

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

**Annual Report**

**01 April 2017 - 31 March 2018**



## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	North East - Tyne & Wear South Research Ethics Committee
<b>Type of REC:</b>	Recognised, CTIMPs in Patients, Type III
<b>Type of Flag:</b>	Phase 1 Studies in Patients Type III (CTIMP)
<b>Chair:</b>	Mr Paddy Stevenson
<b>Vice-Chair:</b>	Mr Ian Campbell
<b>Alternate Vice-Chair:</b>	Mrs Debra J Lett
<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
<b>Telephone:</b>	0207 1048084
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## Chair's overview of the past year:

2017/18 has been quite a year for both our REC and the Northern Region NRES team, several changes in key staff regionally as well as the move to a new home along with significant IT issues have demonstrated how well we all work under adversity. I think the key messages are we have maintained our high standards with all 22 meetings (10 full, 12 PR) being quorate and managed to keep to time with the ever increasing number of amendments being submitted to subcommittee. However I acknowledge that the time taken to provide a final opinion is increasing and this will need to be addressed in the next year. I am as ever grateful for the hard work and dedication of our REC Manager and assistant whose hard work and professionalism can be summarised in our outstanding audit evaluation this year.

## North East - Tyne & Wear South Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Mr Chris Barron	ECMC & CTU Manager	Expert	07/04/2016	31/05/2017
Ms Sam Barron	Clinical Lead, Speech & Language Therapist	Expert	01/06/2014	20/06/2017
Mr Jack Bissett	Student	Lay Plus	16/08/2016	
Mr John Blenkinsopp	Clinical Effectiveness Manager	Lay Plus	14/06/2013	
Mr Ian Campbell	Pharmacist	Expert	12/06/2012	
Dr Dorothy Coe	Senior Research Assistant & Lecturer in Nursing Skills	Lay	01/05/2014	
Mr David Hill	Retired Technical Director	Lay	01/06/2016	
Mrs Louise Jones	Faculty Equality & Diversity Advisor	Lay Plus	23/09/2015	
Mrs Debra J Lett	Manager Newcastle Brain Tissue Resource	Lay	19/09/2011	
Mr Graham McClelland	Research Paramedic	Expert	08/09/2014	
Ms Heather McGrath	School Research Administrator	Lay Plus	11/10/2017	
Miss Rachel Smith	Barrister	Lay Plus	10/08/2015	27/03/2018
Mr Paddy Stevenson	Research Operations Manager	Expert	01/02/2007	
Ms Hannah Stevenson	Trial Co-ordinator	Lay	15/06/2016	
Dr Kate Wilson	Retired Interim Director of Operations	Lay	08/09/2014	

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

Name	Profession	Status	Meeting date attended
Mr John Warden	Clinical Trials Data & Information Systems Manager	Lay	PR Ad Hoc 12/09/2017
Mr Anthony Lockett	Medical Director	Expert	PR Ad Hoc 12/09/2017

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

<b>Name</b>	<b>Declaration of Interest</b>	<b>Date</b>
Mr Chris Barron	Manager of Cancer Trials Unit, Sir Bobby Robson Centre, Freeman Hospital, Newcastle Hospitals Trust	11/05/2017
Mr Jack Bissett	No interests declared.	25/09/2017
Mr John Blenkinsopp	Clinical effectiveness Advisor/Deputy Clinical Effectiveness Manager - North Tees and Hartlepool Foundation Trust. Member of North Tees & Hartlepool REC. Trainer in evidence based practice - organised several workshops nationwide.	11/08/2017
Mr Ian Campbell	Trust Research and Development Capacity and Capability Group Newcastle Hospitals Newcastle upon Tyne Hospitals NHS Foundation Trust.	12/03/2018
Dr Dorothy Coe	Currently employed as a Research Assistant at Newcastle University. Project Coordinator - Local Clinical Research Network (NIHR)	08/02/2018
Mr David Hill	Director - Ronin Solutions Ltd until closure in July 2017. Consultant - Amdel Medical Ltd, Medical Device Creations Ltd. Related connections to: Newcastle School of Medicine, Newcastle University, Lancaster University.	26/06/2017
Mrs Louise Jones	Employed by Newcastle University. Previous role involved supporting the ethical review process in Faculty of Science, Agriculture & Engineering. Role changed from 1.8.17 to Faculty Equality & Diversity Advisor, with no involvement in research governance or support.	18/08/2017
Mrs Debra J Lett	Positions: Employed by Newcastle University on projects funded by Medical Research Council and research active charities (Alzheimer's Research UK and Alzheimer's Society). Funding received from Alzheimer's Research UK and Alzheimer's Society for projects with which I am involved.	18/04/2017
Mr Graham McClelland	Member of College of Paramedics Research Committee. Editorial board member for British Paramedic Journal. Editorial Board Member for British Paramedic Journal.	24/08/2017
Ms Heather McGrath	School Research Administrator - Geograph, Politics, & Sociology Dept. at Newcastle University.	11/10/2017
Miss Rachel Smith	No interests declared.	07/09/2017
Mr Paddy Stevenson	Operations Manager for Newcastle Hospitals Trust, managing all research staff and facilities. I declare any conflicts of interest if there is a study I have a direct link with.	29/08/2017
Ms Hannah Stevenson	Hepatology Research Trial Co-ordinator at Newcastle upon Tyne Hospitals NHS Foundation Trust. Officer/Steward for UNISON Trade Union. Delegate to Executive Committee for Northern Trade Union Congress.	28/07/2017
Dr Kate Wilson	No interests declared.	23/08/2017

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

Month	Date	Number of Members Present at Meeting
April	24/04/2017	10
May	22/05/2017	8
June	26/06/2017	8
July	24/07/2017	9
September	25/09/2017	8
October	23/10/2017	9
November	27/11/2017	10
January	22/01/2018	9
February	26/02/2018	10
March	26/03/2018	8

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	05/04/2017	3
May	03/05/2017	3
June	07/06/2017	3
July	05/07/2017	3
August	02/08/2017	3
September	05/09/2017	3
September	12/09/2017	3
October	04/10/2017	3
November	03/11/2017	3
January	03/01/2018	3
February	07/02/2018	3
March	07/03/2018	3

12 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	13/04/2017	2
April	26/04/2017	2
May	12/05/2017	2
May	26/05/2017	2
June	09/06/2017	2
June	27/06/2017	2

July	11/07/2017	2
July	26/07/2017	2
August	07/08/2017	2
August	17/08/2017	2
August	18/08/2017	2
August	24/08/2017	2
September	01/09/2017	2
September	15/09/2017	2
October	03/10/2017	2
October	13/10/2017	2
October	13/10/2017	3
October	27/10/2017	2
November	10/11/2017	2
November	24/11/2017	2
December	07/12/2017	3
December	11/12/2017	2
December	18/12/2017	2
December	22/12/2017	2
January	10/01/2018	2
January	22/01/2018	2
February	05/02/2018	2
February	12/02/2018	2
February	19/02/2018	2
February	19/02/2018	3
March	05/03/2018	2
March	19/03/2018	2
March	27/03/2018	2
March	30/03/2018	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>
Ms Sam Barron	1
Mr Jack Bissett	5
Mr John Blenkinsopp	8
Mr Ian Campbell	7
Dr Dorothy Coe	7
Mr David Hill	9
Mrs Louise Jones	5
Mrs Debra J Lett	9
Mr Graham McClelland	7
Ms Heather McGrath	4
Miss Rachel Smith	4
Mr Paddy Stevenson	10
Ms Hannah Stevenson	5
Dr Kate Wilson	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>
Mr Jack Bissett	1
Mr John Blenkinsopp	2
Mr Ian Campbell	5
Dr Dorothy Coe	3
Mr David Hill	2
Mrs Louise Jones	2
Mrs Debra J Lett	2
Mr Graham McClelland	2
Miss Rachel Smith	3
Mr Paddy Stevenson	7
Ms Hannah Stevenson	2
Dr Kate Wilson	3

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Mr Jack Bissett	1
Mr John Blenkinsopp	2
Mr Ian Campbell	5
Dr Dorothy Coe	1



Mr David Hill	1
Mrs Debra J Lett	27
Mr Graham McClelland	1
Mr Paddy Stevenson	35

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

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Mr Jack Bissett	07/07/2017	Equality, Diversity & Human Rights
Mr Jack Bissett	28/02/2018	Ethical issues in Phase One Research: Advanced Day
Mr Jack Bissett	28/03/2018	Research involving exposure to radiation
Mr Jack Bissett	28/03/2018	Research involving participants lacking mental capacity
Mr Jack Bissett	30/03/2018	Research involving human tissue
Mr John Blenkinsopp	29/11/2017	Members' Regional Training Day
Mr Ian Campbell	30/03/2018	Self-directed Learning Form - 3 hours of reading in addition to mandatory ethics training
Dr Dorothy Coe	29/11/2017	Members' Regional Training Day
Mr David Hill	09/02/2018	Complex Cases
Mrs Louise Jones	23/05/2017	Medical Devices Training
Mrs Debra J Lett	05/06/2017	Equality & Diversity
Mrs Debra J Lett	14/09/2017	Training for New REC Chairs
Mrs Debra J Lett	09/02/2018	Complex Cases
Mr Graham McClelland	19/10/2017	Quantitative Training
Ms Heather McGrath	29/08/2017	Equality & Diversity
Miss Rachel Smith	10/07/2017	Equality & Diversity
Miss Rachel Smith	29/11/2017	Regional Members' Training Day
Ms Hannah Stevenson	26/09/2017	Certificate Assessing the Consequences of Research
Mr Paddy Stevenson	24/11/2017	HRA National Chairs' Day and Policy Event
Dr Kate Wilson	14/09/2017	Handling Health-Related Findings in Research (Joint MRC/HRA)
Dr Kate Wilson	14/11/2017	Medical Devices Training
Dr Kate Wilson	09/02/2018	Complex cases

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

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

<b>Applications for full ethical review – Study Type</b>	<b>Number</b>	<b>%</b>
Clinical Trial of Investigational Medicinal Product	19	46.34
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	22	53.66
<b>Total Applications Reviewed</b>	<b>41</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	10
Number of paediatric applications reviewed	9
Number of device applications reviewed	3
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	0
Number of applications reviewed that are funded by the US DHHS	0
Number of qualitative applications reviewed	2

**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	7.32
Favourable Opinion with Additional Conditions	5	12.20
Unfavourable Opinion	0	0.00
Provisional Opinion	33	80.49
Provisional Opinion Pending Consultation with Referee	0	0.00
<b>Total</b>	<b>41</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	78.05
Further Information Favourable Opinion with Additional Conditions	0	0.00
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	3	7.32
Favourable Opinion with Additional Conditions	5	12.20
Unfavourable Opinion	0	0.00
Provisional Opinion	1	2.44
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>41</b>	<b>100</b>

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

<b>Total Applications Reviewed</b>	<b>33</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	1
Number of student applications reviewed	13
Number of paediatric applications reviewed	4
Number of device applications reviewed	0
Number of qualitative applications reviewed	7

**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	29	87.88
Favourable Opinion with Additional Conditions	2	6.06
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	2	6.06
Unfavourable Opinion	0	0.00
<b>Total</b>	<b>33</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>	4.10
<b>Number of completed applications for full ethical review</b>	41
<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>	28
<b>Number of completed proportionate review applications for ethical review</b>	33
<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>	12
<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>	128
<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>	2
<b>Number of completed modified amendments over 14 days</b>	0
<b>Number of completed modified amendments over 14 days as a % of total modified amendments</b>	0.00%
<b>Number of non-substantial amendments received</b>	149
<b>Number of substantial amendments received for information</b>	2
<b>Number of substantial amendments received for new sites/PIs</b>	23
<b>Number of annual progress reports received</b>	62
<b>Number of safety reports received</b>	52
<b>Number of Serious Adverse Events received</b>	0
<b>Number of final reports received</b>	19

**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/0131	VISMAC Version 1.0	30
17/NE/0137	TAK-659 in Combination With Nivolumab in Advanced Solid Tumors	18
17/NE/0138	Eosinophilic and Immune Mechanistic Study (BREAD)	24
17/NE/0151	SGI-110 vs Treatment Choice in Adults with Previously Treated AML	39
17/NE/0165	MA30143 - Ocrelizumab in patients with Multiple Sclerosis	29
17/NE/0167	Safety, Pharmacokinetics and Antiviral Activity of RV521 Against RSV	37
17/NE/0169	Interactions between diet and gut microbes in preterm infants (INDIGO)	30
17/NE/0193	Role of low residue diet in managing symptoms of mitochondrial disease	21
17/NE/0201	Observational Study of Primary Mitochondrial Disease (SPIMM-300)	17
17/NE/0207	The Lived Experience of Patients with Cancer of Unknown Primary	27
17/NE/0244	Chronic Omega-3 Fatty Acid Supplementation in Type 1 Diabetes	28
17/NE/0254	The Effect of Bariatric Surgery on Plasma Annexin A1 levels; VN: 1	34
17/NE/0255	D6014C00005, Phase I, Open-label, Food Effects of AZD1775	26
17/NE/0256	D6014C00007, Phase I, Open-label, Continued Access to AZD1775	26
17/NE/0308	Resistance training in adults with Crohn's disease	23
17/NE/0333	Morpheus - Global Registry V1.0.0	29
17/NE/0338	Clinical Evaluation of the FlexDex Surgical Instrument in Thoracics.	33
17/NE/0339	The CLEAR Trial	34
17/NE/0342	U.K. MedEye Study	37
17/NE/0367	VBP15-LTE	46
17/NE/0368	The Route to a Diagnosis of Head and Neck Cancer (V1.1)	24
17/NE/0373	OPTIMUM LT non-comparative extension study of ponesimod 20mg in RMS	38
17/NE/0375	CO40016 - A study of Ipatasertib with Paclitaxel in Breast Cancer	24
18/NE/0017	Experiential perspectives of 'five session CAT' consultancy in CMHTs	30
18/NE/0029	BGB-A317-208: BGB-A317 in Hepatocellular Unresectable Carcinoma	43
18/NE/0032	Parallel Study Comparing Administration of Romosozumab in Osteoporosis	21
18/NE/0077	PORT	27
18/NE/0078	SETS aHUS: Stopping Eculizumab Treatment Safely in aHUS	25
18/NE/0089	Genetics of male infertility	34
18/NE/0102	CA40192:Etrolizumab in patients with moderate to severe UC or CD	45
18/NE/0103	VX17-659-103 Efficacy and Safety of VX-659/TEZ/IVA in CF Homozygous	35
18/NE/0104	VX17-659-102 Efficacy and Safety of VX-659/TEZ/IVA in CF Het-min	29

18/NE/0106	Intolerance of uncertainty in children with ASD: a feasibility trial	27
<b>Further Information Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>

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

<b>Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
17/NE/0150	MASS_PD: Muscle and Ageing Science Study in Parkinson's Disease	25
17/NE/0205	PCYC-1145-LT Rollover study for ibrutinib	19
17/NE/0303	Study to evaluate the efficacy of Ad26.RSV.preF vaccine against RSV	22

<b>Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
17/NE/0127	N-HCC version 1	24
17/NE/0247	Psoriasis and the Circadian Timing System (Version 1)	20
17/NE/0310	Early Onset Depression (EOD-UK & ROI)	19
17/NE/0334	Exploring DNA methylation as an initiating event in childhood cancers	28
18/NE/0023	Enterogel in the treatment of Irritable Bowel Syndrome with Diarrhoea	24

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

<b>Provisional Opinion</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
18/NE/0102	CA40192:Etrolizumab in patients with moderate to severe UC or CD	n/a

<b>Provisional Opinion Pending Consultation with Referee</b>		
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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
17/NE/0105	Quality of life for people living with early stage dementia. v1	16
18/NE/0091	Perceptions of Weight Management Programmes	21

#### 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/0101	Parents' experiences of attending a MDT clinic for children with AMC	16
17/NE/0102	Addressing tobacco dependence in people with mental health problems	18
17/NE/0139	Risk of epilepsy following head injury	16
17/NE/0143	Integration and comparison of evaluation data on P3C	19
17/NE/0179	Patient experience of acute rehabilitation after hip fracture surgery	14
17/NE/0184	Prognostic Features of Small Cell Lung Cancer - version 1	16

17/NE/0211	The pathogenesis of idiopathic sensory ganglionopathy.	14
17/NE/0212	FiTPAD v1.0	17
17/NE/0263	Geographic Atrophy Patient Focus Group Project	14
17/NE/0266	Utilising EVNP as a model for studying kidney cancer v1.0	14
17/NE/0268	Exploring the potential of non-speculum HPV testing in older women	15
17/NE/0290	Exploring patients' perceptions of a narrative group for HD	20
17/NE/0291	EvAluation of ChatHealth (EACH)	21
17/NE/0304	Timing of lymphoscintigraphy for SLNB	10
17/NE/0306	Using language analysis on patient experience feedback	7
17/NE/0307	Patients' thoughts on the Interpersonal Skills Questionnaire (ISQ)	8
17/NE/0314	Polypharmacy in Pakistani patients: A qualitative study	21
17/NE/0316	Nerve Conduction Studies of the Dorsal Cutaneous Branch of the Ulnar.	21
17/NE/0346	Investigation of drug allergy	21
17/NE/0347	Variation in practice following altered fetal movement v1.0	14
17/NE/0352	Validating the BICAMS IPAD in MS	17
18/NE/0010	Fabry Pain Questionnaire English Version	21
18/NE/0011	Developing new tests for ovarian cancer	21
18/NE/0012	OxBP	21
18/NE/0013	Bedtime routines and children's dental health	20
18/NE/0058	Pulse Wave Velocity and Phase Difference as Novel Biomarkers	20
18/NE/0059	How important is Stereopsis in the Ability to Carry Out Microsurgery	10
18/NE/0060	BaSICS (Baby skin integrity comparison survey) - Version 1	21
18/NE/0061	Interventions to reduce inequalities in uptake of routine dental care	20

#### Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
17/NE/0145	BEAST V1.0	21
17/NE/0289	Genital Wart Cell Lifts	18

#### 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/Q0904/78/AM47	Peri-operative Chemotherapy & Bevacizumab in Gastric Cancer (ST03)	Substantial Amendment 13 - 19/10/2017	16/11/2017	28
08/H0904/3/AM16	Treatment of Parkinson's Disease Psychosis with ACP-103	Substantial Amendment Investigator Brochure Edition 11 update dated 7th February 2018	07/02/2018	28
11/NE/0140/AM14	AuToDeCRA	Substantial Amendment 6	16/03/2017	23
11/NE/0361/AM03	Smoking in pregnancy: fetal facial movement markers	Substantial Amendment 1, 5/12/17	04/02/2018	28
12/NE/0323/AM31	: First in Human Study of VX-970/M6620 in Advanced Solid Tumors MS201923-0001	Substantial Amendment 22 - 01/08/2017	01/08/2017	19
12/NE/0323/AM32	: First in Human Study of VX-970/M6620 in Advanced Solid Tumors MS201923-0001	SA23 – Re-Submission of SA22 – 14/09/2017	14/09/2017	19
12/NE/0323/AM33	: First in Human Study of VX-970/M6620 in Advanced Solid Tumors MS201923-0001	Substantial Amendment 24 - 17/10/2017	20/10/2017	24
12/NE/0323/AM34	: First in Human Study of VX-970/M6620 in Advanced Solid Tumors MS201923-0001	Substantial Amendment 25 - 01/12/2017	01/12/2017	35
13/NE/0049/AM17	BAY 94-9027 pediatric pharmacokinetics, safety, and efficacy trial	Substantial Amendment 10 – 0/07/2017.	07/07/2017	21
13/NE/0186/AM06	AZ: D0816C00004 Ph 1 - Effect of Food in Advanced Solid Tumours	SA5	17/05/2017	23
13/NE/0269/AM11	Maintenance Study of Niraparib/Placebo in Patients with	Substantial	21/06/2017	17

	Ovarian Cancer	Amendment 9 dated 21/06/2017		
13/NE/0269/AM12	Maintenance Study of Niraparib/Placebo in Patients with Ovarian Cancer	Protocol Amendment 7 dated 31/09/2017	11/10/2017	30
13/NE/0274/AM05	Robot Assisted Training for the Upper Limb after Stroke	Substantial Amendment 3	06/07/2017	19
14/NE/0058/AM01	Standardised NBIA Patient Registry and Natural History Study	Substantial Amendment 1 - 30/1/2018	21/11/2017	26
14/NE/0072/AM02	U.K. Medication Error and ADE Study_Version 1	SA1	18/05/2017	9
14/NE/0072/AM03	U.K. Medication Error and ADE Study_Version 1	Substantial Amendment 2 - 19th	01/02/2018	21
14/NE/0147/AM05	D081CC00001, PK study Olaparib in combination with Endocrine therapy	SA#4 IB 12, 13 & 14	07/07/2017	19
14/NE/1040/AM09	Pfizer A3921092 - Phase 3 Tofacitinib (Active PsA) Extension Study	Substantial Amendment 9, 12/04/2017	13/09/2017	19
14/NE/1075/AM12	TRAFIC	Substantial Amendment 8 - 08/08/2017	15/08/2017	34
14/NE/1075/AM13	TRAFIC	Substantial Amendment 9 - 26/02/2018	09/03/2018	26
14/NE/1076/AM01	Modelling ciliopathies	Substantial Amendment 1.2 01.06.17	29/06/2017	18
14/NE/1098/AM09	D5160C00012 - Phase I, Open Label, EGFRm positive NSCLC (Inhibitor)	SA8 - IB version 8	03/07/2017	23
14/NE/1144/AM16	The National Trial of Tonsillectomy IN Adults (NATTINA)	SA6	18/05/2017	21
14/NE/1144/AM17	The National Trial of Tonsillectomy IN Adults (NATTINA)	Substantial Amendment 7 - 14 August 2017	18/08/2017	35
14/NE/1177/AM02	Virtual reality intervention for anxiety in children with ASD	Substantial Amendment 1	09/05/2017	33
14/NE/1177/AM03	Virtual reality intervention for anxiety in children with ASD	Substantial	22/08/2017	27

		Amendment 2 - 22.8.17		
14/NE/1179/AM07	ECASS - Evaluation of a Computer Aid for assessing Stomach Symptoms	SA3	07/03/2017	15
14/NE/1214/AM16	A Phase 3 Veliparib plus Chemotherapy Study in Non-Squamous NSCLC	Substantial Amendment 9 - 22/08/2017	18/08/2017	33
14/NE/1214/AM17	A Phase 3 Veliparib plus Chemotherapy Study in Non-Squamous NSCLC	Substantial Amendment 10 – 22.06.17	10/11/2017	16
14/NE/1214/AM18	A Phase 3 Veliparib plus Chemotherapy Study in Non-Squamous NSCLC	Substantial Amendment 11 - 17/11/18	26/01/2018	16
14/NE/1221/AM07	EPOS Trial	Substantial Amendment 4, 25/09/17	26/09/2017	20
14/NE/1221/AM09	EPOS Trial	SA5	15/12/2017	21
14/NE/1253/AM12	D5160C00019 - Phase I, Open Label, PK, EGFRm+ NSCLC (Rosuvastatin)	SA10 - IB edition 8	03/07/2017	23
15/NE/0058/AM06	The Genome Diversity in Africa Project (GDAP)	SA6	19/05/2017	21
15/NE/0058/AM07	The Genome Diversity in Africa Project (GDAP)	Substantial Amendment 7 – September 2017	11/09/2017	22
15/NE/0070/AM07	A Phase 1b study in patients with B-Cell Chronic Lymphocytic Leukemia	Substantial Amendment 7 - 10/11/17	10/11/2017	19
15/NE/0138/AM02	Inflammatory, metabolic, endocrine, immunological pathways in arteries and veins	SA2	23/03/2017	21
15/NE/0149/AM12	Phase 2 study in Patients with Recurrent or Metastatic SCCHN	SA9	05/04/2017	8
15/NE/0149/AM13	Phase 2 study in Patients with Recurrent or Metastatic SCCHN	SA10	30/05/2017	10
15/NE/0149/AM14	Phase 2 study in Patients with Recurrent or Metastatic SCCHN	Substantial Amendment 11 - 02/11/17	02/11/2017	22
15/NE/0149/AM17	Phase 2 study in Patients with Recurrent or Metastatic SCCHN	Substantial Amendment 12 - 30/01/18	30/01/2018	21
15/NE/0155/AM09	Antiplatelet therapy in COPD (APPLE-COPD:ICON 2)	Substantial	02/10/2017	21

		Amendment 4, 29/09/17		
15/NE/0247/AM01	Epidemiology of breast cancer subtypes defined by ER and HER2 status	Substantial Amendment 1 - 15/11/17	20/11/2017	24
15/NE/0247/AM02	Epidemiology of breast cancer subtypes defined by ER and HER2 status	Substantial Amendment 2 - 28/02/18	13/03/2018	20
15/NE/0252/AM11	MK-3475 (Pembrolizumab) in Subjects with Classical Hodgkin Lymphoma	SA11 (REC) 04/08/2017	04/08/2017	25
15/NE/0252/AM12	MK-3475 (Pembrolizumab) in Subjects with Classical Hodgkin Lymphoma	Substantial Amendment 12/13/17	25/10/2017	30
15/NE/0252/AM13	MK-3475 (Pembrolizumab) in Subjects with Classical Hodgkin Lymphoma	Substantial Amendment 14 - 21/02/18	21/02/2018	29
15/NE/0274/AM01	EORTC 1320	Substantial Amendment 2, 18/07/17	20/07/2017	7
15/NE/0277/AM10	OPTIMUM	Substantial Amendment 9 - 18/8/17	18/08/2017	21
15/NE/0277/AM11	OPTIMUM	Substantial Amendment 10 - 07/11/17	07/11/2017	22
15/NE/0379/AM01	Non-invasive vagus nerve stimulation in Primary Sjogrens Syndrome	Substantial Amendment 1 - 05/02/18	15/02/2018	28
15/NE/0381/AM05	ALTAR	Substantial Amendment 5, 24/05/17	06/07/2017	12
15/NE/0381/AM09	ALTAR	Substantial Amendment 7 - 13/12/17	07/03/2018	27
15/NE/0390/AM02	Myotubular and Centronuclear Myopathy Patient Registry	Substantial Amendment 1.2 (19/07/17)	19/07/2017	28

16/NE/0008/AM01	I-KID: Infant Kidney Dialysis and filtration	SA1	19/12/2017	26
16/NE/0008/AM03	I-KID: Infant Kidney Dialysis and filtration	Substantial Amendment 2 - 26 Feb 18	19/03/2018	29
16/NE/0027/AM14	B9991009 Phase 3, avelumab for Platinum-Resistant Ovarian Cancer	SA8 IB 7 & PIS V.7	09/06/2017	18
16/NE/0059/AM02	Derivation of human ear stem cells from fetal tissues	Substantial Amendment 1 - 23/12/17	05/12/2017	27
16/NE/0066/AM05	D4190C00006 - Ph 1b MEDI4736 in Advanced Non-Small Cell Lung Cancer	Substantial Amendment 4 – updated IB 16.06.17	16/06/2017	25
16/NE/0066/AM06	D4190C00006 - Ph 1b MEDI4736 in Advanced Non-Small Cell Lung Cancer	Substantial Amendment 5 - 03/1/18	15/01/2018	20
16/NE/0067/AM11	Dose-Ranging Study of Delayed-Release Deferiprone in Parkinson	SA6	05/05/2017	27
16/NE/0069/AM04	Study of UTTR1147A in Healthy Volunteers & Ulcerative Colitis Patients	Substantial Amendment 2 - 1/11/17	01/11/2017	26
16/NE/0083/AM04	Viral Challenge Asthma Phenotype (VCAP) Study	SA4	26/05/2017	9
16/NE/0118/AM01	Systemo Twin Study	Substantial Amendment 1, 24/07/18	14/03/2018	18
16/NE/0142/AM08	B9991010 Phase 3, avelumab for Untreated Epithelial Ovarian Cancer	SA4 - IB7	21/06/2017	23
16/NE/0147/AM05	RESOLVE-IT: A Study of Elafibranor in Patients with NASH and fibrosis	Substantial Amendment 4 - 20/12/17	28/12/2017	11
16/NE/0200/AM08	FAIRPARK II	Substantial Amendment 3 - 25/09/17	06/12/2017	25
16/NE/0210/AM01	Can microbiome data improve the NHS Bowel Cancer Screening Programme?	Protocol amendment v3	13/04/2017	20
16/NE/0210/AM02	Can microbiome data improve the NHS Bowel Cancer Screening Programme?	Substantial Amendment 4 -	23/10/2017	24



		21.9.17		
16/NE/0239/AM01	ENHANCE	Substantial Amendment 1, 19/09/17	01/11/2017	18
16/NE/0250/AM02	MAP (Muscle Assessment in Peripheral nerve injury)	SA1	10/03/2017	14
16/NE/0253/AM04	Rituximab in Graves' Disease (RIGD)	Substantial Amendment 2, 23/01/18	24/01/2018	21
16/NE/0268/AM01	Health Status and Quality of Life in Congenital Agammaglob	Substantial Amendment 1, 18/07/17	18/07/2017	12
16/NE/0279/AM08	TIDaL	SA6	24/03/2017	14
16/NE/0279/AM09	TIDaL	Substantial Amendment 7, 27/07/17	27/10/2017	26
16/NE/0287/AM01	Non-invasive assessment of cardiac function to identify heart failure	Substantial Amendment 1, 21 <sup>st</sup> Sept 17	13/10/2017	33
16/NE/0311/AM04	A study to describe the impact of AbbVie Care	Substantial Amendment 1 - 12th Oct 17	16/10/2017	29
16/NE/0324/AM01	Myxofibro Sarcoma staging using PET-MRI: comparison to standard MRI	SA1	24/03/2017	16
16/NE/0324/AM03	Myxofibro Sarcoma staging using PET-MRI: comparison to standard MRI	Substantial Amendment 2 - 01/08/17	04/08/2017	26
16/NE/0326/AM01	Pancreatic Acinar Cell Cancer Registry	Substantial Amendment 1 - 27/11/17	27/10/2017	31
16/NE/0342/AM01	A Phase 1 Study of ADCT-402 in Patients with Non-Hodgkin Lymphoma	SA1	10/05/2017	16
16/NE/0342/AM02	A Phase 1 Study of ADCT-402 in Patients with Non-Hodgkin Lymphoma	Substantial Amendment 2 - 09/08/17	09/08/2017	30
16/NE/0342/AM03	A Phase 1 Study of ADCT-402 in Patients with Non-Hodgkin Lymphoma	Substantial Amendment 3	21/11/2017	17
16/NE/0344/AM02	First-in-Human, Phase 1/2 study, JNJ-63723283 in Advanced	Substantial	08/08/2017	21

	Cancers	Amendment 1 - 08/08/17		
16/NE/0344/AM03	First-in-Human, Phase 1/2 study, JNJ-63723283 in Advanced Cancers	Substantial Amendment 2 - 13/10/17	13/10/2017	26
16/NE/0344/AM04	First-in-Human, Phase 1/2 study, JNJ-63723283 in Advanced Cancers	Substantial Amendment 3, 10/12/17	10/12/2017	28
16/NE/0344/AM05	First-in-Human, Phase 1/2 study, JNJ-63723283 in Advanced Cancers	Substantial Amendment 4 - 21/01/18	21/01/2018	22
16/NE/0353/AM03	ARASENS	Substantial Amendment 3	09/06/2017	21
16/NE/0353/AM04	ARASENS	Substantial Amendment 4, 20/07/17	20/07/2017	7
16/NE/0353/AM05	ARASENS	Substantial Amendment 5 - 25/08/17	25/08/2017	32
16/NE/0353/AM06	ARASENS	Substantial Amendment 6 - 24/10/17	24/10/2017	27
16/NE/0374/AM02	RCT - Platelet Rich Plasma vs Placebo in GTPS V1.0	Substantial Amendment 1, 19/07/17	23/07/2017	23
16/NE/0384/AM04	ARNI versus ACE inhibition to reduce Heart Failure events after an MI	SA3	19/05/2017	16
16/NE/0384/AM07	ARNI versus ACE inhibition to reduce Heart Failure events after an MI	SA7 - EQ-5D Subject Call Instruction Guide	10/08/2017	29
16/NE/0384/AM08	ARNI versus ACE inhibition to reduce Heart Failure events after an MI	Substantial Amendment 8 – Temp recruitment halt	11/08/2017	28
16/NE/0384/AM10	ARNI versus ACE inhibition to reduce Heart Failure events after an MI	Substantial Amendment 9 – Recruitment restart	21/09/2017	25

17/NE/0024/AM02	Phase IIa study of Anti-IL-7 receptor- $\alpha$ Mab GSK2618960 in pSS treatment	SA1	20/03/2017	13
17/NE/0026/AM03	LCZ696 versus enalapril on daily physical activity	Substantial Amendment 2, 28/07/17	28/07/2017	10
17/NE/0026/AM05	LCZ696 versus enalapril on daily physical activity	Substantial Amendment 3 - 09/03/18	09/03/2018	22
17/NE/0027/AM04	CRest2	Substantial Amendment 1, 19/09/17	21/09/2017	17
17/NE/0045/AM02	ROSETREES: Personalised ultraviolet B (UVB) treatment of psoriasis	Substantial Amendment 1, 28/09/17	10/10/2017	34
17/NE/0062/AM01	The effects of BAY 1193397 on skin capillary blood flow	SA1	24/03/2017	13
17/NE/0062/AM02	The effects of BAY 1193397 on skin capillary blood flow	Substantial Amendment 2 - 24/08/17	11/09/2017	22
17/NE/0080/AM03	Optimising neonatal service provision for preterm babies (27-31 weeks)	SA3	07/06/2017	25
17/NE/0080/AM04	Optimising neonatal service provision for preterm babies (27-31 weeks)	Substantial amendment 5 on WS 4: 29/08/17	29/08/2017	34
17/NE/0085/AM01	Influence of the Vitabreath device on exercise tolerance in COPD	SA1	22/05/2017	29
17/NE/0093/AM02	PRE-OP BIRDS - Pilot RCT	SA1	05/05/2017	20
17/NE/0131/AM02	VISMAL Version 1.0	Substantial Amendment 1, 08 Jan 2018	22/01/2018	20
17/NE/0137/AM01	TAK-659 in Combination With Nivolumab in Advanced Solid Tumors	SA 01	12/06/2017	18
17/NE/0137/AM02	TAK-659 in Combination With Nivolumab in Advanced Solid Tumors	SA02 Revised GP letter and Participant summary sheet	17/08/2017	22
17/NE/0150/AM01	MASS_PD: Muscle and Ageing Science Study in Parkinson's Disease	Substantial Amendment 1 -	23/08/2017	34

		15/08/17		
17/NE/0151/AM06	SGI-110 vs Treatment Choice in Adults with Previously Treated AML	Substantial Amendment 3 - 29/1/18	05/01/2018	28
17/NE/0151/AM07	SGI-110 vs Treatment Choice in Adults with Previously Treated AML	Substantial Amendment 4 - 02/03/18	02/03/2018	26
17/NE/0165/AM01	MA30143 - Ocrelizumab in patients with Multiple Sclerosis	Substantial Amendment 1 - 11/10/17	11/10/2017	32
17/NE/0165/AM02	MA30143 - Ocrelizumab in patients with Multiple Sclerosis	Substantial Amendment 2 - 17/01/18	17/01/2018	28
17/NE/0167/AM01	Safety, Pharmacokinetics and Antiviral Activity of RV521 Against RSV	Substantial Amendment 1	15/06/2017	23
17/NE/0167/AM02	Safety, Pharmacokinetics and Antiviral Activity of RV521 Against RSV	Substantial Amendment 2	28/11/2017	19
17/NE/0179/AM01	Patient experience of acute rehabilitation after hip fracture surgery	Substantial Amendment 1, 10/08/17	11/08/2017	22
17/NE/0247/AM01	Psoriasis and the Circadian Timing System (Version 1)	Substantial Amendment 1 - 22/11/17	23/11/2017	26
17/NE/0268/AM03	Exploring the potential of non-speculum HPV testing in older women	Substantial Amendment 1, 14/02/18	14/02/2018	25
17/NE/0303/AM03	Study to evaluate the efficacy of Ad26.RSV.preF vaccine against RSV	Substantial Amendment 1 - 22/11/17	22/11/2017	35
17/NE/0308/AM01	Resistance training in adults with Crohn's disease	Substantial Amendment 1 - 16/01/18	07/02/2018	24
17/NE/0339/AM03	The CLEAR Trial	Substantial Amendment 1 - 16/02/18	22/02/2018	28
17/NE/0352/AM01	Validating the BICAMS IPAD in MS	Substantial Amendment 1,	24/01/2018	20

		04/01/18		
17/NE/0373/AM01	OPTIMUM LT non-comparative extension study of ponesimod 20mg in RMS	Substantial Amendment 1, 31/01/18	31/01/2018	22
18/NE/0011/AM01	Developing new tests for ovarian cancer	Substantial Amendment 1, 23/02/18	23/02/2018	26
18/NE/0013/AM01	Bedtime routines and children's dental health	Substantial Amendment 1, 06/03/18	12/03/2018	18

#### Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
17/NE/0040/AM01	The Future of Healthcare: Automation in General Practice Services	Substantial Amendment v1.5 - 0	04/01/2018	17

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

#### Favourable opinion timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
16/NE/0146/AM06/1	2WW v1	Modified Amendment 3, 16/08/17	16/08/2017	14
17/NE/0040/AM01/1	The Future of Healthcare: Automation in General Practice Services	Modified Substantial Amendment	08/02/2018	4

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

**Table 11: Items exceeding timelines**

**Full applications for ethical review over 60 day timeline**

REC Reference	Title	Number of Days on Clock
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**Proportionate review applications for ethical review over 21 day timeline**

REC Reference	Title	Number of Days on Clock
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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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