

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

**Annual Report**

**01 April 2016 - 31 March 2017**



## 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>	Mr Richard Tomlin
<b>Alternate Vice-Chair:</b>	None
<b>REC Manager:</b>	Mrs Hayley Henderson
<b>REC Assistant:</b>	Miss Kerry Dunbar
<b>Committee Address:</b>	Jarrow Business Centre Rolling Mill Road Jarrow NE32 3DT
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## 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.*

*The report is broadly accurate with the exception of the number of applications processed; from my own records of:*

- o copies of the final minutes for Full Meetings held, and*
- o copies of the final minutes for PRSC's (which I Chaired)*

*Those records show a total of 48 applications at Full Meetings (not 47) and 23 for PRSC (not 19). Even a PRSC number of 23 must be an underestimate though (let alone 19). There must have been more than 23 as I didn't Chair all the PRSC's in the period, so there must be PRSC's applications processed at PRSC meeting which I didn't Chair which are also not recorded in this report.*

*We have continued to enjoy exemplary administrative support (from 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, but, new members have joined and they have integrated into the committee well. We are currently seeking an Alternate Vice Chair and Vice Chair, for the Committee.*

## 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	
Mrs Jane Curry	Head of Cardiac and Respiratory Services	Expert	01/10/2013	14/12/2016
Dr Alasdair MacSween	Principal Lecturer in Research Governance	Expert	01/04/2013	
Mr Ben Morrison	Assistant Psychologist	Lay	07/09/2016	
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	21/07/2016 transferred to TWS
Ms Emma Thompson	Research Radiographer	Expert	10/04/2015	
Dr Jared Thornton	Clinical Trials Co-ordinator	Lay	12/07/2011	09/12/2016
Mr Richard Tomlin	Consultant in Research Management (Retired)	Lay Plus	01/05/2015	
Dr Elizabeth Walsh-Heggie	General Practitioner	Expert	14/07/2016	
Mrs Susan Webster	Head Of Psychology	Lay	29/03/2017	
Dr Sumeet Gupta	Consultant Psychiatrist	Expert	09/07/2014	14/06/2016

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

Name	Profession	Status	Meeting date attended
Dr Rhona Bratt	Retired Multimedia Project Manager	Lay plus	Feb 2017, March 2017
Mr Chris Barron	ECMC & CTU Manager	Expert	April 2016, Feb 2016
Mrs Joan Bedlington	Governor of LIVER North Charity	Lay Plus	February 2017
Mr Ian Cawthorne	Pharmacist	Expert	April 2016
Mr Martin Edmunds	Editor	Lay Plus	July 2016
Dr Etta Evans	Senior Psychology Lecturer	Lay	Feb 2017, Aug 2016 (PR)
Mrs Louise Jones	Faculty Research Administrator	Lay Plus	November 2016
Dr Anthony Lockett	Chief Medical Officer	Expert	December 2016
Mrs Gaynor Mitchell	Part-time Biology Lecturer (Retired)	Lay Plus	Feb, 2016, April 2016, May 2016
Dr Robert Phillips	Senior Clinical Academic	Expert	December 2016
Mr Paddy Stevenson	Research Operations Manager	Expert	April 2016, August 2016 (PR)
Dr Deborah Jane Fox	Senior Lecturer in Nursing	Expert	July 2016 (PR)

**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	01/03/2017
Mr Andrew Brenikov	None	01/03/2017
Dr Alasdair MacSween	NONE	01/03/2017
Mr Ben Morrison	None	08/09/2016
Mrs Susan P Phillips	None	01/03/2017
Dr Meiyi Pu	None	01/03/2017
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.	01/03/2017
Ms Emma Thompson	None	01/03/2017
Mr Richard Tomlin	My son is employed as a technician by biocompatibles ltd (a BTG company). Trustee & VC of carers Northumberland. Members of NIHR mental health priorities panel; NIHR fellowship award panel; and NTW RCF panel. Can offer advise in technology transfer and itellectual property. Management of multi-national and other complex projects including analysis of consortium agreements and related contractual matters.	01/03/2017
Dr Elizabeth Walsh-Heggie	None	05/08/2016

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

Month	Date	Number of Members Present at Meeting
April	20/04/2016	8
May	18/05/2016	8
July	20/07/2016	9
September	21/09/2016	10
October	19/10/2016	8
November	16/11/2016	9
December	14/12/2016	8
January	18/01/2017	9
February	15/02/2017	11
March	15/03/2017	8

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
May	03/05/2016	3
July	05/07/2016	4
August	02/08/2016	3
August	31/08/2016	3
October	04/10/2016	3
November	30/11/2016	3
February	03/02/2017	3
March	14/03/2017	3

8 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	08/04/2016	2
April	22/04/2016	2
May	06/05/2016	2
May	20/05/2016	2
June	03/06/2016	2
June	17/06/2016	2
July	01/07/2016	2
July	04/07/2016	2
July	15/07/2016	2
August	12/08/2016	2
August	26/08/2016	3
September	09/09/2016	2
September	23/09/2016	2

October	07/10/2016	2
October	21/10/2016	2
November	07/11/2016	2
November	15/11/2016	4
November	17/11/2016	5
November	18/11/2016	2
December	01/12/2016	2
December	16/12/2016	2
December	21/12/2016	2
January	13/01/2017	4
January	30/01/2017	2
February	08/02/2017	2
February	20/02/2017	2
March	10/03/2017	2
March	24/03/2017	3
March	29/03/2017	4
March	31/03/2017	2

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

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

0

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

Name	Number of Meetings Attended
Mrs Ann Boardman	8
Mr Andrew Brenikov	10
Mrs Jane Curry	6
Dr Alasdair MacSween	9
Mr Ben Morrison	7
Mrs Susan P Phillips	7
Dr Meiyi Pu	6
Ms Vicky Ryan	7
Ms Emma Thompson	10
Mr Richard Tomlin	7
Dr Elizabeth Walsh-Heggie	3

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

Name	Number of Meetings Attended
Mrs Ann Boardman	1
Mr Andrew Brenikov	3
Mrs Jane Curry	1
Dr Alasdair MacSween	4
Mr Ben Morrison	1
Mrs Susan P Phillips	4
Dr Meiyi Pu	1
Ms Emma Thompson	2
Mr Richard Tomlin	5

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

Name	Number of Meetings Attended
Mrs Ann Boardman	5
Mr Andrew Brenikov	4
Mrs Jane Curry	3
Dr Sumeet Gupta	1
Dr Alasdair MacSween	10
Mr Ben Morrison	3
Mrs Susan P Phillips	9
Dr Meiyi Pu	3
Ms Vicky Ryan	6
Ms Emma Thompson	2



Mr Richard Tomlin	15
Dr Elizabeth Walsh Heggie	1

**Training 01 April 2016 - 31 March 2017**

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Mrs Ann Boardman	06/07/2016	Ageing Research in Critical Care Ethics of trials designed to reduce clinical uncertainty WHEAT REC study
Mrs Ann Boardman	20/10/2016	Quantitative Research Methods and Statistics: A Health Research Authority Workshop
Mrs Jane Curry	20/05/2016	Research & Innovation
Dr Alasdair MacSween	04/05/2016	RES regional training
Dr Alasdair MacSween	09/11/2016	The Practicalities of Running a REC - a workshop for Chairs and REC Managers (formerly 'Nuts and Bolts')
Dr Alasdair MacSween	01/12/2016	Training - National Training Day for Committee Chairs
Dr Alasdair MacSween	22/03/2017	National Members Training Day
Mr Ben Morrison	08/09/2016	Committee members induction
Mr Ben Morrison	15/03/2017	Adults lacking capacity
Mrs Susan P Phillips	24/05/2016	Training - Introduction to Phase 1 Research - Trials & Regulation
Mrs Susan P Phillips	20/10/2016	Quantitative Research Methods and Statistics: A Health Research Authority Workshop
Mrs Susan P Phillips	16/02/2017	National Members Training Day
Dr Meiyi Pu	11/04/2016	Ethics & GCP Forum ICR.
Dr Meiyi Pu	11/05/2016	Training - Assessing the Consequences (benefits and harms) of Research: a Health Research Authority workshop
Dr Meiyi Pu	20/10/2016	Quantitative Research Methods and Statistics: A Health Research Authority Workshop
Dr Meiyi Pu	10/11/2016	Researcher Training Day
Dr Meiyi Pu	22/03/2017	National Members Training Day
Ms Vicky Ryan	09/06/2016	Good Clinical Practice (GCP) Refresher
Miss Hannah Stevenson	09/09/2016	Training - Researcher Training Day
Mr Richard Tomlin	11/05/2016	- Assessing the Consequences (benefits and harms) of Research: a Health Research Authority workshop
Mr Richard Tomlin	09/11/2016	Training for New REC Chairs
Mr Richard Tomlin	01/12/2016	National Training Day for Committee Chairs
Mr Richard Tomlin	16/02/2017	National Members Training Day
Dr Elizabeth Walsh-Heggie	15/08/2016	Online induction module
Dr Elizabeth Walsh-Heggie	17/02/2017	Equality & Diversity

Dr Elizabeth Walsh-Heggie	14/03/2017	Committee Members Induction
Mr Andrew Brenikov	26/02/2017	SDL for period 2016-17 Private reading of HRA Literature, mentoring a fellow member & Studied HRA workshop notes.

## 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	13	27.66
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	34	72.34
<b>Total Applications Reviewed</b>	<b>47</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	1
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	14
Number of paediatric applications reviewed	8
Number of device applications reviewed	6
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	1	2.13
Favourable Opinion with Additional Conditions	8	17.02
Unfavourable Opinion	3	6.38
Provisional Opinion	35	74.47
Provisional Opinion Pending Consultation with Referee	0	0.00
<b>Total</b>	<b>47</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	27	57.45
Further Information Favourable Opinion with Additional Conditions	2	4.26
Further Information Unfavourable Opinion	1	2.13
Favourable Opinion with Standard Conditions	1	2.13
Favourable Opinion with Additional Conditions	8	17.02
Unfavourable Opinion	3	6.38
Provisional Opinion	5	10.64
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
<b>Total</b>	<b>47</b>	<b>100</b>

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

<b>Total Applications Reviewed</b>	<b>19</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	4
Number of device applications reviewed	0
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	9	47.37
Favourable Opinion with Additional Conditions	3	15.79
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	7	36.84
Unfavourable Opinion	0	0.00
<b>Total</b>	<b>19</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>	4.70
<b>Number of completed applications for full ethical review</b>	47
<b>Number of completed applications for full ethical review over 60 days</b>	1
<b>Number of completed applications over 60 days as a % of total</b>	2.13%
<b>Number of completed applications for full ethical review over 40 days</b>	10
<b>Number of completed applications over 40 days as a % of total</b>	21.28%
<b>Number of days taken to final decision – average (mean)</b>	33
<b>Number of completed proportionate review applications for ethical review</b>	19
<b>Number of completed proportionate review applications for ethical review over 21 days (PILOT)</b>	0
<b>Number of completed proportionate review applications over 21 days as a % of total</b>	0.00%
<b>Number of SSAs (non-Phase 1) reviewed</b>	1
<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>	114
<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>	0.88%
<b>Number of completed substantial amendments over 28 days</b>	12
<b>Number of completed substantial amendments over 28 days as a % of total substantial amendments</b>	10.53%
<b>Number of modified amendments reviewed</b>	2
<b>Number of completed modified amendments over 14 days</b>	1
<b>Number of completed modified amendments over 14 days as a % of total modified amendments</b>	50.00%
<b>Number of non substantial amendments received</b>	111
<b>Number of substantial amendments received for information</b>	1
<b>Number of substantial amendments received for new sites/Pis</b>	17
<b>Number of annual progress reports received</b>	79

<b>Number of safety reports received</b>	23
<b>Number of Serious Adverse Events received</b>	2
<b>Number of final reports received</b>	56



**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>
16/NE/0138	177Lu-OPS201 phase I/II study for the therapy of NETs, version 4	25
16/NE/0140	EMT2: EPA for Metastasis Trial 2	30
16/NE/0165	Patient's experiences of melanoma	23
16/NE/0169	Phase II/III of MOR00208 with BEN versus Ritux with BEN in R/R DLBCL	21
16/NE/0175	A Study of Gilteritinib in Acute Myeloid Leukaemia with FLT3 Mutation	30
16/NE/0220	Interpersonal art psychotherapy for the treatment of aggression	40
16/NE/0228	BOX Ankle Study	26
16/NE/0240	Advanced Renal Cell Carcinoma (aRCC) Study in the US, Europe	27
16/NE/0312	GWEP1521 - Study of GWP42003-P in Tuberous Sclerosis Complex	30
16/NE/0318	A 2 year clinical follow up of the Single Visit Crown	34
16/NE/0327	Community pHarmacIEs Mood Intervention STudy (CHEMIST)	34
16/NE/0336	Detecting Dementia Earlier using Spatial & Episodic Memory tests.	32
16/NE/0355	Understanding Child-to-Parent Aggression from the Parent's Perspective	33
16/NE/0377	Investigating patterns of influenza evolution in immunosuppression	22
16/NE/0382	COMRADE Exercise and CRPC	41
16/NE/0383	Modelling early onset and congenital retinal disease using iPSC v1.0	55
16/NE/0385	Life after sexual assault: women's experiences of inner resources	24
16/NE/0400	Knee Replacement Bandaging Study (KReBS)	49
16/NE/0405	Vasopressin in Acute Myocardial Infarction	32
16/NE/0413	Efficacy and Safety of Givinostat in Duchenne Muscular Dystrophy	48
16/NE/0415	Phase 2a Study of AL-335, Odalasvir, with/without Simeprevir for Hep C	37
16/NE/0419	SCLC trial with nivolumab and ipilimumab in limited disease (STIMULI)	36
17/NE/0015	MAGMA study	51
17/NE/0020	belimumab and rituximab in subjects with primary Sjögren's syndrome	56
17/NE/0050	Narrative analysis in learning disability	28
17/NE/0051	ActiveCHILD Physical activity in under5s	31
17/NE/0082	M15-925 ABT-494 vs Abatacept Amendment 2.0	47

<b>Further Information Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
16/NE/0170	UX007-CL202	23
16/NE/0317	Tasimelteon in blind children with non-24hrs sleep-wake disorder	34

<b>Further Information Unfavourable Opinion</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
17/NE/0054	Behaviour and Expression of Pain in Autism Spectrum Disorders	36

<b>Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
16/NE/0330	Eggcell trial	26

<b>Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
16/NE/0129	Subglottic cell line	28
16/NE/0137	Decision making in the management of polyp cancers. (V6)	22
16/NE/0168	Infrared imaging in septic illness - v0.1	20
16/NE/0238	The BHF SENIOR-RITA TRIAL	26
16/NE/0319	Understanding the pathogenesis of vasculitis	27
16/NE/0332	Assessing MMode Echo Time-to-Turbulence to confirm CVC tip position	26
16/NE/0334	Emergency Laparotomy Follow-up Study (ELFUS1): protocol version 1.1	26
16/NE/0409	Effectiveness of a pain management programme	21

<b>Unfavourable Opinion</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
16/NE/0215	Understanding Child-to-Parent Aggression from the Parent's Perspective	26
17/NE/0023	Overnight In-ear EEG sleep studies	24
17/NE/0047	Dual Loop algorithm adjustment study in ventilated preterm infants	27

<b>Provisional Opinion</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
17/NE/0014	limited exposure UVB for vitamin D deficiency	n/a
17/NE/0053	Health Effects of Medical Radiation Exposures v1	n/a
17/NE/0078	Phase 2 Efficacy & Safety Study of Elafibranor in patients with PBC	n/a
17/NE/0088	(duplicate) Non-interventional, PASS for patients prescribed JINARC	n/a
17/NE/0089	microRNAs secreted in embryonic cultures; the quest for new biomarkers	n/a

<b>Provisional Opinion Pending Consultation with Referee</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
<b>None</b>		

<b>Further information response not complete</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
<b>None</b>		

<b>Withdrawn after the meeting</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
<b>None</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>
16/NE/0251	A Study Of The Genetic Factors involved in the Post-Meal Response	13
16/NE/0269	Ward Noise Levels and Sleep Quality	13
16/NE/0270	Metabolomic profiling in unstable atherosclerosis	12
16/NE/0339	Association between sleep & cognition in older adults_v.1	11
16/NE/0340	Internet use and views about online mental health support.	12
16/NE/0402	Infant feeding practices of African mothers living in the UK.	11

<b>Further Information Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
16/NE/0246	4D Assessment of static and dynamic asymmetry following cleft surgery	10

<b>Further Information Unfavourable Opinion</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
<b>None</b>		

<b>Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
16/NE/0157	The microbiota associated with Clear Overlay Retainers: a pilot study.	17
16/NE/0158	Early Phosphate Intervention Qualitative Study (version 1.0)	16
16/NE/0271	EMA post-authorisation safety study of influenza vaccine - Year 2	11
16/NE/0302	Diary study of adherence to antiretroviral therapy	11
16/NE/0338	A prospective examination of sleep and functioning in psoriasis	11
16/NE/0403	PSOREAL; Protocol Code Number NIS-ENSTILAR-1285	12
17/NE/0046	A study to isolate bacteria from spinal disc tissue. Version 1.0	11
17/NE/0075	Pitting in SSC: Pathophysiology and impact on the patient	10
17/NE/0076	Peripheral detection of EGFR status in lung cancer patients	10

<b>Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
16/NE/0243	Alcohol Withdrawal Syndrome Version 1	11
16/NE/0303	161301 HyQvia Preg Registry	9
16/NE/0404	The influence of mental health and state on blood pressure variability	12

<b>Unfavourable Opinion</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>

<b>None</b>		
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<b>Provisional Opinion</b>		
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<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
<b>None</b>		

<b>Further information response not complete</b>		
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<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
<b>None</b>		

<b>Withdrawn after the meeting</b>		
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<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
<b>None</b>		

**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>
06/Q0906/169/AM09	Paediatric CT Scan Study	5	15/08/2016	31
06/Q1001/59/AM05	Cylindromatosis: human tissue characterisation and therapeutics	5	03/03/2016	16
10/H0907/47/AM02	Long-term risks of paediatric fluoroscopic cardiology v1.0	Substantial Amendment 2	16/09/2016	26
10/H0907/51/AM02	Propionibacterium Acnes - A cause for Rotator Cuff Tears?	Substantial Amendment 2 - 1/1/	01/01/2017	18
10/H0907/69/AM07	An Epidemiological ASD Study and Establishing a Research Database v1.0	Substantial Amendment 2 - 24/1	24/11/2016	21
10/H0908/39/AM13	Supporting Enhanced Research in Vulnerable Infants (SERVIS)	12	11/05/2016	21
10/H0908/39/AM16	Supporting Enhanced Research in Vulnerable Infants (SERVIS)	Substantial Amendment 13 - 16/	16/12/2016	21
11/NE/0312/AM09	MelResist Version 1.0	Substantial Amendment 7 - 6/5/	06/05/2016	14
11/NE/0348/AM03	Role of prion protein in neurodegenerative disease	2.0	17/03/2016	23
11/NE/0360/AM08	A natural history study of dysferlinopathy	Substantial Amendment 5, 26/05	09/06/2016	25
11/NE/0374/AM17	BSRBR-AS	Substantial Amendment 10 - 1/2	01/02/2017	5
12/NE/0142/AM07	Open-Label Study for Previously Treated PTC124 patients with nmDBMD V1	5.0	18/11/2015	23
12/NE/0142/AM08	Open-Label Study for Previously Treated PTC124 patients with nmDBMD V1	5	02/08/2016	7
12/NE/0251/AM04	Northeast Early Arthritis Cohort	Substantial Amendment 3 -	21/09/2016	15

		21/9		
12/NE/0361/AM11	aHUS Registry	5	01/08/2016	28
12/NE/0410/AM16	An Efficacy and Safety Trial of MK-8931 in Mild to Moderate AD(EPOCH)	12	09/08/2016	14
13/NE/0011/AM14	BMS-936558 versus investigator's choice in advanced melanoma	12	27/06/2016	11
13/NE/0011/AM15	BMS-936558 versus investigator's choice in advanced melanoma	Substantial Amendment 13 - 20/	20/01/2017	15
13/NE/0026/AM03	Stem cells in Endocrine Surgical Disease	2	09/05/2016	11
13/NE/0106/AM06	ASPIRE	6	01/02/2016	15
13/NE/0252/AM04	Visual hallucinations: an EEG and non-invasive stimulation study	Substantial Amendment 3 - 10/1	10/11/2016	20
13/NE/0264/AM09	Frailty assessment in patients with HCC	Substantial Amendment 2 - 2/6/	02/06/2016	7
13/NE/0265/AM09	Frailty assessment in the elderly with Upper GI cancer	Substantial Amendment 2 - 22/7	22/07/2016	7
13/NE/0326/AM02	MitoCohort	Substantial Amendment 1 - 14/9	14/09/2016	17
13/NE/0339/AM16	Glycerine Trinitrate for Retained Placenta (GOT-IT Trial)	11	27/04/2016	14
13/NE/0361/AM08	OPTIMAL - Optimising Renal outcome in Myeloma renal failure	Substantial Amendment 8 - 11/5	11/05/2016	12
13/NE/0361/AM09	OPTIMAL - Optimising Renal outcome in Myeloma renal failure	Substantial Amendment 9 - 13/1	13/10/2016	18
13/NE/0361/AM11	OPTIMAL - Optimising Renal outcome in Myeloma renal failure	Substantial Amendment 10 - 8/2	08/02/2017	12
14/NE/0009/AM03	Infantile FSHD Study	2	10/03/2016	13
14/NE/0100/AM09	CPP-1X and SULINDAC in patients with FAP	2	14/03/2016	27
14/NE/0100/AM10	CPP-1X and SULINDAC in patients with FAP	Substantial Amendment 3,	09/06/2016	25

		09/06		
14/NE/0103/AM11	CaPP3	Substantial Amendment 4 - 30/1	30/11/2016	12
14/NE/0144/AM02	Reproductive Decision Making in Mitochondrial Patients:	2.0	11/03/2016	20
14/NE/1019/AM10	Phase 2a Study Evaluating ABT-981 in Patients with Knee Osteoarthritis	8	06/04/2016	16
14/NE/1057/AM06	RIOPRED	3	03/03/2016	19
14/NE/1063/AM07	GA28950 PHASE III TRIAL OF ETROLIZUMAB IN MODERATE TO SEVERE ACTIVE UC	6	28/09/2016	14
14/NE/1063/AM08	GA28950 PHASE III TRIAL OF ETROLIZUMAB IN MODERATE TO SEVERE ACTIVE UC	Substantial Amendment 7 - IB10	20/02/2017	23
14/NE/1069/AM01	Piloting a specialised Sickle Cell Pain Management Service; Version 1	Substantial Amendment 1 - 4/11	04/11/2016	28
14/NE/1070/AM04	Ciclosporin to reduce reperfusion injury in primary PCI (CAPRI)	Substantial Amendment 3 - 20/1	20/10/2016	14
14/NE/1119/AM05	Lenvatinib in Children With Refractory or Relapsed Solid Malignancies	Substantial Amendment 4 - 1/11	01/11/2016	28
14/NE/1176/AM02	UK FROST (United Kingdom Frozen Shoulder Trial)	Substantial Amendment 2 - 7/5/	07/05/2016	15
14/NE/1176/AM04	UK FROST (United Kingdom Frozen Shoulder Trial)	Substantial Amendment 3 - 15/1	15/11/2016	27
15/NE/0013/AM03	Radiation versus Observation following surgery for Atypical Meningioma	Substantial Amendment 2 - 6/5/	06/05/2016	21
15/NE/0013/AM04	Radiation versus Observation following surgery for Atypical Meningioma	3	17/06/2016	12
15/NE/0013/AM05	Radiation versus Observation following surgery for Atypical Meningioma	4	13/07/2016	27
15/NE/0023/AM02	Identification of Novel Psychoactive Substances (IONA)	Substantial Amendment 2 - 12/5	12/05/2016	11



15/NE/0023/AM10	Identification of Novel Psychoactive Substances (IONA)	Substantial Amendment 3 - 12/1	12/01/2017	20
15/NE/0061/AM01	TSH Receptor Activatory Mutation (TRAM) study	1	04/08/2016	25
15/NE/0062/AM01	Stress Control Study	Substantial Amendment 1 - 24/1	24/01/2017	22
15/NE/0088/AM04	GX29633 - PROXIMA Study A	Substantial Amendment 4, 13/04	19/04/2016	17
15/NE/0088/AM05	GX29633 - PROXIMA Study A	5	15/08/2016	7
15/NE/0089/AM04	GX29639 - PROXIMA Study B	4	15/08/2016	28
15/NE/0103/AM04	ME Research UK severe ME/CFS	Substantial Amendment 3 - 3/2/	03/02/2017	16
15/NE/0131/AM01	Indocyanine green near-infrared laparoscopy in surgery	Substantial Amendment 1 - 15/8	15/08/2016	22
15/NE/0131/AM02	Indocyanine green near-infrared laparoscopy in surgery	Substantial Amendment 2 - 10/1	10/01/2017	16
15/NE/0143/AM07	GA29144 Phase III ETRO IN MODERATE TO SEVERE ACTIVE CROHNS DISEASE	Substantial Amendment 5 - 27/5	27/05/2016	11
15/NE/0143/AM09	GA29144 Phase III ETRO IN MODERATE TO SEVERE ACTIVE CROHNS DISEASE	Substantial Amendment 7 - Prot	17/02/2017	23
15/NE/0144/AM02	GA29145 – Open label extension & safety monitoring study	2	16/03/2016	33
15/NE/0144/AM03	GA29145 – Open label extension & safety monitoring study	Substantial Amendment 3 - 27/5	27/05/2016	10
15/NE/0159/AM01	NASH-EX-1114	1	05/10/2015	24
15/NE/0159/AM02	NASH-EX-1114	2	01/05/2016	22
15/NE/0210/AM02	20140128 GLAGOV Extension study	Substantial Amendment 1 - 12/5	12/05/2016	12
15/NE/0210/AM03	20140128 GLAGOV Extension study	2	04/07/2016	29
15/NE/0257/AM03	Feasibility of high intensity interval training in people with IPD	Substantial	21/04/2016	10

		Amendment 2, 15/03		
15/NE/0269/AM02	A Long Term Safety Trial of MK-8931 in AD (EPOCH)	2	15/03/2016	19
15/NE/0269/AM04	A Long Term Safety Trial of MK-8931 in AD (EPOCH)	4	11/08/2016	12
15/NE/0270/AM04	D5136C00008 HESTIA2, Phase IIB, Sickle Cell Disease (Ticagrelor)	Substantial Amendment 4 - 3/11	03/11/2016	28
15/NE/0324/AM06	Simvastatin as a neuroprotective treatment for moderate PD (PD STAT)	4.0	23/03/2016	20
15/NE/0324/AM08	Simvastatin as a neuroprotective treatment for moderate PD (PD STAT)	5	21/07/2016	21
15/NE/0350/AM02	PneumRX registry	Substantial Amendment 2 - 15/2	15/02/2017	5
15/NE/0353/AM01	DECIDE	Substantial Amendment 1 - 18/1	18/11/2016	19
15/NE/0406/AM02	Safety and Tolerability of MTL-CEBPA in Advanced Liver Cancer	Substantial Amendment 1, 18/05	18/05/2016	17
15/NE/0406/AM03	Safety and Tolerability of MTL-CEBPA in Advanced Liver Cancer	03	24/08/2016	19
15/NE/0406/AM06	Safety and Tolerability of MTL-CEBPA in Advanced Liver Cancer	Substantial Amendment 4 - 10/2	10/02/2017	26
15/NE/0415/AM01	CHRONOS-4	Substantial Amendment 2 - 23/5	23/05/2016	23
15/NE/0415/AM02	CHRONOS-4	Substantial Amendment 1 - 26/4	26/04/2016	12
15/NE/0415/AM03	CHRONOS-4	3.0	31/08/2016	21
15/NE/0415/AM04	CHRONOS-4	4	27/09/2016	15
15/NE/0415/AM05	CHRONOS-4	Substantial Amendment 5 -	15/02/2017	5
15/NE/0419/AM03	PRE-OP BIRDS - Feasibility Study	1	25/07/2016	7

15/NE/0420/AM01	SUPERB version 1.0	1	31/03/2016	22
15/NE/0420/AM02	SUPERB version 1.0	2	27/05/2016	12
15/NE/0420/AM03	SUPERB version 1.0	Substantial Amendment 3 - 8/11	08/11/2016	8
16/NE/0011/AM05	Developing an Intervention for Fall Related Injury in Dementia	Substantial Amendment 1 - 21/1	21/11/2016	35
16/NE/0011/AM06	Developing an Intervention for Fall Related Injury in Dementia	Substantial Amendment 2 - 28/2	28/02/2017	29
16/NE/0024/AM02	Dexketoprofen Analgesic eVolution wltH tramaDol- DAVID Study	Substantial Amendment 2 - 30/1	30/11/2016	21
16/NE/0050/AM02	Efficacy & Safety of TANEZUMAB in subjects Osteoarthritis of Hip/Knee	Substantial Amendment 2 - 5/5/	05/05/2016	21
16/NE/0050/AM06	Efficacy & Safety of TANEZUMAB in subjects Osteoarthritis of Hip/Knee	4	16/08/2016	7
16/NE/0050/AM07	Efficacy & Safety of TANEZUMAB in subjects Osteoarthritis of Hip/Knee	5	01/09/2016	32
16/NE/0057/AM01	Safety & Efficacy of Tideglusib in Type 1 Myotonic Dystrophy	Substantial Amendment 1 - 10/5	10/05/2016	16
16/NE/0057/AM02	Safety & Efficacy of Tideglusib in Type 1 Myotonic Dystrophy	Substantial Amendment 2 - 10/1	10/01/2017	22
16/NE/0108/AM02	Leeds Observational Cohort Ultrasound Study (LOCUS)	1	08/07/2016	20
16/NE/0108/AM03	Leeds Observational Cohort Ultrasound Study (LOCUS)	Substantial Amendment 2 - 21/1	21/12/2016	26
16/NE/0138/AM01	177Lu-OPS201 phase I/II study for the therapy of NETs, version 4	1	20/06/2016	14
16/NE/0138/AM03	177Lu-OPS201 phase I/II study for the therapy of NETs, version 4	2	29/07/2016	11
16/NE/0138/AM04	177Lu-OPS201 phase I/II study for the therapy of NETs, version 4	Substantial Amendment 3 -	27/10/2016	12

		27/1		
16/NE/0138/AM06	177Lu-OPS201 phase I/II study for the therapy of NETs, version 4	Substantial Amendment 4 - 7/2/	07/02/2017	12
16/NE/0169/AM02	Phase II/III of MOR00208 with BEN versus Ritux with BEN in R/R DLBCL	Substantial Amendment 1 - 21/1	21/11/2016	12
16/NE/0170/AM02	UX007-CL202	2	30/06/2016	3
16/NE/0170/AM04	UX007-CL202	Substantial Amendment 4 - 16/9	16/09/2016	9
16/NE/0170/AM05	UX007-CL202	Substantial Amendment 5 - 13/1	13/12/2016	7
16/NE/0170/AM06	UX007-CL202	Substantial Amendment 6 - 13/1	13/01/2017	23
16/NE/0175/AM01	A Study of Gilteritinib in Acute Myeloid Leukaemia with FLT3 Mutation	1	25/08/2016	32
16/NE/0175/AM03	A Study of Gilteritinib in Acute Myeloid Leukaemia with FLT3 Mutation	Substantial Amendment 3 - 23/2	23/02/2017	21
16/NE/0238/AM01	The BHF SENIOR-RITA TRIAL	1	08/08/2016	1
16/NE/0302/AM02	Diary study of adherence to antiretroviral therapy	Substantial Amendment 1 - 3/1/1	03/01/2017	24
16/NE/0312/AM01	GWEP1521 - Study of GWP42003-P in Tuberous Sclerosis Complex	Substantial Amendment 1 - 2/12	02/12/2016	33
16/NE/0327/AM01	Community pHarmacIes Mood Intervention STudy (CHEMIST)	Substantial Amendment 1 - 6/1/	06/01/2017	30
16/NE/0338/AM01	A prospective examination of sleep and functioning in psoriasis	Substantial Amendment 1 - 2/11	02/11/2016	25

### Unfavourable opinion

<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>
11/NE/0374/AM13	BSRBR-AS	Substantial Amendment 9, 31/03	22/04/2016	16
12/NE/0139/AM04	Support at home for infants with feeding tubes (SHIFT)	Substantial Amendment 2 - 14/7	14/07/2016	29
15/NE/0324/AM12	Simvastatin as a neuroprotective treatment for moderate PD (PD STAT)	Substantial Amendment 7 - 9/2/	09/02/2017	22
16/NE/0175/AM02	A Study of Gilteritinib in Acute Myeloid Leukaemia with FLT3 Mutation	Substantial Amendment 2	03/10/2016	30

**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>
11/NE/0374/AM13/1	BSRBR-AS	Modified Amendment 1	11/08/2016	16
15/NE/0324/AM12/1	Simvastatin as a neuroprotective treatment for moderate PD (PD STAT)	Modified Amendment 1 - Sub Ame	28/03/2017	3

<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>
<b>None</b>				

**Table 11: Items exceeding timelines****Full applications for ethical review over 60 day timeline**

REC Reference	Title	Number of Days on Clock
17/NE/0014	limited exposure UVB for vitamin D deficiency	69

**Proportionate review applications for ethical review over 21 day timeline**

REC Reference	Title	Number of Days on Clock
None		

**SSAs (non Phase 1) over 25 day timeline**

REC Reference	Title	Number of Days on Clock
None		

**SSAs (Phase 1) over 14 day timeline**

REC Reference	Title	Number of Days on Clock
None		

**Substantial Amendments over 35 day timeline**

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
16/NE/0405/AM01	Vasopressin in Acute Myocardial Infarction	Substantial Amendment 1 - 23/2	23/02/2017	60

**Modified Amendments over 14 day timeline**

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
11/NE/0374/AM13/1	BSRBR-AS	Modified Amendment 1	11/08/2016	16