

North East - York Research Ethics Committee

Annual Report

01 April 2016 - 31 March 2017



Part 1 – Committee Membership and Training

Name of REC:	North East - York Research Ethics Committee
Type of REC:	Recognised, Type I & Type III
Type of Flag:	Phase I in CTIMPs involving Healthy Volunteers, Type III CTIMPs, Prison Research, Paediatric Research, Gene Therapy Advisory Committee (Low Risk), Medical Device Studies
Chair:	Mr Chris Turnock
Vice-Chair:	Mr Steve Chandler
Alternate Vice-Chair:	Mrs Janet Hattle
REC Manager:	Mrs Helen Wilson (wef 10/10/2016) Ms Gillian Mayer (until 09/10/2016)
REC Assistant:	Mrs Amanda Carr (wef 01/01/2017) Ms Kerry Dunbar (wef 10/10/2016 – 31/12/2016) Ms Donna Bennett (until 09/10/2016)
Committee Address:	Jarrow Business Centre Rolling Mill Road Jarrow NE32 3DT
Telephone:	0207 1048091
Email:	nrescommittee.northeast-york@nhs.net

Chair's overview of the past year:

This is my second year as chair of the committee following the resignation of Peter Heasman.

Three members left the committee, Danni Coledridge-Moore, Peter Hopley and Giles McCracken, the latter having been a committee member for a long period of time and whose contributions to committee business were considerable.

Their contributions to the Committee's business has been invaluable and I would like to thank them all for their input as committee members.

The work of the Committee remains busy, predominately consisting of Phase 1 studies, normal range of CTIMPS and prison based studies. Whilst administrative support for the Committee has changed during the year, the continued efficiency of administrative support for full Committee meetings and the various Sub-Committee meetings has enabled members to perform their duties effectively.

North East - York Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Dr David Cairns	Principal Statistician	Expert	08/10/2013	
Ms Linda Chadd	Library assistant and archivist	Lay Plus	01/10/2013	
Mr Steve Chandler	Retired Consultant Medical Physicist	Expert	01/04/2013	
Professor Chris Colbourn	Clinical Psychology	Expert	01/07/2015	
Ms Danni Collingridge Moore	Research Fellow	Lay	01/04/2016	31/07/2016
Dr Mary Connor	Coaching & Mentoring Consultant	Lay Plus	05/10/2010	
Mr Michael Davidson	Retired Personnel Manager	Lay Plus	13/03/2017	
Miss Jill Dunbar	Consultant BME Project Officer	Lay Plus	08/09/2016	10/10/2016
Mrs Janet Hattle	Lay Member	Lay	01/05/2008	
Dr James Philip Hobkirk	Lecturer in Physiology & Scientific Director of Cardio-thoracic Surgery	Expert	08/09/2016	
Mr Peter Hopley	Pharmacist	Expert	01/01/2016	14/09/2016
Dr Jocelyn Hudson	General Practitioner	Expert	21/06/2016	
Mrs Fan Hutchison	Principal Teacher	Lay	01/01/2013	
Mr Anthony Lockett	Medical Director	Expert	01/05/2016	
Dr Giles McCracken	Senior Clinical Lecturer	Expert	01/04/2008	02/04/2016
Mrs Biserka Ross	Retired Research Advisor	Lay	08/09/2016	
Dr John Toy	Retired Honorary Professor of Cancer Medicine	Expert	01/07/2016	
Mr Chris Turnock	Head of Technology Enhanced Learning	Expert	01/09/2014	
Mr John Warden	Clinical Trials Data and Information Systems Manager	Lay	15/06/2016	
Ms Lorraine Wright	Senior Research Nurse	Expert	01/04/2010	

North East - York Research Ethics Committee: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Dr David Cairns	NIHR Clinical Trial Fellowship Award Panel Member	22/02/2017
Ms Linda Chadd	None.	15/02/2017
Mr Steve Chandler	Member National Osteoporosis Society Research Grants Committee	15/02/2017
Professor Chris Colbourn	Research Director for the Doctorate in Clinical Psychology, School of Health and Social Care, Teesside University: This involves me in teaching research methods and supervising some of the doctoral research projects that trainee clinical psychologists on the programme are required to complete as part of their qualification. My teaching on this programme includes sessions on research ethics and overseeing (including acting as Chief Investigator) their submissions for ethical approval of their research projects from University, HRA RECs, Trust R&D and any other necessary committees. I am also a member of the Teesside University, School of Health & Social Care, Research Governance & Ethics Committee that reviews submissions for ethical approval from all students and staff in the School intending to carry out research projects. I am also an occasional peer reviewer for research funding applications to various private and public bodies and for manuscripts submitted for publication in various psychology research journals.	15/02/2017
Ms Danni Collingridge Moore	None.	01/04/2016
Dr Mary Connor	None.	15/02/2017
Mr Michael Davidson	None.	12/03/2017
Mrs Janet Hattle	Voluntary ceased membership of General Pharmaceutical Council on 31/12/16. Membership status on REC changed to reflect this.	17/03/2017
Dr James Philip Hobkirk	None.	12/09/2016
Dr Jocelyn Hudson	None.	04/07/2016
Mrs Fan Hutchison	None.	31/03.2017
Mr Anthony Lockett	Medical Director at MEDQP Ltd conducting research into head and neck cancer and palliative care. Owner/ shareholder at MEDQP Ltd conducting research into head and neck cancer and palliative care.	01/05/2016
Mrs Biserka Ross	None.	29/09/2016
Dr John Toy	Shareholdings: "Possibly but via a third party managing member's interests".	01/07/2016
Mr Chris Turnock	Member of University of Hull, School of Education and Culture Research Committee.	15/02/2017
Mr John Warden	None.	30/06/2016
Ms Lorraine Wright	None.	31/03/2017

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

Month	Date	Number of Members Present at Meeting
April	01/04/2016	11
May	06/05/2016	12
June	03/06/2016	10
July	01/07/2016	11
August	05/08/2016	11
October	07/10/2016	12
November	04/11/2016	14
December	02/12/2016	9
January	06/01/2017	12
February	03/02/2017	12

10 full committee meetings were held during the reporting period.

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

Month	Date	Number of Members Present at Meeting
April	18/04/2016	3
May	18/05/2016	3
June	22/06/2016	3
July	14/07/2016	3
August	17/08/2016	3
October	21/10/2016	3
November	22/11/2016	3
December	15/12/2016	3
February	16/02/2017	3
March	20/03/2017	3

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	05/04/2016	2
April	12/04/2016	3
April	13/04/2016	2
April	26/04/2016	2
May	11/05/2016	2
May	23/05/2016	4
May	26/05/2016	2
June	06/06/2016	2
June	14/06/2016	3
June	20/06/2016	3
June	22/06/2016	2

July	07/07/2016	2
July	22/07/2016	2
August	03/08/2016	2
August	04/08/2016	4
August	17/08/2016	2
August	30/08/2016	2
September	14/09/2016	2
September	27/09/2016	2
October	12/10/2016	2
October	26/10/2016	2
November	08/11/2016	2
November	23/11/2016	2
December	02/12/2016	2
December	19/12/2016	2
January	06/01/2017	2
January	18/01/2017	2
February	01/02/2017	2
February	15/02/2017	2
March	02/03/2017	2
March	14/03/2017	2
March	24/03/2017	2

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

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

No inquorate meetings were held during the reporting period.

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

Name	Number of Meetings Attended
Dr David Cairns	7
Ms Linda Chadd	9
Mr Steve Chandler	10
Professor Chris Colbourn	8
Ms Danni Collingridge Moore	2
Dr Mary Connor	6
Mrs Janet Hattle	8
Dr James Philip Hobkirk	2
Mr Peter Hopley	3
Dr Jocelyn Hudson	6
Mrs Fan Hutchison	8
Mr Anthony Lockett	9
Dr Giles McCracken	1
Mrs Biserka Ross	5
Dr John Toy	7
Mr Chris Turnock	8
Mr John Warden	6
Ms Lorraine Wright	9

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

Name	Number of Meetings Attended
Dr David Cairns	1
Ms Linda Chadd	5
Mr Steve Chandler	5
Professor Chris Colbourn	3
Ms Danni Collingridge Moore	1
Dr Mary Connor	1
Mrs Janet Hattle	4
Mrs Fan Hutchison	4
Mr Anthony Lockett	1
Mr Chris Turnock	3
Ms Lorraine Wright	2

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

Name	Number of Meetings Attended
Dr David Cairns	1

Ms Linda Chadd	6
Mr Steve Chandler	26
Mrs Janet Hattle	3
Mrs Fan Hutchison	2
Mr Anthony Lockett	2
Dr John Toy	1
Mr Chris Turnock	29
Ms Lorraine Wright	1

Training 01 April 2016 - 31 March 2017

Name of Member	Date	Event(s) attended
Ms Linda Chadd	06/07/2016	Local Training Day - North East and Yorkshire Regional Training
Ms Linda Chadd	22/03/2017	National Members Training Day
Mr Steve Chandler	06/04/2016	Quantitative Research Methods and Statistics: A Health Research Authority Workshop
Mr Steve Chandler	30/06/2016	Training for New REC Chairs
Mr Steve Chandler	06/07/2016	Regional Members' Training Day
Mr Steve Chandler	11/09/2016	Equality & Diversity
Mr Steve Chandler	22/03/2017	National Members Training Day
Professor Chris Colbourn	22/03/2017	National Members Training Day
Dr Mary Connor	06/07/2016	Regional Members' Training Day
Mrs Janet Hattle	06/07/2016	Local Training Day - North East and Yorkshire Regional Training
Mrs Janet Hattle	22/03/2017	National Members Training Day
Dr James Philip Hobkirk	10/01/2017	Induction
Dr James Philip Hobkirk	22/03/2017	National Members Training Day
Dr Jocelyn Hudson	06/07/2016	Regional Members' Training Day
Dr Jocelyn Hudson	07/07/2016	Members Induction - Online
Dr Jocelyn Hudson	29/08/2016	Equality & Diversity
Dr Jocelyn Hudson	15/09/2016	Members' Induction
Dr Jocelyn Hudson	22/03/2017	National Members Training Day
Mrs Fan Hutchison	22/03/2017	National Members Training Day
Mr Anthony Lockett	08/06/2016	Induction
Mr Anthony Lockett	27/06/2016	Equality & Diversity
Mr Anthony Lockett	29/06/2016	Training - Handling Health-Related Findings in Research (Joint MRC/HRA)
Mr Anthony Lockett	06/07/2016	Members' Regional Training Day
Mr Anthony Lockett	01/02/2017	Medical Devices Training Day
Mrs Biserka Ross	29/09/2016	Equality, Diversity & Human Rights
Mrs Biserka Ross	03/10/2016	Induction On-line Module
Mrs Biserka Ross	10/01/2017	Members Induction
Mrs Biserka Ross	01/02/2017	Medical Devices Training Day
Mrs Biserka Ross	22/03/2017	National Members Training Day
Dr John Toy	01/11/2016	Equality and Diversity
Dr John Toy	06/12/2016	Induction
Dr John Toy	16/02/2017	National Members Training Day
Mr Chris Turnock	17/08/2016	Equality & Diversity
Mr Chris Turnock	09/11/2016	Practicalities of Running a REC
Mr Chris Turnock	01/12/2016	National Training Day for Committee Chairs
Mr Chris Turnock	27/03/2017	Chairs Review Programme Workshop

Mr John Warden	06/07/2016	Regional Members' Training Day
Mr John Warden	05/09/2016	Equality & Diversity
Mr John Warden	27/09/2016	Induction On-line Module
Mr John Warden	10/01/2017	Induction
Ms Lorraine Wright	31/03/2017	SDL 2016 – 2017 – Ethics presentation, work related training surrounding ethical issues.

PART 2: REC WORKLOAD AND ACTIVITY DURING THE REPORTING PERIOD

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

Applications for full ethical review – Study Type	Number	%
Clinical Trial of Investigational Medicinal Product	5	10.20
Phase 1	12	24.49
Gene Therapy	3	6.12
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	0	0.00
Others	29	59.18
Total Applications Reviewed	49	100

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	4
Number of student applications reviewed	8
Number of paediatric applications reviewed	7
Number of device applications reviewed	9
Number of prisoner applications reviewed	5
Number of applications involving adults unable consent reviewed	1
Number of applications reviewed that are funded by the US DHHS	0
Number of qualitative applications reviewed	6

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

Decisions taken at meetings following review of applications	Number	%
Favourable Opinion with Standard Conditions	5	10.20
Favourable Opinion with Additional Conditions	3	6.12
Unfavourable Opinion	3	6.12
Provisional Opinion	38	77.55
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	49	100
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

Status of applications at date of generation of report	Number	%
Further Information Favourable Opinion with Standard Conditions	33	67.35
Further Information Favourable Opinion with Additional Conditions	4	8.16
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	5	10.20
Favourable Opinion with Additional Conditions	3	6.12
Unfavourable Opinion	3	6.12
Provisional Opinion	0	0.00
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	1	2.04
Total	49	100

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

Total Applications Reviewed	24
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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	0
Number of student applications reviewed	8
Number of paediatric applications reviewed	2
Number of device applications reviewed	1
Number of qualitative applications reviewed	5

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

Decisions taken at proportionate review sub-committee meetings	Number	%
Favourable Opinion with Standard Conditions	16	66.67
Favourable Opinion with Additional Conditions	4	16.67
No Opinion transfer to full committee for review	3	12.50
Provisional Opinion	1	4.17
Unfavourable Opinion	0	0.00
Total	24	100

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

Average number of applications reviewed per full meeting	4.90
Number of completed applications for full ethical review	48
Number of completed applications for full ethical review over 60 days	0
Number of completed applications over 60 days as a % of total	0.00%
Number of completed applications for full ethical review over 40 days	1
Number of completed applications over 40 days as a % of total	2.04%
Number of days taken to final decision – average (mean)	26
Number of completed proportionate review applications for ethical review	21
Number of completed proportionate review applications for ethical review over 21 days	0
Number of completed proportionate review applications over 21 days as a % of total	0.00%
Number of SSAs (non-Phase 1) reviewed	5
Number of completed applications for SSA review over 25 days	0
Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs	0.00%
Number of SSAs (Phase 1) reviewed	15
Number of completed applications for SSA review over 14 days	0
Number of completed applications for SSA review over 14 days as % of all Phase 1 SSAs	0.00%
Number of substantial amendments reviewed	84
Number of completed substantial amendments over 35 days	0
Number of completed substantial amendments over 35 days as a % of total substantial amendments	0.00%
Number of completed substantial amendments over 28 days	0
Number of completed substantial amendments over 28 days as a % of total substantial amendments	0.00%
Number of modified amendments reviewed	2
Number of completed modified amendments over 14 days	0
Number of completed modified amendments over 14 days as a % of total modified amendments	0.00%
Number of non substantial amendments received	107
Number of substantial amendments received for information	2
Number of substantial amendments received for new sites/PIs	8
Number of annual progress reports received	64

Number of safety reports received	20
Number of Serious Adverse Events received	1
Number of final reports received	115

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

Further Information Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
16/NE/0074	MAD, two period crossover study in type 2 diabetics	30
16/NE/0077	A Single Dose Study in Healthy Japanese and Non-Japanese subjects	23
16/NE/0078	DTX101 in adults with moderate/severe Haemophilia B	36
16/NE/0095	PReDicT: Predicting Response to Depression Treatment	34
16/NE/0114	Validity and reliability of Multiple Sclerosis Quality of Life -29	21
16/NE/0133	Describing patterns of cardiovascular disease risk profiles in Prisons	29
16/NE/0139	DA-8010 - A SAD/MAD Study	21
16/NE/0141	Gastric pH PPI	32
16/NE/0145	802HV106 PK and Safety Study of BIIB074 in Healthy Japanese subjects	31
16/NE/0174	Chronic Kidney Disease Patient Digital Resource Design v1	22
16/NE/0187	SENZA - UEP	23
16/NE/0198	Fimaporfin-induced Photochemical Internalisation in Healthy Subjects.	27
16/NE/0201	CRISP	26
16/NE/0218	The familial experience of adolescent self-harm (Version2)	26
16/NE/0221	Opportunistic Detection of Atrial Fibrillation v1	29
16/NE/0227	A Phase IIb study on the efficacy of FLU-v	28
16/NE/0264	Patient experience feedback in prison healthcare	21
16/NE/0291	Local Laboratory Reference Intervals	24
16/NE/0308	Mitochondrial Donation: Outcome at 18 months	29
16/NE/0315	SENZA SCI	25
16/NE/0316	Phase 1 Study CYP-001 for the Treatment of Acute Graft vs Host Disease	20
16/NE/0345	PRISM	23
16/NE/0346	ReActiv8-B, Revision B	22
16/NE/0370	SIDEROS, V1	30
16/NE/0381	Investigating Body Perception Disturbances in Eating Disorders	22
16/NE/0386	Ila: VBP15-002	28
16/NE/0387	Ila extension: VBP15-003	28
17/NE/0002	17208A Itraconazole on the PK, Safety and Tolerability of Lu AF35700	20
17/NE/0006	Electroencephalographic changes in spinal cord stimulation therapy	22
17/NE/0009	CAPSTONE 2	33
17/NE/0012	Alleviating Specific Phobias Experienced by Children Trial (ASPECT)	32
17/NE/0013	Single-Dose Study to Assess Bioavailability of LY3074828	24

17/NE/0033	MAP-BRONJ	29
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Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/NE/0098	The efficacy and effectiveness of insomnia management	27
16/NE/0180	Talking about hearing voices with close family, friends, or others 1.1	32
16/NE/0194	Water immersion in chronic stable heart failure - IMMERSE HF	30
16/NE/0195	Study into perpetrators of child sexual exploitation	25

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/0284	LY3305677 SAD Study in Healthy Subjects	9
16/NE/0371	Sepsis diagnosis testing v1	28
16/NE/0373	A Phase 1 study to assess the effect of BCX7353 on healthy volunteers	14
16/NE/0398	Clinical Study of the BioVentrix Revivent TCâ„¢	16
17/NE/0039	Influence of Body Position on Identification of Tuffier's Line	21

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/NE/0101	MT-3995-E11 - Mass Balance Study	24
16/NE/0199	I6F-MC-JJCG Bioavailability study of LY3039478 in healthy subjects	17
17/NE/0036	SIR-Spheres for the treatment of cholangiocarcinoma	24

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
16/NE/0126	NIR light as a treatment for age-related intellectual impairment	54
16/NE/0372	Clinical Study of the BioVentrix Revivent TCâ„¢	21
17/NE/0008	PROTECT: ProTmune in Hematologic Malignancies	28

Provisional Opinion		
REC Reference	Title	Number of Days on Clock

Provisional Opinion Pending Consultation with Referee		
REC Reference	Title	Number of Days on Clock

Further information response not complete		
REC Reference	Title	Number of Days on Clock

Withdrawn after the meeting		
REC Reference	Title	Number of Days on Clock
16/NE/0300	The effect of NIR light on cognitive function in over 50	28

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
16/NE/0178	patient experience of cognitive and mood assessment in stroke	13

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

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

Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
16/NE/0124	Blood spot insulin as an alternative to plasma insulin in children	8
16/NE/0125	Consent in paediatric and neonatal intensive care units	9
16/NE/0134	Service user involvement in the governance of Mental Health NHS FTs	6
16/NE/0177	Assessing data quality and under-coverage in administrative sources	20
16/NE/0179	The Meaning and Experience of Gratitude in Dementia	13
16/NE/0223	Case-control study investigating the psychology of recurrent DKA	18
16/NE/0285	SABR CtE v2.0	19
16/NE/0290	Assessment of DOAC therapy analysis at TGH (Version 1).	11
16/NE/0389	Social Prescribing: Engagement and outcomes for service users	11
16/NE/0390	ACT-FLARE pilot study	12
16/NE/0423	Promoting Dignity and Patient-Centred Care	14
16/NE/0424	I-ACT Study - Improving access to primary care	18
16/NE/0425	Experience of blended diet via gastrostomy in Leicestershire/Rutland	14
17/NE/0055	Behavioural design for bowel cancer screening uptake; A quasi RCT.	8
17/NE/0084	The ASSESS Study	14
17/NE/0087	May Measurement Month	14

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
16/NE/0225	The efficacy of pineapple juice for tissue dissolution	18
16/NE/0226	Survival outcomes in elderly/poor PS patients with glioblastoma	18
16/NE/0257	Enhancing Post-Injury Psychological Intervention and Care (EPPIC) v1.5	20
16/NE/0260	Self-care and mental health in Essex	15

Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock

Provisional Opinion		
REC Reference	Title	Number of Days on Clock

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

Favourable opinion				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
00/3/001/AM05	Yorkshire Specialist Register of Cancer in Children and Young People	Amendment 8, Jan 2017	20/01/2017	12
01/3/022/AM07	UK and Ireland JDM Registry and Repository	Substantial Amendment 11, 10/0	23/05/2016	3
04/3/006/AM09	Arterial Revascularisation Trial (ART)	Amendment 2a, dated 15 November 2016	13/12/2016	18
04/MRE03/80/AM09	Alexion PNH Registry M07-001	PA6.0 – 08-Jun-16	15/02/2017	15
05/MRE03/4/AM06	Randomised controlled trial of adjuvant imatinib for GIST - Version 1	Substantial Amendment 5	30/03/2016	13
08/H0903/62/AM09	Prognostic and predictive factors in colorectal cancer	Substantial Amendment 9 - 1/11	01/11/2016	17
09/H0903/10/AM16	Ofatumumab fludarabine cyclophosphamide in relapsed CLL V1.0	Change if Sponsor	26/07/2016	22
09/H0903/7/AM18	Study of ofatumumab plus chlorambucil in previously untreated CLL: v01	Substantial Amendment - Change	17/05/2016	9
11/NE/0245/AM04	Responding to diversity in 3 Yorkshire prisons:an Appreciative Inquiry	Substantial Amendment 3	06/07/2016	6
12/NE/0010/AM07	Study of Brentuximab Vedotin in Pediatric Patients with Lymphoma	Substantial Amendment to IB (Edition 14) dated 21 Oct 2016	21/02/2017	9
12/NE/0388/AM09	The AMICI trial	Protocol Amendment v8.0	10/08/2016	7
13/NE/0005/AM06	Product Surveillance Registry Base Protocol, Version 2.	Substantial amendment 3, 14/09	15/09/2016	13
13/NE/0104/AM03	Product Surveillance Registry Base Protocol, Version 3.	Substantial	14/10/2016	17

		Amendment 2 - 14/1		
13/NE/0201/AM11	Olaparib maintenance monotherapy in ovarian cancer	Substantial Amendment 8, 15/03	18/03/2016	21
13/NE/0234/AM03	Effect of Pulsed RF treatment of dorsal root ganglion on fMRI	Substantial Amendment 2, 26/04	29/04/2016	8
13/NE/0292/AM08	Cardiac MRI in HF-PEF	Substantial Amendment 4, 23/03	06/04/2016	11
14/NE/0122/AM05	WA29231 - Long term extension study of tocilizumab in children	Substantial Amendment 4, 23/11	31/03/2016	12
14/NE/0122/AM06	WA29231 - Long term extension study of tocilizumab in children	Substantial Amendment 5	19/09/2016	11
14/NE/0124/AM03	Targeted chemotherapy using focused ultrasound for liver tumours	Substantial Amendment 5, 14/03	06/04/2016	14
14/NE/1001/AM03	ReActiv8-A	Substantial Amendment 3 - 29/1	29/11/2016	16
14/NE/1006/AM01	Sodium Accumulation in Multiple sclerosis	Substantial Amendment 1 - 1/11	01/11/2016	10
14/NE/1037/AM03	Parkinson's pen project 1	Substantial Amendment 3, 21/06	22/06/2016	8
14/NE/1049/AM07	Einstein Junior Phase II: Paediatric oral rivaroxaban (BAY59-7939)	Substantial Amendment 6 - Chan	13/05/2016	13
14/NE/1103/AM09	Pfizer A3921187- Phase 3b/4 Tofacitinib (CP-690,550-10)for RA	Substantial Amendment - Update	11/05/2016	15
14/NE/1169/AM08	Impact of RA characteristics on outcome of study drug dose tapering	Substantial Amendment 5, 25/02	14/04/2016	8

14/NE/1189/AM08	Single ascending dose study for Two Glucagon compounds	Substantial Amendment Protocol	09/03/2016	28
14/NE/1249/AM07	Phase 2 study of Cobimetinib in TNBC	SA7	16/09/2016	10
15/NE/0006/AM07	ADSTEM	Substantial amendment 3	20/02/2017	7
15/NE/0042/AM03	Peer led interventions to address NCD risk factors in prisons	Substantial Amendment 2	18/07/2016	10
15/NE/0052/AM02	PEDAL: Long-term Outcome of Children Enrolled in Study ROPP-2008-01	Substantial Amendment 1.2	27/04/2016	6
15/NE/0104/AM02	MYOPROSP	Substantial Amendment 2, 07/03	11/05/2016	13
15/NE/0104/AM03	MYOPROSP	Substantial Amendment 3, 12/07	14/07/2016	7
15/NE/0104/AM07	MYOPROSP	Substantial Amendment 16/10/16	16/10/2016	9
15/NE/0167/AM13	MLN9708 in Multiple Myeloma Not Treated with Stem Cell transplantation	Amendment 8	28/07/2016	20
15/NE/0167/AM14	MLN9708 in Multiple Myeloma Not Treated with Stem Cell transplantation	Substantial Amendment 9 - 26/1	26/10/2016	13
15/NE/0167/AM19	MLN9708 in Multiple Myeloma Not Treated with Stem Cell transplantation	Amendment 12	10/03/2017	14
15/NE/0375/AM02	Advanced solid tumours Phase 1 safety & tolerability study U3-1784	Substantial Amendment 2	14/07/2016	14
15/NE/0378/AM01	Brain imaging and cognition in DMD	SA1	03/08/2016	13
15/NE/0389/AM04	ABY-035 - Phase I study in healthy subjects and psoriasis patients	Substantial amendment 3, 15/06	16/06/2016	20
15/NE/0389/AM05	ABY-035 - Phase I study in healthy subjects and psoriasis patients	Substantial Amendment 4, 20/06	30/06/2016	7
15/NE/0389/AM06	ABY-035 - Phase I study in healthy subjects and psoriasis	SA 5 - 06/07/2016	08/07/2016	17

	patients			
15/NE/0389/AM09	ABY-035 - Phase I study in healthy subjects and psoriasis patients	Substantial Amendment 6	30/08/2016	14
15/NE/0389/AM10	ABY-035 - Phase I study in healthy subjects and psoriasis patients	Substantial amendment 7, 15/09	21/09/2016	27
15/NE/0389/AM12	ABY-035 - Phase I study in healthy subjects and psoriasis patients	Substantial Amendment 8 - 15/9	15/09/2016	22
15/NE/0389/AM13	ABY-035 - Phase I study in healthy subjects and psoriasis patients	Substantial Amendment 9 (Proto	06/02/2017	9
15/NE/0389/AM14	ABY-035 - Phase I study in healthy subjects and psoriasis patients	Substantial Amendment 10	27/02/2017	15
15/NE/0417/AM01	Ultrasound assessment of Bladder Sphericity in diagnosis of OAB	Substantial Amendment 01, 28.1	20/12/2016	14
15/NE/0426/AM01	Validating and piloting the ACHE Tool	Substantial Amendment 1	25/05/2016	11
16/NE/0010/AM01	ALN-GO1 in Healthy Adult Subjects and Patients with PH1	Substantial Amendment 1	24/03/2016	22
16/NE/0010/AM03	ALN-GO1 in Healthy Adult Subjects and Patients with PH1	Substantial Amendment 2	09/05/2016	17
16/NE/0010/AM04	ALN-GO1 in Healthy Adult Subjects and Patients with PH1	SA 3	07/07/2016	17
16/NE/0010/AM05	ALN-GO1 in Healthy Adult Subjects and Patients with PH1	Substantial amendment 4	26/09/2016	22
16/NE/0010/AM06	ALN-GO1 in Healthy Adult Subjects and Patients with PH1	Substantial Amendment 5 - 31/1	31/10/2016	6
16/NE/0010/AM08	ALN-GO1 in Healthy Adult Subjects and Patients with PH1	Substantial Amendment 7 - 19/1	19/12/2016	18
16/NE/0010/AM09	ALN-GO1 in Healthy Adult Subjects and Patients with PH1	Substantial Amendment 9	03/03/2017	11
16/NE/0030/AM01	Skin Camouflage for Women Prisoners with Self-Harm Scarring: Version 2	Substantial Amendment 1	19/04/2016	16

16/NE/0074/AM01	MAD, two period crossover study in type 2 diabetics	Substantial Amendment 1, 14/06	04/07/2016	20
16/NE/0074/AM02	MAD, two period crossover study in type 2 diabetics	Substantial amendment 2, 31/08	15/09/2016	12
16/NE/0074/AM04	MAD, two period crossover study in type 2 diabetics	Substantial Amendment 3 - 9/11	09/11/2016	5
16/NE/0078/AM02	DTX101 in adults with moderate/severe Haemophilia B	Substantial amendment 1	19/09/2016	9
16/NE/0078/AM05	DTX101 in adults with moderate/severe Haemophilia B	Amendment 2	06/01/2017	15
16/NE/0095/AM04	PReDicT: Predicting Response to Depression Treatment	1.0, 17th January 2017	18/01/2017	12
16/NE/0139/AM01	DA-8010 - A SAD/MAD Study	Substantial Amendment 1, 27/05	03/06/2016	15
16/NE/0145/AM01	802HV106 PK and Safety Study of BIIB074 in Healthy Japanese subjects	Substantial Amendment 1, 09/08	30/08/2016	15
16/NE/0187/AM02	SENZA - UEP	SA1	23/08/2016	23
16/NE/0194/AM01	Water immersion in chronic stable heart failure - IMMERSE HF	Substantial Amendment 1, 21/07	06/09/2016	7
16/NE/0198/AM01	Fimaporfin-induced Photochemical Internalisation in Healthy Subjects.	Substantial Amendment 1 - 30/1	30/11/2016	13
16/NE/0199/AM01	I6F-MC-JJCG Bioavailability study of LY3039478 in healthy subjects	Substantial Amendment 1, 16/08	26/08/2016	8
16/NE/0227/AM01	A Phase IIb study on the efficacy of FLU-v	SA1	26/09/2016	21
16/NE/0257/AM02	Enhancing Post-Injury Psychological Intervention and Care (EPPIC) v1.5	SA 1	30/09/2016	22
16/NE/0260/AM01	Self-care and mental health in Essex	Substantial Amendment 1	23/09/2016	25
16/NE/0260/AM02	Self-care and mental health in Essex	Substantial	21/10/2016	15

		Amendment 2 - 21/1		
16/NE/0316/AM01	Phase 1 Study CYP-001 for the Treatment of Acute Graft vs Host Disease	Substantial Amendment 1 - 28/1	28/11/2016	7
16/NE/0346/AM01	ReActiv8-B, Revision B	Substantial Amendment #1 dd. 2	23/01/2017	8
16/NE/0370/AM02	SIDEROS, V1	SA2	08/02/2017	13
16/NE/0373/AM01	A Phase 1 study to assess the effect of BCX7353 on healthy volunteers	Substantial Amendment 1 - 9/12	09/12/2016	6
16/NE/0386/AM01	Ila: VBP15-002	Protocol #2 20 Jan 17 and IB v	29/01/2017	17
16/NE/0386/AM03	Ila: VBP15-002	New IB v5 22 Feb 2017	03/03/2017	15
16/NE/0387/AM01	Ila extension: VBP15-003	New IB v4 10 Jan 2017	29/01/2017	17
16/NE/0387/AM04	Ila extension: VBP15-003	New IB V5 dated 22 Feb 2017	14/03/2017	10
16/NE/0424/AM01	I-ACT Study - Improving access to primary care	version 2	23/02/2017	19
17/NE/0033/AM01	MAP-BRONJ	Substantial Amendment 1 10/03/	10/03/2017	14
17/NE/0039/AM01	Influence of Body Position on Identification of Tuffier's Line	1 22/02/17	06/03/2017	9

Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
15/NE/0363/AM01	Corneal imaging to monitor disease progression and/or treatments	Substantial Amendment 1, 21/03	30/03/2016	15

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
15/NE/0363/AM01/1	Corneal imaging to monitor disease progression and/or treatments	Modified Substantial Amendment	02/06/2016	3
15/NE/0389/AM01/1	ABY-035 - Phase I study in healthy subjects and psoriasis patients	Modified Amendment 3, 11/04/20	14/04/2016	4

Unfavourable opinion timeline				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock

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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