

**North East - Newcastle & North Tyneside 1  
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 1 Research Ethics Committee
<b>Type of REC:</b>	Recognised, Type 3
<b>Type of Flag:</b>	Adults Lacking Capacity, Phase 1 in Patients, Research in Children, Research Tissue Banks, Research Databases,
<b>Chair:</b>	Professor Philip Preshaw
<b>Vice-Chair:</b>	Dr Mike Bone
<b>Alternate Vice-Chair:</b>	Dr Etta Evans
<b>REC Manager:</b>	Ms Gillian Mayer
<b>REC Assistant:</b>	Donna Bennett (until 30.9.16) Sarah Prothero ( 1.10.16 – 2.1.17) Rheanneon Fuller/Kirstie Penman (from 3.1.17 to date)
<b>Committee Address:</b>	Jarrow Business Centre Room 001 Rolling Mill Road Jarrow NE32 3DT
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## Chair's overview of the past year:

I would like to thank the Committee members for continued excellent work over the last year. This has been in the face of a challenging environment, both in terms of the difficulties for busy people in getting time to be able to work on the Committee, as well as a large number of meetings that require their involvement (including full meetings, PR meetings and subcommittee meetings). It is testament to their hard work as well as the support of the REC Manager and REC assistants that we have achieved, almost completely, to adhere to the timelines required of us for review of applications. The introduction of HRA review has also complicated the process, with sometimes conflicting information and requirements from the HRA assessment process, as compared to the REC review. This has been raised at a national level, and we continue to escalate these issues to senior HRA management. It is hoped that the situation will improve over the next 12 months. Committee members have also been very diligent in undertaking relevant training and development in relation to their role on the Committee – again, this is much appreciated. We continue to experience difficulties (as do other Committees) with a lack of certain expert Committee members, particularly pharmacists, and are grateful to pharmacist members of other Committees who continue to review our applications and provide advice. Two experienced Committee members have left in this reporting period, but we have also welcomed new members to the Committee, and look forward to working with them in the future. We continue to rely on the excellent support of our REC Manager (Gillian Mayer), and the REC assistants in the REC office (Donna Bennett, Sarah Prothero, Kirstie Penman, Rheanneon Fuller) and I would like to thank them all for their outstanding and very efficient work.

## North East - Newcastle & North Tyneside 1 Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Dr Liz Baker	Clinical Research Scientist	Expert	01/04/2013	
Mrs Joan Bedlington	Governor of LIVER North Charity	Lay Plus	01/04/2013	
Dr Mike Bone	Consultant Physician	Expert	01/07/2006	
Miss Angela Brecknell	Finance Officer	Lay Plus	03/10/2016	31/01/2017
Dr Thomas J Chadwick	Clinical Trials Statistician	Expert	01/10/2009	
Dr David Ekers	Senior Clinical Lecturer	Expert	01/09/2015	
Dr Etta Evans	Senior Psychology Lecturer	Lay	01/03/2008	
Reverend Nigel Goodfellow	Head of Chaplaincy	Lay Plus	04/06/2014	
Dr Annette Hames	Consultant Clinical Psychologist (Retired)	Lay	14/09/2011	
Mr Robert Hanson	Student/Mentor	Lay	01/06/2016	
Ms Heather McGrath	School Research Administrator	Lay Plus	01/12/2012	
Miss Jessica Pearce	Student	Lay Plus	07/09/2016	
Mrs Julie Potts	Cross-Specialty Research Nurse	Expert	22/09/2014	30/01/2017
Professor Philip Preshaw	Professor of Periodontology & Consultant in Restorative Dentistry	Expert	01/09/2013	
Mrs Agnieszka Skotnicka	Pharmacist	Expert	01/08/2013	31/01/2017
Mr Tom Wooldridge	Learning & Development Manager	Lay	01/09/2013	
Mr Mike Wyatt	Consultant Vascular Surgeon	Expert	01/08/2014	

## North East - Newcastle & North Tyneside 1 Research Ethics Committee: Deputy Members

Name	Profession	Status	Meeting date attended
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N/A

## North East - Newcastle & North Tyneside 1 Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended
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N/A

**North East - Newcastle & North Tyneside 1 Research Ethics Committee: Members' Declarations of Interest:**

<b>Name</b>	<b>Declaration of Interest</b>	<b>Date</b>
Dr Liz Baker	Trust R&D Committee Member - North Tees & Hartlepool NHS Foundation Trust.	10/01/2017
Mrs Joan Bedlington	Connection with charity or voluntary body: Governor LIVERNORTH. Other activities: PPI NIHR HPRU Liver Theme Steering Committee; PPI Leeds DEC; PPI Elucidate Trial Steering Committee; PPI RITPBC Steering Committee; NIHR EME PPI Reviewer; NETSCC PPI Reviewer.	31/01/2017
Dr Mike Bone	Board of Advisors Research Integrity Office UK. Other interests: Visiting Professor, Dept of Pharmacy, University of Lyon (Claude Bernard)	31/03/2017
Dr Thomas J Chadwick	Employment by Newcastle University/Occasional Peer Reviewer for some NIHR funding streams and medical research journals. Independent/external member of DMEC for one ongoing clinical trial (Goal-oriented cognitive rehabilitation in early stage Alzheimer's disease: multicentre, single, blind, randomised controlled trial (GREAT), Bangor University. Independent/external member of TSC for ongoing clinical trial (Optimizing Pelvic Floor Muscle Exercises to Achieve Long term benefits (OPAL), Glasgow Caledonia University).	10/03/2017
Dr David Ekers	Member of Tees, Esk & Wear Valley NHS Foundation Trust Research Governance Group/Chair Durham University School for Medicine Pharmacy & Health Research Ethics Sub-Committee/Reviewer for NIHR.	10/03/2017
Dr Etta Evans	No interests declared.	31/01/2017
Reverend Nigel Goodfellow	Governor of LIVERNORTH. Member of Newcastle Upon Tyne Hospitals NHS Foundation Trust.	10/01/2017
Dr Annette Hames	Trustee - Jesmond Community Leisure.	10/01/2017
Mr Robert Hanson	No interests declared.	09/08/2016
Ms Heather McGrath	School research administrator - University of Newcastle.	10/01/2017
Miss Jessica Pearce	University of Sheffield Student	15/11/2016
Professor Philip Preshaw	Grant reviewer for NIHR (National Institute for Health Research). Editorial board member for DRWF (Diabetes Research & Wellness Foundation).	10/01/2017
Mr Tom Wooldridge	No interests declared.	12/02/2017
Mr Mike Wyatt	No interests declared.	24/03/2017

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

Month	Date	Number of Members Present at Meeting
April	12/04/2016	8
May	10/05/2016	12
June *	14/06/2016	7
June *	17/06/2016	7
August	09/08/2016	10
September	13/09/2016	10
October	11/10/2016	8
November	08/11/2016	9
December	13/12/2016	8
January	10/01/2017	8
March	14/03/2017	10

10 full committee meetings were held during the reporting period.

\* 2 REC meetings recorded but counted as 1 meeting (14/06/2016 was inquorate, followed by Teleconference meeting 17/06/2017).

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

Month	Date	Number of Members Present at Meeting
April	26/04/2016	3
May	23/05/2016	3
June	28/06/2016	3
August	23/08/2016	3
September	26/09/2016	3
October	24/10/2016	3
November	22/11/2016	2
December	08/12/2016	3
February	27/02/2017	3
March	27/03/2017	4

10 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	07/04/2016	2
April	21/04/2016	2
May	03/05/2016	2
May	16/05/2016	3
May	31/05/2016	2
June	13/06/2016	2
June	27/06/2016	2
July	12/07/2016	2
July	14/07/2016	10

August	04/08/2016	2
August	08/08/2016	2
August	22/08/2016	2
September	06/09/2016	2
September	19/09/2016	2
October	06/10/2016	2
October	17/10/2016	2
October	17/10/2016	2
October	31/10/2016	2
November	14/11/2016	2
November	28/11/2016	2
December	05/12/2016	2
December	12/12/2016	2
December	21/12/2016	2
December	21/12/2016	2
January	06/01/2017	2
January	23/01/2017	2
January	27/01/2017	2
February	06/02/2017	2
February	20/02/2017	2
March	02/03/2017	2
March	06/03/2017	2
March	20/03/2017	2

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

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

Date	Reason	Action taken
14/06/2016	3 late apologies given. 7 members actually attended, however the only lay plus member who had planned to attend was taken ill on the afternoon of the meeting.	A quorate teleconference was held on 17/06/2017 to agree the decisions.

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Dr Liz Baker	8
Mrs Joan Bedlington	7
Dr Mike Bone	2
Dr Thomas J Chadwick	9
Dr David Ekers	5
Dr Etta Evans	6
Reverend Nigel Goodfellow	8
Dr Annette Hames	8
Mr Robert Hanson	4**
Ms Heather McGrath	6
Miss Jessica Pearce	3**
Mrs Julie Potts	4*
Professor Philip Preshaw	9
Mrs Agnieszka Skotnicka	2*
Mr Tom Wooldridge	7
Mr Mike Wyatt	9

\* Resigned

\*\* New members

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Dr Liz Baker	3
Mrs Joan Bedlington	3
Dr Mike Bone	1
Dr Thomas J Chadwick	1
Dr David Ekers	1
Dr Etta Evans	3
Reverend Nigel Goodfellow	2
Dr Annette Hames	1
Ms Heather McGrath	2
Professor Philip Preshaw	7
Mrs Agnieszka Skotnicka	1
Mr Tom Wooldridge	3
Mr Mike Wyatt	2



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

<b>Name</b>	<b>Number of Meetings Attended</b>
Dr Liz Baker	3
Mrs Joan Bedlington	3
Dr Mike Bone	4
Dr Thomas J Chadwick	5
Dr David Ekers	2
Dr Etta Evans	4
Reverend Nigel Goodfellow	5
Dr Annette Hames	4
Ms Heather McGrath	2
Mrs Julie Potts	2
Professor Philip Preshaw	32
Mrs Agnieszka Skotnicka	2
Mr Tom Wooldridge	2
Mr Mike Wyatt	3

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

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Dr Liz Baker	11/04/2016	Ethics & GP Forum
Dr Liz Baker	06/06/2016	Equality & Diversity On-line Module
Dr Liz Baker	06/07/2016	Regional Members' Training Day
Mrs Joan Bedlington	07/11/2016	Equality & Diversity On-line HRA Module
Dr Thomas J Chadwick	30/09/2016	Equality, Diversity & Human Rights On-line HRA Module
Dr Thomas J Chadwick	31/10/2016	Self-Directed Learning Form
Dr David Ekers	15/04/2016	Equality & Diversity On-line Module
Dr David Ekers	08/06/2016	Induction for New Members (face to face)
Dr Etta Evans	30/10/2016	Equality & Diversity On-line HRA Module
Mr Robert Hanson	06/07/2016	Regional Members' Training Day
Mr Robert Hanson	07/11/2016	Equality & Diversity HRA On-line Training Module
Mr Robert Hanson	17/11/2016	Induction for New Members (On-line Module)
Mr Robert Hanson	06/12/2016	Induction for New Members (Face to Face)
Ms Heather McGrath	22/03/2017	National Members' Training Day
Miss Jessica Pearce	02/11/2016	Induction for New Members' (On-line module)
Miss Jessica Pearce	02/11/2016	Equality & Diversity On-line Module
Miss Jessica Pearce	10/01/2017	Induction for New Members (face to face)
Mrs Julie Potts	06/07/2016	Members' Regional Training Day
Professor Philip Preshaw	01/12/2016	National Chairs' Training Day
Mr Tom Wooldridge	20/10/2016	Quantitative Research Methods and Statistics: A Health Research Authority Workshop
Dr Mike Bone	31/03/2017	Self-Directed Learning Form
Dr Annette Hames	31/03/2017	SDLF

## 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	14	26.42
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	4	7.55
Research Database (including renewals)	3	5.66
Others	32	60.38
<b>Total Applications Reviewed</b>	<b>53</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	1
Number of student applications reviewed	4
Number of paediatric applications reviewed	19
Number of device applications reviewed	4
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	4
Number of applications reviewed that are funded by the US DHHS	0
Number of qualitative applications reviewed	3

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

<b>Decisions taken at meetings following review of applications</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	3	5.66
Favourable Opinion with Additional Conditions	5	9.43
Unfavourable Opinion	3	5.66
Provisional Opinion	42	79.25
Provisional Opinion Pending Consultation with Referee	0	0.00
<b>Total</b>	<b>53</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	40	75.47
Further Information Favourable Opinion with Additional Conditions	1	1.89
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	3	5.66
Favourable Opinion with Additional Conditions	5	9.43
Unfavourable Opinion	3	5.66
Provisional Opinion	1	1.89
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>53</b>	<b>100</b>

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

<b>Total Applications Reviewed</b>	<b>24</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	2
Number of studies withdrawn prior to the meeting	2
Number of student applications reviewed	14
Number of paediatric applications reviewed	2
Number of device applications reviewed	1
Number of qualitative applications reviewed	4

**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	22	91.67
Favourable Opinion with Additional Conditions	2	8.33
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	0	0.00
Unfavourable Opinion	0	0.00
<b>Total</b>	<b>24</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>	5.3
<b>Number of completed applications for full ethical review</b>	53
<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 completed applications for full ethical review over 40 days</b>	0
<b>Number of completed applications over 40 days as a % of total</b>	0.00%
<b>Number of days taken to final decision – average (mean)</b>	29
<b>Number of completed proportionate review applications for ethical review (Pilot)</b>	24
<b>Number of completed proportionate review applications for ethical review over 21 days</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>	6
<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>	104
<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>	0.96%
<b>Number of completed substantial amendments over 28 days</b>	2
<b>Number of completed substantial amendments over 28 days as a % of total substantial amendments</b>	1.92%
<b>Number of modified amendments reviewed</b>	3
<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>	124
<b>Number of substantial amendments received for information</b>	0
<b>Number of substantial amendments received for new sites/PIs</b>	20

<b>Number of annual progress reports received</b>	115
<b>Number of safety reports received</b>	33
<b>Number of Serious Adverse Events received</b>	0
<b>Number of final reports received</b>	28

**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/0106	Skin Selfie - a self-monitoring phone app for dermatology patients	31
16/NE/0111	Patient - Reported Taste Changes in Head and Neck cancer	31
16/NE/0121	SEM200-008 Study	40
16/NE/0154	Treatment of anxiety using a transdiagnostic IU module	31
16/NE/0159	CC-220-MM-001_Phase 1B/2A_Multiple Myeloma_CC-220	31
16/NE/0161	Characterising electrophysiological patterns in neuromuscular disease	28
16/NE/0163	First Trimester Pregnancy Biochemical Marker Performance Evaluation	29
16/NE/0166	Phase 1/2 Study of G100 for Non-Hodgkin's Lymphoma Patients	29
16/NE/0167	Newcastle Uteroplacental Tissue Bank	33
16/NE/0185	Probiotics after Discharge (PAD) study	34
16/NE/0189	Phase 3b extension study using Aceneuramic acid	39
16/NE/0190	COMET	29
16/NE/0191	RVT-101 in subjects with dementia with Lewy bodies (DLB)	40
16/NE/0255	SNT-IV-005 LEROS study	23
16/NE/0259	UX007G-CL202 extension study for Participants with Glut1 DS	26
16/NE/0267	The Newcastle Mitochondrial Research Biobank	37
16/NE/0282	LIFT: Lung magnetic resonance Imaging of Fluorocarbon Tracer gases	25
16/NE/0283	Cognitive weakness in children under 5 with sleep disordered breathing	25
16/NE/0296	Barriers to physical activity and associated falls risk in Parkinson's	39
16/NE/0298	Couples' experiences of managing recurrent pregnancy loss	24
16/NE/0299	Quantitative MRI in children with juvenile idiopathic arthritis	39
16/NE/0307	Acne Research Database: Improved Baseline Assessments in Acne	31
16/NE/0325	ECUSTEC	40
16/NE/0328	Wearable Aurora watch system for syncope assessment : a pilot study	27
16/NE/0356	SEED WS4	40
16/NE/0358	Perinatal Mental Health in Rural North Yorkshire	37
16/NE/0359	PUSKAS V1.0	34
16/NE/0363	IVA_01_337_HNAS_16_002	28
16/NE/0399	RVT-101 extension study in subjects with dementia with Lewy Bodies	32
16/NE/0408	Effect of phototherapy on pruritus in primary biliary cholangitis	27
16/NE/0418	iROC	37
17/NE/0004	A possible new treatment for transplant associated microangiopathy	35



17/NE/0010	Obstructive sleep apnoea and post-operative complications	22
17/NE/0011	Diabetes registry for people aged less than 18 years at diagnosis	28
17/NE/0019	EUS guided pancreatic tissue sampling (SharkBITE Study)	21
17/NE/0022	Newcastle Institute of Transplantation Tissue Biobank	18
17/NE/0058	GARNET	23
17/NE/0060	Transdiagnostic uncertainty in obsessional and psychotic processes	23
17/NE/0061	CONVINCE - Protocol Version 2.1 29th November 2016	22
17/NE/0074	Cortical activity when walking in people with Parkinson's disease	26

#### Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/NE/0420	Injury, inflammatory markers & the exacerbation of confusion: ASCRIBED	34

#### Further Information Unfavourable Opinion

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

REC Reference	Title	Number of Days on Clock
16/NE/0112	ALT GIST (EORTC 1321)	24
16/NE/0155	Comprehensive Patient Records for Cancer Outcomes	24
16/NE/0369	Assessing BD OneFlow (TM) cost effectiveness in leukaemia diagnosis	28

#### Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/NE/0123	SOLID-Supporting Looked After Children in Decreasing Drugs & alcohol	24
16/NE/0164	IV Drug users' experience of DVT	24
16/NE/0230	Improving transplant outcomes by novel organ preservation protocols.	22
16/NE/0297	Establishing DRLs and optimisation strategies in paediatric CT imaging	22
17/NE/0070	CEPA Biobank Newcastle	21

#### Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
16/NE/0197	A2 milk for autism	19
16/NE/0293	Evaluation of the BHX implant in children with a BAHS	21
16/NE/0417	eTRYTON Left main Registry	28

#### Provisional Opinion

REC Reference	Title	Number of Days on Clock
16/NE/0401	Long term outcomes of functional neurological symptoms in children	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
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**Table 9.2: Breakdown of current status of all PRS applications reviewed within the reporting period**

#### Further Information Favourable Opinion with Standard Conditions

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

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

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

REC Reference	Title	Number of Days on Clock
16/NE/0152	False lactate project	19
16/NE/0181	Narrative analysis: Parents whose children may be assessed for ASD	9
16/NE/0184	EAPC Basic Dataset	9
16/NE/0188	Quality of life and adherence in patients with severe asthma	9
16/NE/0236	Can commercial activity monitor be used to prescribe exercise in PR	15
16/NE/0292	PREDICT-GTN v1.0	12
16/NE/0295	Rights-based Rehabilitation	14
16/NE/0331	Informal Carers' Communication with a Deaf Mental Health Service	14
16/NE/0333	Men's experience and use of treatments for ED.	16
16/NE/0335	Th2-low endotype biomarkers in exercise-induced asthma (Version 1.0)	14
16/NE/0366	Blood mononuclear cells in GvHD patients receiving MSC	18
16/NE/0367	Orthodontic Appliance Impact Questionnaire Development	20
16/NE/0368	PACE Neural prosthetic advancement: identification of circuitry	21
16/NE/0392	CORMAC: Core Outcome Research Measures in Anal Cancer phase 2	11
16/NE/0393	Screening and diagnosis in psoriasis and psoriatic arthritis	10
16/NE/0394	Version 1.0- Micronutrient Provision following Bariatric Surgery	15
16/NE/0414	PRO and lupus	15
16/NE/0422	Quality of Life after emergency laparotomy v1	17
17/NE/0063	Fan Therapy in COPD patients	12
17/NE/0066	Psychological flexibility and outcomes in dialysis patients	13
17/NE/0094	Crossover Evaluation of Eye Drops in Symptomatic Lens Wearers (Part 1)	21
17/NE/0098	Paediatric SBS and PS: Utility Study	16

### Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/NE/0151	Self-focus attention and depressive symptoms in ASD	20
16/NE/0235	Synovial Fluid pH and Lactate in Adult Native Septic Arthritis	15

### 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**

<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/Q0905/2/AM20	The Newcastle 85+ Study: Version 1	SA19	20/07/2016	22
08/H0902/9/AM03	Assessment of bladder contractility in men	SA3 (31.5.16)	08/07/2016	26
08/H0902/9/AM04	Assessment of bladder contractility in men	Substantial Amendment 4, 25/08/16	30/11/2016	1
08/H0906/136+5/AM01	Newcastle Brain Tissue Resource	SA1	01/08/2016	7
08/H0906/147/AM29	ICICLE-PD	SA16	25/10/2016	14
08/H0906/147/AM30	ICICLE-PD	Substantial Amendment 17, 21/1/16	22/11/2016	22
08/H0906/28+5/AM03	Newcastle MRC Centre Biobank for Neuromuscular Diseases	Substantial amendment 2, 15/02/16	28/06/2016	19
08/H0906/28+5/AM04	Newcastle MRC Centre Biobank for Neuromuscular Diseases	Substantial Amendment 3, 31/01/17	01/02/2017	7
09/H0906/82/AM08	Gait, cognitive decline and Parkinson's Disease (V1)	Substantial Amendment 4, 03/05/16	10/05/2016	22
09/H0906/82/AM10	Gait, cognitive decline and Parkinson's Disease (V1)	Substantial Amendment 5, 21/11/16	24/11/2016	21
11/NE/0291/AM03	Cellular and Molecular Mechanisms in Chronic Lung Diseases Version 1	Substantial Amendment 3, 15/01/17	16/01/2017	5
12/NE/0004/AM18	A study of OCA in Patients with Primary Biliary Cirrhosis (747-301)	SA2	19/08/2016	11
12/NE/0041/AM08	AF-PROMS	Substantial Amendment 2	24/03/2016	22
12/NE/0041/AM10	AF-PROMS	Substantial	14/06/2016	13

		Amendment 3, 13/06/16		
12/NE/0095/AM12	RITPBC Study	Substantial Amendment 5	06/07/2016	28
12/NE/0314/AM15	NN7999-3774. NNC0156-0009 in paediatric, previously treated subjects.	Substantial Amendment 11	19/12/2016	3
12/NE/0343/AM16	The OPEN Trial: Open urethroplasty versus endoscopic urethrotomy	Substantial Amendment 12, 03/1/16	19/10/2016	11
13/NE/0001/AM19	NN7088-3885 Paediatric PTP Study in Haemophilia A	Substantial amendment 10	23/06/2016	15
13/NE/0001/AM20	NN7088-3885 Paediatric PTP Study in Haemophilia A	SA11	30/01/2017	12
13/NE/0123/AM07	International HIBM Registry	Substantial Amendment 2	12/04/2016	15
14/NE/0005/AM03	MAVRIC: Manubrium-limited ministernotomy versus conventional sternotomy	Substantial Amendment 3.0	16/05/2016	24
14/NE/0007/AM02	Understanding age inequalities and inequities in the cancer pathway	SA1	08/08/2016	11
14/NE/0093/AM03	Study of respiratory physiology during HFNC in preterm neonates	Substantial Amendment 1, 26/04/16	10/06/2016	14
14/NE/0093/AM04	Study of respiratory physiology during HFNC in preterm neonates	Substantial Amendment 3	20/07/2016	28
14/NE/0135/AM01	Imaging lung ventilation by MRI of fluorocarbon gases	Substantial amendment 1, 06/06/16	20/06/2016	8
14/NE/0135/AM03	Imaging lung ventilation by MRI of fluorocarbon gases	SA2	02/03/2017	11
14/NE/1018/AM34	Benralizumab treatment in moderate to very severe COPD (GALATHEA)	SA13	15/02/2017	18
14/NE/1050/AM08	Einstein Junior Phase III: Paediatric oral rivaroxaban (BAY 59-7939)	Substantial Amendment 4	10/05/2016	22
14/NE/1050/AM10	Einstein Junior Phase III: Paediatric oral rivaroxaban (BAY 59-7939)	Substantial Amendment 5, 20/10/16	17/11/2016	20
14/NE/1050/AM11	Einstein Junior Phase III: Paediatric oral rivaroxaban (BAY 59-7939)	Substantial Amendment 6,	14/12/2016	1

		14/12/16		
14/NE/1050/AM12	Einstein Junior Phase III: Paediatric oral rivaroxaban (BAY 59-7939)	SA7	13/02/2017	14
14/NE/1050/AM14	Einstein Junior Phase III: Paediatric oral rivaroxaban (BAY 59-7939)	SA8	28/02/2017	10
14/NE/1073/AM04	Riociguat study in PAH insufficient response to PDE-5i patients (IIIb)	Substantial Amendment 4	08/06/2016	19
14/NE/1073/AM05	Riociguat study in PAH insufficient response to PDE-5i patients (IIIb)	Substantial Amendment 5, 02/08/16	29/07/2016	21
14/NE/1073/AM06	Riociguat study in PAH insufficient response to PDE-5i patients (IIIb)	Substantial amendment 6	07/09/2016	28
14/NE/1082/AM03	Amylase in Localised Infection	Substantial amendment 3	28/06/2016	9
14/NE/1099/AM08	GA29103 - PATIENTS WITH MODERATE TO SEVERE ACTIVE ULCERATIVE COLITIS	Substantial Amendment 6	28/09/2016	23
14/NE/1099/AM09	GA29103 - PATIENTS WITH MODERATE TO SEVERE ACTIVE ULCERATIVE COLITIS	SA7 Prot v5, IB 10, ICF V5.0	22/02/2017	11
14/NE/1100/AM06	GA28951 – Open-label extension & safety monitoring study	Substantial amendment 5	28/09/2016	27
14/NE/1102/AM15	IMPACT Study: Triple dose therapy in COPD patients	SA14	28/07/2016	28
14/NE/1174/AM07	GS-5806 in HCT Recipients with Upper Respiratory Tract Infection	Substantial Amendment 7	02/08/2016	44
14/NE/1174/AM10	GS-5806 in HCT Recipients with Upper Respiratory Tract Infection	Substantial Amendment 8, 14/11/16	14/11/2016	13
14/NE/1174/AM11	GS-5806 in HCT Recipients with Upper Respiratory Tract Infection	Substantial Amendment 9, 03/02/17	03/02/2017	7
14/NE/1175/AM02	Study in Adult Subjects with Primary Immune Thrombocytopenia (ITP)	Substantial amendment 2	06/09/2016	28
14/NE/1180/AM01	GRACE-RRCT	SA1	16/09/2016	18
14/NE/1192/AM03	Genetic and telomere characteristics of high grade soft tissue sarcoma	Substantial Amendment 3 (v1.3)	22/11/2016	10
14/NE/1202/AM03	A Phase III Study of the Effects of Multikine on Cancer of the	Am 4	28/06/2016	23

	Oral Ca			
14/NE/1202/AM05	A Phase III Study of the Effects of Multikine on Cancer of the Oral Ca	SA5	26/09/2016	21
14/NE/1204/AM04	GS-5806 in HCT Recipients with Lower Respiratory Tract Infection	SA04	03/08/2016	28
14/NE/1204/AM05	GS-5806 in HCT Recipients with Lower Respiratory Tract Infection	Substantial Amendment 5, 22/11/16	22/11/2016	7
14/NE/1204/AM06	GS-5806 in HCT Recipients with Lower Respiratory Tract Infection	Substantial Amendment 6, 03/02/17	03/02/2017	7
14/NE/1212/AM01	Newcastle bone and joint biobank	2.1	30/08/2016	19
14/NE/1238/AM05	Novel pulse device for diagnosis of PAD (NOTEPAD)	Substantial Amendment 2, 17/03/16	21/03/2016	22
14/NE/1238/AM06	Novel pulse device for diagnosis of PAD (NOTEPAD)	Substantial amendment 3, 30/06/16	04/07/2016	10
14/NE/1238/AM07	Novel pulse device for diagnosis of PAD (NOTEPAD)	Substantial Amendment 4, 28/10/16	31/10/2016	15
14/NE/1240/AM05	B1371012 Phase 1B/2 study of patients with MDS,AML,MLD OR CMML	Substantial Amendment 5	19/05/2016	8
15/NE/0012/AM04	Heartware MVADÂ® System for advanced heart failure	Substantial Amendment 2, 29/03/16	05/04/2016	22
15/NE/0024/AM06	Newcastle NIHR BioResource	Substantial Amendment 4	17/08/2016	12
15/NE/0034/AM03	MIDAS	Substantial Amendment 2, 08/11/16	17/11/2016	1
15/NE/0036/AM06	Life after prostate cancer diagnosis - Version 1	Substantial Amendment 2, 05/04/16	17/05/2016	9
15/NE/0036/AM07	Life after prostate cancer diagnosis - Version 1	Substantial Amendment 3, 23/08/16	06/09/2016	12



15/NE/0041/AM06	UX007G-CL201 For Participants with Glut 1 DS	Substantial amendment 4	28/06/2016	16
15/NE/0066/AM01	Which factors influence the end of life experience in PD?	Substantial Amendment 1, 13/09/16	13/10/2016	14
15/NE/0067/AM06	TROPICCAL: TROPonin I in Cardiovascular disease in CriticAl care	Substantial Amendment 2, 09/03/16	31/03/2016	15
15/NE/0074/AM01	(duplicate) The SITS Open - Artery by thrombectomy in acute occlusive	Substantial Amendment 1	26/05/2016	20
15/NE/0086/AM06	GX29176 CHROMA Lampalizumab in Geographic Atrophy	Substantial Amendment 4	28/09/2016	28
15/NE/0166/AM05	A Feasibility Study of Bezafibrate in Mitochondrial Myopathy	Substantial amendment 4.0	10/06/2016	17
15/NE/0170/AM03	Tenofovir DF in Adolescent CHB	Substantial Amendment 3	28/07/2016	28
15/NE/0170/AM04	Tenofovir DF in Adolescent CHB	Substantial Amendment 4, 18/11/2016	18/11/2016	19
15/NE/0178/AM01	PhenoDM1	Substantial Amendment 1, April 2016	27/05/2016	17
15/NE/0183/AM07	GNE SA-ER Phase III	Substantial Amendment 3, 25/03/16	04/05/2016	22
15/NE/0195/AM01	The Cognitive Impact of Gabapentinoids in Patients with Fibromyalgia	Substantial Amendment 1.0, 10/3/16	31/03/2016	20
15/NE/0197/AM02	Hypo Unawareness in type 2 diabetes mellitus	Substantial Amendment 2 - 5/6/16	05/06/2016	28
15/NE/0237/AM03	Environmental particles and pneumonia	Substantial Amendment 3, 03/05/16	10/05/2016	27
15/NE/0261/AM01	PACE 'Six steps to Success' Intervention Study	Substantial Amendment 1, 07/04/16	29/04/2016	17

15/NE/0261/AM02	PACE 'Six steps to Success' Intervention Study	Substantial Amendment 2, 26/10/16	22/11/2016	14
15/NE/0317/AM05	BN29854 - Olesoxime in patients with SMA	Substantial Amendment 5	15/08/2016	28
15/NE/0341/AM03	Group self-management after stroke	Substantial Amendment 1, 14/10/16	19/10/2016	26
15/NE/0361/AM01	The Carrot Study	Substantial Amendment 1, 27/04/16	04/05/2016	20
15/NE/0374/AM01	Multi-part, double blind study to assess safety, tolerability and efficacy	Substantial Amendment 1	22/03/2016	22
15/NE/0374/AM02	Multi-part, double blind study to assess safety, tolerability and efficacy	Substantial Amendment 2	13/05/2016	19
15/NE/0374/AM04	Multi-part, double blind study to assess safety, tolerability and efficacy	SA3	23/08/2016	23
15/NE/0374/AM06	Multi-part, double blind study to assess safety, tolerability and efficacy	SA4	20/09/2016	28
15/NE/0374/AM08	Multi-part, double blind study to assess safety, tolerability and efficacy	SA5	07/03/2017	10
15/NE/0397/AM02	Review of existing interventions for fall-related injuries in dementia	Substantial Amendment 2, 30/03/16	22/04/2016	7
15/NE/0397/AM03	Review of existing interventions for fall-related injuries in dementia	Substantial Amendment 3, 01/06/16	07/06/2016	20
15/NE/0403/AM02	VX15-809-110 Cystic Fibrosis	SA2	18/08/2016	19
15/NE/0405/AM01	Physical activity in young people with Cerebral Palsy	Substantial Amendment 1, 06/06/16	08/06/2016	21
16/NE/0014/AM02	AF219-012 12-Week Study in Subjects with Refractory Chronic Cough	Substantial Amendment 2, 21/03/16	30/03/2016	16
16/NE/0084/AM01	MM398 first line in metastatic pancreatic cancer	Substantial amendment 1, 24/03/16	17/06/2016	8

16/NE/0084/AM02	MM398 first line in metastatic pancreatic cancer	SA2	20/02/2017	13
16/NE/0106/AM01	Skin Selfie - a self-monitoring phone app for dermatology patients	Substantial Amendment 1, 24/10/16	25/10/2016	22
16/NE/0106/AM02	Skin Selfie - a self-monitoring phone app for dermatology patients	Substantial Amendment 2, 20/02/17	21/02/2017	27
16/NE/0159/AM01	CC-220-MM-001_Phase 1B/2A_Multiple Myeloma_CC-220	Substantial Amendment 2, 25/08/16	02/09/2016	17
16/NE/0188/AM01	Quality of life and adherence in patients with severe asthma	Substantial amendment 1	26/09/2016	28
16/NE/0190/AM01	COMET	SA1	04/10/2016	24
16/NE/0191/AM02	RVT-101 in subjects with dementia with Lewy bodies (DLB)	Substantial Amendment 3	22/09/2016	29
16/NE/0191/AM05	RVT-101 in subjects with dementia with Lewy bodies (DLB)	SA5	11/10/2016	20
16/NE/0191/AM07	RVT-101 in subjects with dementia with Lewy bodies (DLB)	Substantial Amendment 6, 01/12/16	01/12/2016	12
16/NE/0191/AM10	RVT-101 in subjects with dementia with Lewy bodies (DLB)	SA7	08/02/2017	7
16/NE/0236/AM02	Can commercial activity monitor be used to prescribe exercise in PR	Substantial Amendment 1, 13/12/16	20/12/2016	13
16/NE/0282/AM01	LIFT: Lung magnetic resonance Imaging of Fluorocarbon Tracer gases	SA1	10/02/2017	20
16/NE/0283/AM01	Cognitive weakness in children under 5 with sleep disordered breathing	Substantial Amendment 1, 05/01/17	11/01/2017	10

### Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
15/NE/0317/AM06	BN29854 - Olesoxime in patients with SMA	SA6	04/10/2016	28

**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>
14/NE/1072/AM08/1	GB29260 - Lebrikizumab in patients with uncontrolled asthma.	Modified Amendment 6	18/02/2016	14
15/NE/0317/AM06/2	BN29854 - Olesoxime in patients with SMA	Modified Amendment 6 (2), 16/1	16/12/2016	1

<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>
15/NE/0317/AM06/1	BN29854 - Olesoxime in patients with SMA	Modified Amendment 6, 04/10/16	14/11/2016	14

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

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

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

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
14/NE/1174/AM07	GS-5806 in HCT Recipients with Upper Respiratory Tract Infection	Substantial Amendment 7	02/08/2016	44

**Modified Amendments over 14 day timeline**

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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