinib in Acute Myeloid Leukaemia with FLT3 Mutation	Substantial Amendment 5 - 18/8/17	18/08/2017	32
16/NE/0238/AM11	The BHF SENIOR-RITA TRIAL	Substantial Amendment 2 - 10/5/17	10/05/2017	7
16/NE/0238/AM16	The BHF SENIOR-RITA TRIAL	Substantial Amendment 3 - 21/7/17	21/07/2017	20
16/NE/0238/AM17	The BHF SENIOR-RITA TRIAL	Substantial Amendment 4, 15/12/2017	16/01/2018	20
16/NE/0269/AM01	Ward Noise Levels and Sleep Quality	Substantial Amendment 1 - 20/3/17	20/03/2017	35
16/NE/0270/AM02	Metabolomic profiling in unstable atherosclerosis	SA1	13/12/2017	26
16/NE/0312/AM03	GWEP1521 - Study of GWP42003-P in Tuberous Sclerosis Complex	SA3	25/08/2017	33
16/NE/0312/AM04	GWEP1521 - Study of GWP42003-P in Tuberous Sclerosis Complex	SA04	19/02/2018	30
16/NE/0327/AM03	Community pHarmacIEs Mood Intervention STudy (CHEMIST)	Substantial Amendment 2 -	18/05/2017	14

		18/5/17		
16/NE/0327/AM05	Community pHarmaciacEs Mood Intervention Study (CHEMIST)	Substantial Amendment 3 - 7/6/17	07/06/2017	12
16/NE/0327/AM06	Community pHarmaciacEs Mood Intervention Study (CHEMIST)	Substantial Amendment 4 - 16/6/17	16/06/2017	28
16/NE/0327/AM08	Community pHarmaciacEs Mood Intervention Study (CHEMIST)	Substantial Amendment 5 - 8/9/17	08/09/2017	25
16/NE/0327/AM10	Community pHarmaciacEs Mood Intervention Study (CHEMIST)	Substantial Amendment 6	16/01/2018	23
16/NE/0327/AM11	Community pHarmaciacEs Mood Intervention Study (CHEMIST)	Substantial Amendment 7	16/01/2018	20
16/NE/0327/AM12	Community pHarmaciacEs Mood Intervention Study (CHEMIST)	Substantial Amendment 8	16/01/2018	20
16/NE/0377/AM01	Investigating patterns of influenza evolution in immunosuppression	Substantial Amendment 1 - 14/2/17	14/02/2017	25
16/NE/0382/AM01	COMRADE Exercise and CRPC	Substantial Amendment 1 - 21/3/17	21/03/2017	35
16/NE/0400/AM06	Knee Replacement Bandaging Study (KReBS)	Substantial Amendment 1 - 19/6/17	19/06/2017	19
16/NE/0402/AM01	Infant feeding practices of African mothers living in the UK.	Substantial Amendment 1 - 15/6/17	15/06/2017	31
16/NE/0403/AM03	PSOREAL; Protocol Code Number NIS-ENSTILAR-1285	Substantial Amendment 1 - 2/6/17	02/06/2017	29
16/NE/0403/AM04	PSOREAL; Protocol Code Number NIS-ENSTILAR-1285	Substantial Amendment 2 - 17/07/17	21/07/2017	24
16/NE/0413/AM02	Efficacy and Safety of Givinostat in Duchenne Muscular Dystrophy	Substantial Amendment 2 - 16/3/17	16/03/2017	33



16/NE/0413/AM03	Efficacy and Safety of Givinostat in Duchenne Muscular Dystrophy	Substantial Amendment 3 - 11/9/17	11/09/2017	32
16/NE/0413/AM05	Efficacy and Safety of Givinostat in Duchenne Muscular Dystrophy	SA4	21/12/2017	19
16/NE/0415/AM03	Phase 2a Study of AL-335, Odalasvir, with/without Simeprevir for Hep C	SA1	24/04/2017	29
16/NE/0415/AM05	Phase 2a Study of AL-335, Odalasvir, with/without Simeprevir for Hep C	Substantial Amendment 2 - 14/6/17	14/06/2017	30
16/NE/0419/AM02	SCLC trial with nivolumab and ipilimumab in limited disease (STIMULI)	SA02	15/12/2017	30
17/NE/0014/AM02	limited exposure UVB for vitamin D deficiency	Substantial Amendment 2 - 02/08/17	02/08/2017	20
17/NE/0020/AM02	belimumab and rituximab in subjects with primary Sjögren's syndrome	Substantial Amendment 1	15/02/2018	19
17/NE/0051/AM05	ActiveCHILD Physical activity in under5s	Substantial Amendment 2	15/11/2017	21
17/NE/0078/AM03	Phase 2 Efficacy & Safety Study of Elafibranor in patients with PBC	Substantial Amendment 3, 04/12/2017	21/02/2018	13
17/NE/0082/AM02	M15-925 ABT-494 vs Abatacept Amendment 2.0	Substantial Amendment 2 - 28/03/17	28/03/2017	13
17/NE/0082/AM03	M15-925 ABT-494 vs Abatacept Amendment 2.0	Substantial Amendment 3 - 10/8/17	10/08/2017	21
17/NE/0082/AM04	M15-925 ABT-494 vs Abatacept Amendment 2.0	SA04	23/11/2017	25
17/NE/0088/AM02	(duplicate) Non-interventional, PASS for patients prescribed JINARC fo	Substantial Amendment 1 - 14/7/17	14/07/2017	25
17/NE/0117/AM05	Phase 2b Dose Finding Study in Adult Patients Osteogenesis Imperfecta	Substantial Amendment 2 - 20/07/17	20/07/2017	25
17/NE/0117/AM06	Phase 2b Dose Finding Study in Adult Patients Osteogenesis Imperfecta	Substantial Amendment 3,	14/02/2018	34

17/NE/0118/AM01	SUGAR-DM-HF	18/01/2018 Substantial amendment 1, 21/11/2017	11/12/2017	27
17/NE/0149/AM01	ROVA-T Maintenance in SCLC (MERU)	Substantial Amendment 1 - Protocol Amend 3 - 9/5/17	09/05/2017	34
17/NE/0149/AM03	ROVA-T Maintenance in SCLC (MERU)	SA2	28/09/2017	15
17/NE/0159/AM02	POLARIS Retreatment	SA01	22/11/2017	8
17/NE/0200/AM03	SMART Registry_Boston Scientific_(0393-0026)	Substantial Amendment 1, 14/02/2018	14/02/2018	20
17/NE/0239/AM03	NAIROS	Substantial Amendment 1, 20/11/2017	02/12/2017	32
17/NE/0294/AM01	Value of CEUS as a surrogate for CTA for EVAR surveillance (Ver 1.1)	Substantial Amendment 1, 07/09/2017	12/12/2017	28
17/NE/0297/AM01	Developing an intervention for Falls in Dementia WP4	Substantial Amendment 1, 07/02/2018	15/02/2018	7
17/NE/0300/AM01	UM203	Substantial Amendment 1, 15/01/2018	23/01/2018	31

### Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
16/NE/0175/AM06	A Study of Gilteritinib in Acute Myeloid Leukaemia with FLT3 Mutation	SA06	24/11/2017	27

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

<b>Favourable opinion timeline</b>				
<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>
15/NE/0324/AM12/2	Simvastatin as a neuroprotective treatment for moderate PD (PD STAT)	MA07	28/03/2017	13
16/NE/0175/AM06/1	A Study of Gilteritinib in Acute Myeloid Leukaemia with FLT3 Mutation	Modified Substantial amendment	12/02/2018	8

<b>Unfavourable opinion timeline</b>				
<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>

**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
18/NE/0088	An exploration of self management physiotherapy programmes (SMPP)	27

**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
13/NE/0011/AM16	BMS-936558 versus investigator's choice in advanced melanoma	Substantial Amendment 14 - 17/3/17	17/03/2017	37

**Modified Amendments over 14 day timeline**

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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