

**North East - Newcastle & North Tyneside 1  
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 1 Research Ethics Committee
<b>Type of REC:</b>	Recognised, CTIMPs in Patients, Type III
<b>Type of Flag:</b>	Phase I Studies in Patients Adults Lacking Capacity 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>	Mrs Amanda Carr - August 2017 – present Miss Rheanneon Fuller – January-July 2017
<b>Committee Address:</b>	NHSBT Newcastle Blood Donor Centre Holland Drive Newcastle upon Tyne NE2 4NQ
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## Chair's overview of the past year:

The Newcastle and North Tyneside 1 Research Ethics Committee (NNT1 REC) provides a very high quality service for researchers. The committee functions well, with all members of the committee actively engaged in the process and able to voice their opinions freely. We routinely engage in meaningful and effective discussions about applications and virtually always achieve consensus on our decisions. The committee is well regarded by local researchers who frequently submit their applications to our committee out of preference.

A major challenge for RECs is recruitment and retention of members. A number of individuals have left the committee during 2017-18 for a variety of reasons, but we also have welcomed excellent new members to the committee during this timescale. For all members (lay, non-lay, clinical, non-clinical) the pressures of time seem greater than ever before, with employers seemingly less willing to permit individuals to be absent from their 'day job' to attend committee meetings. Additionally, the workload for REC members seems to increase year on year, with main REC meetings, PR meetings and multiple subcommittees all occurring each month, plus training requirements for members. It is important for HRA to remember that committee members are volunteers and should strive to facilitate everything that is asked of members.

As I write this text, I have announced my resignation from the committee, and this is due to the workload of being a REC chair becoming incompatible with the requirements of my day job. HRA will need to address the issue of recruitment and retention at a national level, and potentially could work with Trusts and Universities and request information from them on how many employees they have who are members of RECs. If the number is low, then it would be important to remind them of the benefits they derive from research that is occurring in their organisations, and that RECs are an essential component of the research process. Potentially, NHS Trusts could be required to ensure that a minimum percentage of their staff members are permitted to be REC members. This requires discussion at a national level, and without this sort of strategic planning, I do envisage significant consequences for the REC service as numbers dwindle.

I would like to thank all members of the NNT1 REC for being such excellent individuals to work with. I also would like to thank the committee manager, Gillian Mayer, who is truly outstanding, performing a very challenging role, and who we all rely on very much. I also thank the REC assistants, Amanda Carr and Sarah Prothero (and Rheanneon Fuller), for their excellent work too.

## 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 LIVErNORTH Charity	Lay Plus	01/04/2013	
Dr Maria Bokhari	Clinical Trials Officer/Co-ordinator.	Lay	11/10/2017	
Dr Mike Bone	Consultant Physician	Expert	01/07/2006	
Dr Thomas J Chadwick	Clinical Trials Statistician	Expert	01/10/2009	
Dr David Ekers	Nurse Consultant/Senior Visiting Research Fellow	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/Tutor	Lay	01/06/2016	31/05/2017
Miss Taniya Hussain	Biomedical Scientist	Expert	18/10/2017	
Ms Heather McGrath	School Research Administrator	Lay Plus	01/12/2012	31/10/2017
Miss Jessica Pearce	Student	Lay Plus	07/09/2016	
Professor Philip Preshaw	Professor of Periodontology & Consultant in Restorative Dentistry	Expert	01/09/2013	
Mr Tom Wooldridge	Learning & Development Manager	Lay	01/09/2013	03/07/2017
Mr Mike Wyatt	Consultant Vascular Surgeon	Expert	01/08/2014	

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

Name	Profession	Status	Meeting date attended
Mr Andrew Brenikov	Historian	Lay Plus	09/07/2017

**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 Trust	11/01/2018
Mrs Joan Bedlington	Connection LIVErNORTH charity. 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.	01/02/2018
Dr Maria Bokhari	Medical Research Council - Involved with sourcing reviewers for research grants.	31/10/2017
Dr Mike Bone	Board of Advisers Integrity Office UK. Visiting Professor Dept of Pharmacy, University of Lyon (Claude Bernard).	09/05/2017
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).	16/03/2018
Dr David Ekers	Member of Tees, Esk & Wear Valley NHS Foundation Trust Research Governance Group. Chair Durham University School for Medicine, Pharmacy and Health Research Ethics Sub-Committee. NIHR Reviewer.	12/03/2018
Dr Etta Evans	Supervisor of graduate students in role as lecturer at Sunderland University	13/02/2018
Reverend Nigel Goodfellow	Trustee of LIVErNORTH - an adult liver patient support group based as the Freeman Hospital. Objects of the charity: The relief of persons suffering from liver disease and those persons caring for sufferers, in particular but not exclusively, by: a) Offering support, advice and information to all those who suffer from liver disease; b) Offering support, advice and information to all formal and informal carers of liver disease sufferers; c) Assisting in the funding of research into the causes of, treatments for, and prevention of all forms of liver disease; d) Assisting with the provision of amenities, equipment and funding for the care of liver patients, their carers and families providing that such provision shall be for the general benefit of a liver patient or liver patients; e) Advancing the public awareness of liver disease, the treatment of liver disease and the prevention of liver disease. Chair of CEPA Biobank Steering Committee, Newcastle upon Tyne Hospitals NHS Foundation	12/01/2018

	Trust.	
Dr Annette Hames	Trustee at Jesmond Community Centre	11/01/2018
Miss Taniya Hussain	No interests declared.	09/11/2017
Miss Jessica Pearce	No interests declared.	10/05/2017
Professor Philip Preshaw	Consultant for Colgate Europe. Paid in this role, but the payment goes to Newcastle University (as employer), and not to member personally. Editorial board member of Diabetes Research and Wellness Foundation. Strategic Clinical Lead for the NIHR North East and North Cumbria Clinical Research Network.	31/01/2018
Mr Mike Wyatt	No interests declared.	14/03/2018

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

Month	Date	Number of Members Present at Meeting
April	11/04/2017	7
May	09/05/2017	13
June	13/06/2017	7
July	11/07/2017	9
August	08/08/2017	8
October	10/10/2017	8
November	14/11/2017	10
December	12/12/2017	9
January	09/01/2018	10
February	13/02/2018	10

10 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	21/04/2017	3
May	16/05/2017	3
June	08/06/2017	3
July	07/07/2017	3
August	04/08/2017	3
October	06/10/2017	3
November	03/11/2017	3
December	01/12/2017	3
January	05/01/2018	3
February	02/02/2018	3
March	02/03/2018	3

11 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	03/04/2017	2
April	18/04/2017	2
April	23/04/2017	2
May	02/05/2017	2
May	15/05/2017	2
May	30/05/2017	2
June	12/06/2017	2
June	27/06/2017	2
July	11/07/2017	2
July	25/07/2017	2

August	09/08/2017	2
August	10/08/2017	2
August	22/08/2017	2
September	07/09/2017	2
September	21/09/2017	2
October	02/10/2017	2
October	03/10/2017	2
October	16/10/2017	2
October	31/10/2017	2
November	13/11/2017	2
November	14/11/2017	3
November	27/11/2017	2
December	01/12/2017	3
December	18/12/2017	2
December	20/12/2017	2
January	08/01/2018	2
January	22/01/2018	2
February	05/02/2018	2
February	06/02/2018	2
February	19/02/2018	2
March	05/03/2018	2
March	05/03/2018	2
March	19/03/2018	2
March	19/03/2018	2
March	27/03/2018	2

35 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>
Dr Liz Baker	10
Mrs Joan Bedlington	5
Dr Maria Bokhari	2
Dr Mike Bone	8
Dr Thomas J Chadwick	9
Dr David Ekers	4
Dr Etta Evans	6
Reverend Nigel Goodfellow	8
Dr Annette Hames	7
Mr Robert Hanson	1
Miss Taniya Hussain	2
Ms Heather McGrath	5
Miss Jessica Pearce	5
Professor Philip Preshaw	9
Mr Tom Wooldridge	1
Mr Mike Wyatt	8

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Dr Liz Baker	2
Mrs Joan Bedlington	3
Dr Mike Bone	4
Dr Thomas J Chadwick	1
Dr David Ekers	2
Dr Etta Evans	2
Reverend Nigel Goodfellow	1
Dr Annette Hames	3
Ms Heather McGrath	2
Miss Jessica Pearce	1
Professor Philip Preshaw	9
Mr Tom Wooldridge	1
Mr Mike Wyatt	2

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Dr Liz Baker	2

Mrs Joan Bedlington	4
Dr Mike Bone	3
Dr Thomas J Chadwick	2
Dr David Ekers	4
Dr Etta Evans	8
Reverend Nigel Goodfellow	7
Dr Annette Hames	4
Ms Heather McGrath	2
Professor Philip Preshaw	32
Mr Mike Wyatt	4

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

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Dr Liz Baker	14/09/2017	Training - Handling Health-Related Findings in Research (Joint MRC/HRA)
Dr Liz Baker	26/09/2017	Assessing the Consequences (benefits and harms) of Research: a Health Research Authority workshop
Mrs Joan Bedlington	14/09/2017	Handling Health-Related Findings in Research
Mrs Joan Bedlington	19/10/2017	Quantitative Research Methods and Statistics: A Health Research Authority Workshop
Mrs Joan Bedlington	29/11/2017	Regional Members' Training Day
Dr Maria Bokhari	31/01/2018	Equality, Diversity & Human Rights
Dr Maria Bokhari	15/02/2018	Induction
Dr Mike Bone	29/11/2017	Regional Members' Training Day
Dr Thomas J Chadwick	29/11/2017	Regional Members' Training Day
Dr David Ekers	29/11/2017	Regional Members' Training Day
Dr Etta Evans	29/11/2017	Regional Members' Training Day
Reverend Nigel Goodfellow	29/11/2017	Regional Members' Training Day
Dr Annette Hames	29/11/2017	Regional Members' Training Day
Ms Heather McGrath	29/08/2017	Medical Devices
Ms Heather McGrath	29/08/2017	Equality, Diversity & Human Rights
Ms Heather McGrath	14/09/2017	Joint Health Related Research Findings
Miss Jessica Pearce	30/03/2018	Self-directed Learning Form - 5 hours worth of reading surrounding ethical issues
Professor Philip Preshaw	29/11/2017	Regional Members' Training Day
Mr Mike Wyatt	30/03/2018	SDLF - Focus group concentrating on the informed consent process

## 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	23	46.94
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	1	2.04
Research Database (including renewals)	1	2.04
Others	24	48.98
<b>Total Applications Reviewed</b>	<b>49</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	8
Number of paediatric applications reviewed	10
Number of device applications reviewed	3
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	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	2.04
Favourable Opinion with Additional Conditions	4	8.16
Unfavourable Opinion	7	14.29
Provisional Opinion	35	71.43
Provisional Opinion Pending Consultation with Referee	2	4.08
<b>Total</b>	<b>49</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	32	65.31
Further Information Favourable Opinion with Additional Conditions	4	8.16
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	1	2.04
Favourable Opinion with Additional Conditions	4	8.16
Unfavourable Opinion	7	14.29
Provisional Opinion	0	0.00
Provisional Opinion Pending Consultation with Referee	0	0.00
Further Information response not complete	1	2.04
No decision entered on system	0	0.00
Number of studies withdrawn after the meeting	0	0.00
<b>Total</b>	<b>49</b>	<b>100</b>

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

<b>Total Applications Reviewed</b>	<b>28</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	0
Number of studies withdrawn prior to the meeting	3
Number of student applications reviewed	12
Number of paediatric applications reviewed	2
Number of device applications reviewed	0
Number of qualitative applications reviewed	10

**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	24	85.71
Favourable Opinion with Additional Conditions	3	10.71
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	1	3.57
Unfavourable Opinion	0	0.00
<b>Total</b>	<b>28</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>	4.90
<b>Number of completed applications for full ethical review</b>	49
<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>	31
<b>Number of completed proportionate review applications for ethical review</b>	27
<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>	2
<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>	118
<b>Number of completed substantial amendments over 35 days</b>	0
<b>Number of completed substantial amendments over 35 days as a % of total substantial amendments</b>	0.00%
<b>Number of modified amendments reviewed</b>	4
<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>	96
<b>Number of substantial amendments received for information</b>	0
<b>Number of substantial amendments received for new sites/PIs</b>	29
<b>Number of annual progress reports received</b>	63
<b>Number of safety reports received</b>	27
<b>Number of Serious Adverse Events received</b>	0
<b>Number of final reports received</b>	22

**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/0092	B5091007 Phase III Study of a Clostridium Difficile Vaccine	22
17/NE/0100	Psychological Flexibility in Pulmonary Rehabilitation engagement	30
17/NE/0106	Values and decision-making in acute medicine	21
17/NE/0113	PIONEER	34
17/NE/0114	The Strengths and Subjective Wellbeing Research Intervention	29
17/NE/0115	MA39189 Trial Of Pirfenidone in Patients with Fibrosing uILD	29
17/NE/0123	MAESTRO Study	30
17/NE/0124	TEMPO Study	30
17/NE/0128	Infant weight: health visitor and parent conversations (1)	22
17/NE/0148	MEN1309-01, CD205-SHUTTLE, Solid Tumours and Non-Hodgkin Lymphoma	27
17/NE/0172	ME Research UK AMPK project	28
17/NE/0176	JEWELFISH	44
17/NE/0197	Hearing voices in psychosis (VIP): How do they change over time?	24
17/NE/0208	Molecular PROfiling in Early Clinical Trials- North East (PROSPECT-NE)	22
17/NE/0234	Phase 2 Study of Pembrolizumab in Participants With R/M cSCC	28
17/NE/0238	A Single-dose Pharmacokinetics Study of MK-7655A in Pediatric Subjects	29
17/NE/0257	HUBBLE	41
17/NE/0258	HUBBLE ZOOM	41
17/NE/0270	Performance Evaluation of ADVIA Centaur Free Beta hCG assay	36
17/NE/0277	Norfolk and Norwich Stroke & TIA Register	31
17/NE/0325	EMPOWER	34
17/NE/0329	REFLECT	36
17/NE/0358	My-CRA, Liquid 13 Cis Retinoic Acid	41
17/NE/0363	A Phase 1 Study of AMG 757 in Participants with Small Cell Lung Cancer	38
17/NE/0377	A Phase 3b Study to Reduce the Incidence of Pre-dialysis Hyperkalaemia	26
17/NE/0386	The BIO-FLARE study version 1.0	37
18/NE/0003	GEN1029 in patients with malignant solid tumours	39
18/NE/0008	PRESTO (Treatment of stable thoracolumbar fractures: feasibility)	35
18/NE/0009	Phenomenology of Visual Hallucinations in Lewy Body Disease	33
18/NE/0021	Rucaparib Hepatic Impairment Study in Patients with a Solid Tumor	38
18/NE/0024	Developing an anxiety scale for autistic adults with ID	30
18/NE/0052	Avacopan in Patients with C3 Glomerulopathy	45



<b>Further Information Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
17/NE/0271	HMB-ICU Reproducibility	26
17/NE/0351	Evaluation of the MCM5 ELISA in the diagnosis of Prostate Cancer	34
18/NE/0063	Alpha Defensin use in Periprosthetic Joint Infection revision surgery	32

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

<b>Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
17/NE/0362	DIAMOND-Lewy Work Package 1 Review (WP1R)	28

<b>Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
17/NE/0203	Adult attachment, sensory processing and persistent pain (v.1)	22
17/NE/0259	A Holistic Model of Rehabilitation to improve QoL in Sarcoma.	27
17/NE/0267	Mobile Autonomy in Children with End-Stage Heart Failure	27
17/NE/0384	Reversing T2 diabetes upon normalisation of energy intake in non-obese	24

<b>Unfavourable Opinion</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
17/NE/0186	Phase 1b/2a study of WVE-120101 in patients with Huntington's Disease	28
17/NE/0187	Phase 1b/2a study of WVE-120102 in patients with Huntington's Disease	28
17/NE/0275	Evaluation of the BHX implant in children with a BAHS	28
17/NE/0330	000278 AWAKEN - Open-label trial of desmopressin ODT	33
17/NE/0387	EULO v01	24
18/NE/0019	To Evaluate the Effect of ALKS3831 vs olanzapine in Young Adults (307)	39
18/NE/0020	Safety, Efficacy & Tolerability of ALKS3831 in Schizophrenia (308)	39

### **Provisional Opinion**

REC Reference	Title	Number of Days on Clock
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#### 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/0380	BGB-290-103 A Phase 1b Study of BGB-290	n/a

#### 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
17/NE/0126	Measuring lip scar in cleft lip/palate patients	20

17/NE/0129	OA ankle_Version 1	21
17/NE/0152	Employment Transitions, Economic Costs, Mental Health and Caregiving	10
17/NE/0155	The functional status of ACLR patients at discharge from rehab.	17
17/NE/0189	Legionnaires' disease risk factor study	14
17/NE/0190	Understanding the decision making process of GPs about Lyme disease	21
17/NE/0237	Method development for measuring oral hypoglycaemic agents in serum.	12
17/NE/0278	Does the hormone cortisol affect fertility?	10
17/NE/0320	Vascular Access and Quality of Life	15
17/NE/0322	Establishing the threshold of material risk. Version 1	21
17/NE/0324	Neuropsychological and emotional correlates of mindfulness traits	20
17/NE/0348	MetRICs to Assess Handover (MICAH)	14
17/NE/0360	What is a good psychiatrist? Professionalism in psychiatry	14
17/NE/0372	MONITOR US WP2	16
17/NE/0376	East Midlands Charcot Incidence Study (EMCIS)	20
17/NE/0378	Psychological Processes and Cough in IPF	17
18/NE/0014	Core Health Outcomes In Childhood Epilepsy (CHOICE)	21
18/NE/0016	HATRIC-Q	21
18/NE/0018	Critical Care PR COS - PPI	21
18/NE/0022	An Exploration of Patients' Perceptions of Self-management of Wounds	21
18/NE/0053	EMHeP: Efficiency, cost and quality of mental healthcare provision	19
18/NE/0054	Does treatment delay affect symptom duration in CDI?	21
18/NE/0057	Isolation, expansion and differentiation of CD34+ progenitor cells	17
18/NE/0087	Patient experience of craniectomy and cranioplasty version 1.0	21

#### Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
17/NE/0188	ESMIA v1.0	21
17/NE/0279	Supported integrated discharge case study	15
18/NE/0086	Liverpool CCG FIT study	15

#### Unfavourable Opinion

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

<b>Further information response not complete</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>

<b>Withdrawn after the meeting</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
18/NE/0056	The impact of FASD on caregivers in Scotland	18

**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/AM21	The Newcastle 85+ Study: Version 1	Amendment 20 - 12/06/2017	04/07/2017	23
08/H0906/21+5/AM02	Human Developmental Biology Resource	SA2	13/03/2017	21
08/H0906/28+5/AM05	Newcastle MRC Centre Biobank for Neuromuscular Diseases	Substantial Amendment 4 – 31/01/17	09/01/2018	27
09/h0906/52+5/AM04	The Manchester Brain Bank	Substantial Amendment 1 - 25 July 2017	25/06/2017	25
10/H0906/58/AM08	Development of an in vitro assay for drug safety and skin sensitivity	Substantial Amendment No. 8 -	17/08/2017	23
10/H0906/58/AM09	Development of an in vitro assay for drug safety and skin sensitivity	Substantial Amendment 9 – October 2017	01/10/2017	11
11/NE/0214/AM15	PARAGON	Substantial Amendment 10 - 13/02/2018	14/02/2018	34
12/NE/0004/AM22	A study of OCA in Patients with Primary Biliary Cirrhosis (747-301)	Substantial Amendment 4, 22/06/17	08/08/2017	18
12/NE/0004/AM24	A study of OCA in Patients with Primary Biliary Cirrhosis (747-301)	Substantial Amendment 5, 6/12/18	09/02/2018	27
12/NE/0314/AM17	NN7999-3774. NNC0156-0009 in paediatric, previously treated subjects.	Substantial Amendment 12 dated 28 Nov 2018	28/11/2017	27
12/NE/0314/AM18	NN7999-3774. NNC0156-0009 in paediatric, previously treated subjects.	Substantial Amendment 13 (Protocol amendment 9)	26/01/2018	14

		01/12/17		
12/NE/0343/AM17	The OPEN Trial: Open urethroplasty versus endoscopic urethrotomy	Substantial Amendment 13, 25/09/17	04/10/2017	12
12/NE/0395/AM07	Newcastle Academic Health Partners Bioresource	SA5	10/05/2017	19
13/NE/0001/AM21	NN7088-3885 Paediatric PTP Study in Haemophilia A	SA12	15/01/2018	17
13/NE/0123/AM08	International HIBM Registry	Substantial Amendment 3, 01/12/17	14/12/2017	27
13/NE/0225/AM09	Pharmacokinetic variation and toxicity in Ewing's sarcoma	Substantial Amendment 8	17/05/2017	8
13/NE/0266/AM05	Global FKRP Registry	SA1	03/04/2017	14
14/NE/0093/AM06	Study of respiratory physiology during HFNC in preterm neonates	SA4	07/03/2017	23
14/NE/0150/AM10	LTS13769 - NeoGAA long-term treatment study	Substantial Amendment 4 - 27/11/18	15/02/2018	22
14/NE/1050/AM18	Einstein Junior Phase III: Paediatric oral rivaroxaban (BAY 59-7939)	SA09 - 20 June 2017	20/06/2017	17
14/NE/1050/AM22	Einstein Junior Phase III: Paediatric oral rivaroxaban (BAY 59-7939)	Substantial Amendment 11 - 27/09/17	03/11/2017	26
14/NE/1100/AM07	GA28951 – Open-label extension & safety monitoring study	SA6	18/04/2017	14
14/NE/1200/AM01	Airway Intervention Registry (AIR)	Substantial Amendment 1, 23/01/18	23/01/2018	11
14/NE/1200/AM02	Airway Intervention Registry (AIR)	Substantial Amendment 2	16/02/2018	28
14/NE/1202/AM06	A Phase III, Open-label, Randomized, Multi-center Study of the Effects of Leukocyte Interleukin, Injection [Multikine] Plus Standard of Care (Surgery + Radiotherapy or Surgery + Concurrent Chemo radiotherapy) in Subjects with Advanced Primary Squamous Cell Carcinoma of the Oral Cavity / Soft Palate Versus Standard of Care Only.	SA6	19/09/2016	20
14/NE/1202/AM07	A Phase III, Open-label, Randomized, Multi-center Study of the Effects of Leukocyte Interleukin, Injection [Multikine] Plus Standard of Care (Surgery + Radiotherapy or Surgery +	Substantial Amendment 7 - 16/10/17	14/11/2017	24

	Concurrent Chemo radiotherapy) in Subjects with Advanced Primary Squamous Cell Carcinoma of the Oral Cavity / Soft Palate Versus Standard of Care Only			
14/NE/1202/AM08	A Phase III, Open-label, Randomized, Multi-center Study of the Effects of Leukocyte Interleukin, Injection [Multikine] Plus Standard of Care (Surgery + Radiotherapy or Surgery + Concurrent Chemo radiotherapy) in Subjects with Advanced Primary Squamous Cell Carcinoma of the Oral Cavity / Soft Palate Versus Standard of Care Only	Substantial Amendment 8, 04/12/17	04/01/2018	24
14/NE/1240/AM06	B1371012 Phase 1B/2 study of patients with MDS,AML,MLD OR CMML	Substantial Amendment 6	10/01/2018	29
15/NE/0012/AM05	Heartware MVAD® System for advanced heart failure	SA3	16/05/2017	8
15/NE/0024/AM07	Newcastle NIHR BioResource	SA5	03/04/2017	15
15/NE/0024/AM08	Newcastle NIHR BioResource	SA6	01/06/2017	12
15/NE/0036/AM10	Life after prostate cancer diagnosis - Version 1	SA4	24/04/2017	11
15/NE/0036/AM13	Life after prostate cancer diagnosis - Version 1	Substantial Amendment 5, October 2017	25/10/2017	24
15/NE/0074/AM02	(duplicate) The SITS Open - Artery by thrombectomy in acute occlusive	SA2	01/03/2017	19
15/NE/0074/AM03	(duplicate) The SITS Open - Artery by thrombectomy in acute occlusive	Substantial Amendment 03 – March 2017	15/06/2017	15
15/NE/0086/AM07	GX29176 CHROMA Lampalizumab in Geographic Atrophy	Substantial Amendment 6, 22/09/17	22/09/2017	24
15/NE/0086/AM08	GX29176 CHROMA Lampalizumab in Geographic Atrophy	Substantial Amendment 7, 18/10/17	18/10/2017	29
15/NE/0086/AM09	GX29176 CHROMA Lampalizumab in Geographic Atrophy	SA8	21/12/2017	25
15/NE/0170/AM06	Tenofovir DF in Adolescent CHB	Substantial Amendment 5, 07/07/17	07/07/2017	14
15/NE/0170/AM07	Tenofovir DF in Adolescent CHB	Substantial Amendment 6 - 17/11/17	17/11/2017	32
15/NE/0172/AM02	BronchUK Study	Substantial	18/07/2017	16

		Amendment 1 - 03/03/17		
15/NE/0183/AM09	GNE SA-ER Phase III	Substantial Amendment 5 - 25 May 2017	20/07/2017	11
15/NE/0254/AM01	Attention and memory in Progressive Supranuclear Palsy	Substantial Amendment 1, 19/09/17	02/10/2017	20
15/NE/0309/AM03	Paramedic Acute Stroke Treatment Assessment (PASTA)	Substantial Amendment 1 : 1 No	02/11/2017	28
15/NE/0314/AM02	RCT of compression therapy following foam sclerotherapy	SA2	04/05/2017	13
15/NE/0317/AM08	BN29854 - Olesoxime in patients with SMA	Substantial Amendment 8, 25/01/18	25/01/2018	29
15/NE/0374/AM09	Multi-part, double blind study to assess safety, tolerability and efficacy of LJN452 in patients with primary biliary cirrhosis	Substantial Amendment 6, 10/07/17	10/07/2017	23
15/NE/0374/AM10	Multi-part, double blind study to assess safety, tolerability and efficacy of LJN452 in patients with primary biliary cirrhosis	Substantial Amendment 7 - 16/08/2017	16/08/2017	26
15/NE/0374/AM11	Multi-part, double blind study to assess safety, tolerability and efficacy of LJN452 in patients with primary biliary cirrhosis	Substantial Amendment 8, 30/01/2018	30/01/2018	33
15/NE/0403/AM03	VX15-809-110 Cystic Fibrosis	Substantial Amendment 3 - 14/09/17	15/09/2017	27
16/NE/0036/AM01	High-resolution cortical mapping for epilepsy surgery in children	Amendment number 1	13/06/2017	14
16/NE/0073/AM01	Metabolism of senescent T cells Version 1.0	Substantial Amendment 1 05/06/2017	07/06/2017	20
16/NE/0123/AM01	SOLID-Supporting Looked After Children in Decreasing Drugs & alcohol	SA1	28/02/2017	21
16/NE/0123/AM02	SOLID-Supporting Looked After Children in Decreasing Drugs & alcohol	SA2	31/05/2017	10
16/NE/0155/AM01	Comprehensive Patient Records for Cancer Outcomes	Substantial	06/02/2018	28



		Amendment 2, 05/02/2018		
16/NE/0159/AM02	CC-220-MM-001_Phase 1B/2A_Multiple Myeloma_CC-220	Substantial Amendment 3, 17/03/2017	26/04/2017	19
16/NE/0159/AM04	CC-220-MM-001_Phase 1B/2A_Multiple Myeloma_CC-220	Substantial Amendment 5 - 21/12/17	06/03/2018	17
16/NE/0166/AM02	Phase 1/2 Study of G100 for Non-Hodgkin's Lymphoma Patients	SA1	13/04/2017	28
16/NE/0166/AM03	Phase 1/2 Study of G100 for Non-Hodgkin's Lymphoma Patients	SA2	26/05/2017	17
16/NE/0166/AM05	Phase 1/2 Study of G100 for Non-Hodgkin's Lymphoma Patients	SA03 Insurance Provider Update	18/08/2017	28
16/NE/0166/AM08	Phase 1/2 Study of G100 for Non-Hodgkin's Lymphoma Patients	Substantial Amendment 4 - 16/01/2018	16/01/2018	18
16/NE/0167/AM01	Newcastle Uteroplacental Tissue Bank	SA1	01/04/2017	15
16/NE/0188/AM03	Quality of life and adherence in patients with severe asthma	SA2	31/05/2017	12
16/NE/0189/AM02	Phase 3b extension study using Aceneuramic acid	Substantial Amendment Change of CI 14/02/2018	14/02/2018	19
16/NE/0190/AM03	COMET	Substantial Amendment 2 - 18/0/2017	07/09/2017	22
16/NE/0191/AM15	RVT-101 in subjects with dementia with Lewy bodies (DLB)	Substantial Amendment 10, 18/12/2017	18/12/2017	24
16/NE/0255/AM03	SNT-IV-005 LEROS study	SA2	13/04/2017	19
16/NE/0255/AM04	SNT-IV-005 LEROS study	Substantial Amendment 3 - 07/02/2018	07/02/2018	27
16/NE/0259/AM01	UX007G-CL202 extension study for Participants with Glut1 DS	Substantial Amendment 1, 24/07/2017	28/09/2017	24
16/NE/0259/AM02	UX007G-CL202 extension study for Participants with Glut1 DS	Substantial	24/01/2018	24

		Amendment 2, 24/01/2018		
16/NE/0267/AM01	The Newcastle Mitochondrial Research Biobank	SA1	07/03/2017	13
16/NE/0282/AM03	LIFT: Lung magnetic resonance Imaging of Fluorocarbon Tracer gases	SA2	15/11/2017	21
16/NE/0283/AM02	Cognitive weakness in children under 5 with sleep disordered breathing	Substantial Amendment 2, 05/01/2018	05/01/2018	27
16/NE/0299/AM01	Quantitative MRI in children with juvenile idiopathic arthritis	Substantial Amendment 1, 06/06/2017	07/06/2017	22
16/NE/0325/AM02	ECUSTEC	SA1	20/04/2017	11
16/NE/0325/AM05	ECUSTEC	Substantial Amendment 2 - 18/0/2018	05/02/2018	27
16/NE/0333/AM01	Men's experience and use of treatments for ED.	Amendment number 1 - 19.07.2017	25/06/2017	26
16/NE/0356/AM02	SEED WS4	SA2	30/03/2017	15
16/NE/0356/AM03	SEED WS4	Substantial Amendment 3, 25/04/2017	25/04/2017	19
16/NE/0356/AM04	SEED WS4	SA4, 11 July 2017	13/07/2017	22
16/NE/0358/AM01	Perinatal Mental Health in Rural North Yorkshire	SA1	25/05/2017	20
16/NE/0363/AM01	IVA_01_337_HNAS_16_002	SA1	10/03/2017	15
16/NE/0399/AM04	RVT-101 extension study in subjects with dementia with Lewy Bodies	Substantial Amendment - 24/08/2017	24/08/2017	35
16/NE/0399/AM05	RVT-101 extension study in subjects with dementia with Lewy Bodies	Substantial Amendment Early End of study notification 15/01/18	22/01/2018	18
16/NE/0401/AM01	Long term outcomes of functional neurological symptoms in children	Substantial Amendment 1 - 14/1/2017	15/12/2017	27
16/NE/0408/AM01	Effect of phototherapy on pruritus in primary biliary cholangitis	SA1	15/03/2017	21

16/NE/0414/AM01	PRO and lupus	SA1	09/03/2017	14
16/NE/0418/AM02	iROC	SA1	22/05/2017	12
16/NE/0420/AM01	Injury, inflammatory markers & the exacerbation of confusion: ASCRIBED	SA1	03/05/2017	11
16/NE/0420/AM03	Injury, inflammatory markers & the exacerbation of confusion: ASCRIBED	Substantial Amendment 2 - 17.0.2017	08/09/2017	21
16/NE/0420/AM06	Injury, inflammatory markers & the exacerbation of confusion: ASCRIBED	Substantial Amendment 3, 12/10/2017	23/10/2017	25
17/NE/0010/AM01	Obstructive sleep apnoea and post operative complications	Substantial Amendment 1 12/06/2017	13/06/2017	19
17/NE/0019/AM01	EUS guided pancreatic tissue sampling (SharkBITE Study)	Substantial Amendment 1 - 15/0/2017	13/09/2017	20
17/NE/0058/AM01	GARNET	Substantial Amendment 1 - 17/1/2017	17/11/2017	21
17/NE/0061/AM02	CONVINCE - Protocol Version 2.1 29th November 2016	Substantial Amendment 2 - 19/09/2017	03/10/2017	12
17/NE/0061/AM03	CONVINCE - Protocol Version 2.1 29th November 2016	Substantial Amendment 3 - 31/10/2017	01/11/2017	15
17/NE/0070/AM01	CEPA Biobank Newcastle	SA1	01/08/2017	25
17/NE/0094/AM01	Crossover Evaluation of Eye Drops in Symptomatic Lens Wearers (Part 1)	SA1	19/05/2017	21
17/NE/0124/AM02	TEMPO Study	Substantial Amendment 1, 13/09/17	15/09/2017	25
17/NE/0124/AM03	TEMPO Study	Substantial Amendment 2 - 14/12/17	14/12/2017	28
17/NE/0126/AM01	Measuring lip scar in cleft lip/palate patients	Substantial Amendment 1 - 18/10/2017	19/10/2017	12

17/NE/0176/AM01	JEWELFISH	Substantial Amendment 1 - 02/1/2018	19/01/2018	20
17/NE/0188/AM01	ESMIA v1.0	Substantial Amendment 1, 24/10/2017	27/10/2017	27
17/NE/0203/AM01	Adult attachment, sensory processing and persistent pain (v.1)	Substantial Amendment 1.0 : 30/10/2017	03/11/2017	24
17/NE/0234/AM02	Phase 2 Study of Pembrolizumab in Participants With R/M cSCC	Substantial Amendment 2 - 10/10/2017	10/10/2017	22
17/NE/0257/AM01	HUBBLE	Substantial Amendment 1, 19/02/2018	19/02/2018	30
17/NE/0258/AM01	HUBBLE ZOOM	Substantial Amendment 1 - 23/11/2017	23/11/2017	21
17/NE/0259/AM02	A Holistic Model of Rehabilitation to improve QoL in Sarcoma.	Substantial Amendment 1, 16/01/2018	18/01/2018	27
17/NE/0267/AM02	Mobile Autonomy in Children with End-Stage Heart Failure	Substantial Amendment 1, 21/11/2017	10/12/2017	30
17/NE/0278/AM01	Does the hormone cortisol affect fertility?	Final version 1 30/10/2017	01/11/2017	14
17/NE/0325/AM01	EMPOWER	Substantial Amendment 1 - 18/1/2018	03/01/2018	32
17/NE/0358/AM01	My-CRA, Liquid 13 Cis Retinoic Acid	1	13/02/2018	27
17/NE/0362/AM01	DIAMOND-Lewy Work Package 1 Review (WP1R)	Substantial Amendment 1, 31/01/2018	31/01/2018	21
2003/163/AM02	Genetic Factors Contributing to Renal Calcium Oxalate Stone Formation	Substantial Amendment 1 - 13.7.2017	02/10/2017	32

<b>Unfavourable opinion</b>				
<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>
14/NE/1100/AM13	GA28951 – Open-label extension & safety monitoring study	Substantial Amendment 10 - 25/10/2017	25/10/2017	17
16/NE/0005/AM04	What can gait analysis tell us about dementia and its subtypes?	Substantial Amendment - 07/07/17	14/07/2017	34
16/NE/0159/AM03	CC-220-MM-001_Phase 1B/2A_Multiple Myeloma_CC-220	Substantial Amendment 4, 03/10/17	24/10/2017	35
16/NE/0190/AM04	COMET	Substantial Amendment 3, 05/02/18	06/02/2018	26

**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/1100/AM13/1	GA28951 – Open-label extension & safety monitoring study	Modified Substantial Amendment	14/12/2017	3
16/NE/0005/AM04/1	What can gait analysis tell us about dementia and its subtypes?	Modified Amendment of Substant	27/09/2017	5
16/NE/0159/AM03/1	CC-220-MM-001_Phase 1B/2A_Multiple Myeloma_CC-220	Modified Substantial Amendment	01/02/2018	14

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

Reference				Clock
16/NE/0190/AM04/1	COMET	Modified Substantial Amendment	20/03/2018	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
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**Modified Amendments over 14 day timeline**

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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