

North East - York Research Ethics Committee

Annual Report

01 April 2015 - 31 March 2016



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 Healthy Volunteers, Phase I in Patients, Prisoners, Paediatrics, Medical Devices, Gene Therapy or Stem Cell Clinical Trials, Type III (CTIMP)
Chair:	Mr Chris Turnock (from 01/02/16) Professor Peter Heasman (until 31/01/16)
Vice-Chair:	Mr Steve Chandler (from 10/08/15)
Alternate Vice-Chair:	Dr Giles McCracken
REC Manager:	Gillian Mayer (from 01/02/16 – Present) Helen Wilson (from 01/08/15 – 31/01/2016) Hayley Henderson (from 30/04/15 – 31/07/2015)
REC Assistant:	Donna Bennett
Committee Address:	HRA Jarrow Jarrow Business Centre Rolling Mill Road Jarrow NE32 3DT
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Chair's overview of the past year:

I have recently taken over as chair of the committee following the resignation of Peter Heasman. On behalf of the committee, I would like to convey the members' gratitude for the efficient way Peter chaired committee meetings and we all wish him good luck as he moves onto pastures new. Two other members left the committee including the Vice Chair, Sarah Bartlett. I would like to thank both Sarah and Malcolm Harrison 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 Sarah Bartlett	Consultant Child & Adolescent Psychiatrist	Expert	01/07/2008	10/04/2015
Dr David Cairns	Principal Statistician	Expert	08/10/2013	
Ms Linda Chadd	Library Assistant & 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	
Dr Mary Connor	Coaching & Mentoring Consultant	Lay Plus	05/10/2010	
Mr Malcolm G Harrison	Retired Lawyer	Lay Plus	13/07/2007	18/01/2016
Professor Peter Heasman	Professor of Periodontology	Expert	01/01/2006	31/01/2016
Mrs Janet Hattle	Pharmacist	Expert	01/05/2008	
Mr Peter Hopley	Pharmacist	Expert	01/01/2016	
Mrs Fan Hutchison	Principal Teacher	Lay Plus	16/12/2012	
Dr Giles McCracken	Senior Clinical Lecturer	Expert	01/04/2008	
Mrs Viktoria McDonald	Senior Consultant	Lay	01/06/2015	29/02/2016
Mr Chris Turnock	Head of Technology Enhanced Learning	Expert	01/09/2014	
Ms Lorraine Wright	Senior Research Nurse	Expert	01/04/2010	

North East - York Research Ethics Committee: Deputy Members

N/A

North East - York Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended
Ms Danni Collingridge Moore	Research Fellow	Lay	12/06/15
Dr Rhona Bratt	Retired Multimedia Project Manager	Lay Plus	10/07/2015 11/12/2015
Mr Satti Saggu	Senior Associate for Research	Lay Plus	10/07/2015
Mr Michael Davidson	Retired Personnel Manager	Lay Plus	11/09/2015
Mrs Ann Kay	Retired Special Needs Co-ordinator	Lay	11/09/2015
Dr Nana Theodorou	Specialist Orthoptist	Expert	13/11/2015
Dr Caroline Magee	Communications Consultant	Lay	23/04/15 (PR)
Mr Paddy Stevenson	Research Operations Manager	Expert	12/08/15 (PR) 26/11/15 (PR)

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

Name	Declaration of Interest	Date
Dr David Cairns	Independent peer-reviewer for Cancer Research UK, the National Institute of Health Research and the UK Medical Research Council.	17/01/2016
Ms Linda Chadd	No interests declared.	13/01/16
Mr Steve Chandler	No interests declared.	13/01/2016
Professor Chris Colbourn	Member of Teesside University, School of Health and Social Care, Research Governance and Ethics Committee. Research Director for the Doctorate of Clinical Psychology Programme, School of Health and Social Care, Teesside University. Occasional peer review for research funding applications to various private and public bodies and for manuscripts submitted for publication in various psychology research journals.	29/01/2016
Dr Mary Connor	No interests declared.	10/02/2016
Mrs Janet Hattle	No interests declared.	13/02/16
Mr Peter Hopley	No interests declared.	12/01/2016
Mrs Fan Hutchison	No interests declared.	15/01/16
Dr Giles McCracken	Works as a clinical academic at Newcastle university undertaking clinical research. Peer reviewer for journals.	18/01/2016
Mrs Viktoria McDonald	The possibility of occasional declarations of interest cannot be excluded due to part time employment with a scientific consultancy that is primarily engaged in non-clinical safety assessment of pharmaceuticals and could sometimes relate to a clinical research project. Any special interests will be declared as soon as possible should they arise.	22/06/2015
Mr Chris Turnock	Member of University of Hull, Faculty of Education Research Committee.	13/01/2016
Ms Lorraine Wright	No interests declared.	17/02/2016

Meetings for Full Ethical Review 01 April 2015 - 31 March 2016:

Month	Date	Number of Members Present at Meeting
April	10/04/2015	8
May	08/05/2015	8
June	12/06/2015	9
July	10/07/2015	8
September	11/09/2015	8
October	09/10/2015	10
November	13/11/2015	8
December	11/12/2015	9
January	15/01/2016	13
February	12/02/2016	9

10 full committee meetings were held during the reporting period.

Proportionate Review Sub-Committee Meetings held during 01 April 2015 - 31 March 2016:

Month	Date	Number of Members Present at Meeting
April	23/04/2015	3
May	22/05/2015	3
June	26/06/2015	3
July	24/07/2015	3
August	12/08/2015	3
September	24/09/2015	3
October	22/10/2015	3
November	26/11/2015	3
December	11/12/2015	3
January	26/01/2016	3
February	18/02/2016	3
March	23/03/2016	3

12 proportionate review sub-committee meetings were held during the reporting period.

Sub-Committee Meetings held during 01 April 2015 - 31 March 2016:

Month	Date	Number of Members Present at Meeting
April	02/04/2015	2
April	17/04/2015	2
May	01/05/2015	2
May	15/05/2015	2
May	29/05/2015	2
June	12/06/2015	2
June	26/06/2015	2
July	10/07/2015	2
July	24/07/2015	2
August	07/08/2015	2

August	21/08/2015	2
September	04/09/2015	2
September	18/09/2015	2
September	29/09/2015	2
October	16/10/2015	2
October	30/10/2015	2
November	02/11/2015	3
November	13/11/2015	2
November	27/11/2015	2
December	23/12/2015	2
January	11/01/2016	2
January	25/01/2016	2
February	03/02/2016	2
February	17/02/2016	2
March	02/03/2016	3
March	16/03/2016	2
March	16/03/2016	2

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

Details of inquorate meeting held:01 April 2015 - 31 March 2016

Date	Reason	Action taken

N/A

Attendance of Members at full committee meetings: 01 April 2015 - 31 March 2016

Name	Number of Meetings Attended
Dr Sarah Bartlett *	1
Dr David Cairns	6
Ms Linda Chadd	9
Mr Steve Chandler	9
Professor Chris Colbourn	5
Dr Mary Connor *	5
Mr Malcolm G Harrison*	2
Mrs Janet Hattle	7
Professor Peter Heasman	7
Mr Peter Hopley *	2
Mrs Fan Hutchison *	3
Dr Giles McCracken	7
Mrs Viktoria McDonald	6
Mr Chris Turnock	8
Ms Lorraine Wright	6

- * SB : Resigned 10/04/15
 MC: Period of leave 24/04/15 – 10/09/15
 PH: Resigned: 31/01/16
 FH: Period of leave 10/09/15 - 05/01/16
 PH: Appointed 01/01/16
 MH: Resigned 15/01/16

Attendance of Members at proportionate review sub-committee meetings: 01 April 2015 - 31 March 2016

Name	Number of Meetings Attended
Ms Linda Chadd	3
Mr Steve Chandler	4
Dr Mary Connor	3
Mr Malcolm G Harrison	3
Mrs Janet Hattle	3
Professor Peter Heasman	3
Mrs Fan Hutchison	2
Dr Giles McCracken	4
Mr Chris Turnock	6
Ms Lorraine Wright	2

Attendance of Members at sub-committee meetings: 01 April 2015 - 31 March 2016

Name	Number of Meetings Attended
Dr David Cairns	2
Mr Steve Chandler	22
Mrs Janet Hattle	1
Professor Peter Heasman	1
Dr Giles McCracken	25
Mrs Viktoria McDonald	1
Mr Chris Turnock	4

Training 01 April 2015 - 31 March 2016

Name of Member	Date	Event(s) attended
Dr David Cairns	16/03/2016	National Members' Training Day
Ms Linda Chadd	04/06/2015	Regional Members' Training Day
Ms Linda Chadd	06/10/2015	Quantitative Research Methods and Statistics: A Health Research Authority Workshop
Ms Linda Chadd	11/03/2016	Training - Genetic and Genomic Research (previously HTA Advanced)
Ms Linda Chadd	16/03/2016	National Members' Training Day
Mr Steve Chandler	04/06/2015	Regional Members' Training Day
Professor Chris Colbourn	04/11/2015	Induction
Professor Chris Colbourn	16/03/2016	National Members' Training Day
Mrs Janet Hattle	04/06/2015	Regional Members' Training Day
Mr Peter Hopley	16/03/2016	National Members' Training Day
Mrs Fan Hutchison	16/03/2016	National Members' Training Day
Dr Giles McCracken	27/11/2015	CTIMP Training Day
Mrs Viktoria McDonald	24/09/2015	Members' Induction Training
Mr Chris Turnock	19/11/2015	Personal Data in Research - A Workshop
Ms Lorraine Wright	15/03/2016	GCP Training

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	8	18.60
Phase 1	12	27.91
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	0	0.00
Others	23	53.49
Total Applications Reviewed	43	100

Table 2: Breakdown of full applications and other activity during reporting period

Number of applications made invalid by the REC Manager	1
Number of applications withdrawn prior to the meeting	2
Number of student applications reviewed	10
Number of paediatric applications reviewed	6
Number of device applications reviewed	
Number of prisoner applications reviewed	3
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	3

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	11.63
Favourable Opinion with Additional Conditions	6	13.95
Unfavourable Opinion	3	6.98
Provisional Opinion	29	67.44
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	43	100
Number of studies sent back to full committee meeting for final opinion	1	

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	27	62.79
Further Information Favourable Opinion with Additional Conditions	1	2.33
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	5	11.63
Favourable Opinion with Additional Conditions	6	13.95
Unfavourable Opinion	3	6.98
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	2.33
Total	43	100

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

Total Applications Reviewed	30
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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	7
Number of studies withdrawn prior to the meeting	0
Number of student applications reviewed	12
Number of paediatric applications reviewed	4
Number of device applications reviewed	2
Number of qualitative applications reviewed	1

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	15	50.00
Favourable Opinion with Additional Conditions	3	10.00
No Opinion transfer to full committee for review	3	10.00
Provisional Opinion	8	26.67
Unfavourable Opinion	1	3.33
Total	30	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	4.30
Number of completed applications for full ethical review	42
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	2.33%
Number of days taken to final decision – average (mean)	24
Number of completed proportionate review applications for ethical review	26
Number of completed proportionate review applications for ethical review over 14 days	0
Number of completed proportionate review applications over 14 days as a % of total	0.00%
Number of SSAs (non-Phase 1) reviewed	0
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	12
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	79
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	2
Number of completed substantial amendments over 28 days as a % of total substantial amendments	2.53%
Number of modified amendments reviewed	0
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 minor amendments received	68
Number of substantial amendments received for information	0
Number of substantial amendments received for new sites/PIs	14
Number of annual progress reports received	54
Number of safety reports received	21
Number of Serious Adverse Events received	3
Number of final reports received	46

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
15/NE/0092	GB29751 Single and Multiple ascending dose study	18
15/NE/0163	ADjuST study	22
15/NE/0167	MLN9708 in Multiple Myeloma Not Treated with Stem Cell transplantation	24
15/NE/0168	CA2014OUS CM Rev A 26 February 2015	17
15/NE/0203	Brain PET/MR versus PET/CT	32
15/NE/0204	PROSPER - Hepatic Encephalopathy Observational Study ZZ2014GL03	25
15/NE/0207	PICTURE project - Magnetic Resonance Elastography	29
15/NE/0214	Prediction of early pregnancy viability	20
15/NE/0218	FKB327-005	25
15/NE/0220	Intra-cranial pressure changes between supine and upright	25
15/NE/0241	TAK-094 First in Human Study	21
15/NE/0293	Open Label ESL Extension (FROM IMPORT)	35
15/NE/0298	Phase IIIB/IV study of NVA237 in patients with moderate to severe COPD	42
15/NE/0304	Does FENIX Magnetic Sphincter Augmentation alter Anorectal Physiology?	27
15/NE/0319	Neutrophil function after cardiopulmonary bypass	23
15/NE/0332	Testosterone therapy in Duchenne Muscular Dystrophy	19
15/NE/0367	Comprehensive framework to support & assess surgical training progress	31
15/NE/0375	Advanced solid tumours Phase 1 safety & tolerability study U3-1784	28
15/NE/0376	Phase I Mass Balance Study	20
15/NE/0378	Brain imaging and cognition in DMD	26
15/NE/0389	ABY-035 - Phase I study in healthy subjects and psoriasis patients	29
15/NE/0407	SCS modulates central sensitization processes	26
16/NE/0001	802HV104 DDI Itraconazole effect on the PK of BIIB074	26
16/NE/0007	Managing Fatigue with physical ACTivity monitors (FACT study)	25
16/NE/0010	ALN-GO1 in Healthy Adult Subjects and Patients with PH1	31
16/NE/0012	LMTM DDI Study	30
16/NE/0054	Jasint-2	25

Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/NE/0041	Palliative care in pulmonary arterial hypertension	27

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
15/NE/0111	Phase I study to determine the BE of TA-8995 in healthy males	17
15/NE/0145	NAK-10 AME Study	18
15/NE/0299	MoRE: Models of Reablement Evaluation (Version 1)	24
15/NE/0345	Agreement of ECG and Echocardiogram at Stress Echocardiography (1)	18
16/NE/0009	SILO2 (Signal Intensity Lung washOut)	18

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/NE/0108	OPS 2071 AME study in healthy male Japanese subjects	17
15/NE/0219	PCF and the perceived care of older people on MH inpatient wards.	24
15/NE/0262	Language profiles of the male, juvenile, custodial population in UK	24
15/NE/0380	Jewel ACL Study	25
15/NE/0398	Mi-ECMO	26
16/NE/0030	Skin Camouflage for Women Prisoners with Self-Harm Scarring: Version 2	20

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
15/NE/0193	Phase IIIB/IV study of NVA237 in patients with moderate to severe COPD	24
15/NE/0356	NIR light as a treatment for age-related intellectual impairment	25
15/NE/0404	Skin Camouflage for Women Prisoners with Self-Harm Scarring	36

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

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/0013	Gastric pH/PPI	10

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
15/NE/0161	Pharmacokinetics of rivaroxaban: Genomic effects	10
15/NE/0162	Describing the management of fibromyalgia by community pain clinic-V1	8
15/NE/0235	Mirvaso® Utilization and Patient Satisfaction Study - MUSE	12
15/NE/0344	Direct Muscle Stimulation in Critical Illness Myopathy	12
15/NE/0346	Motor Cortex Excitability in Neuromuscular disorders	13
16/NE/0071	US-PEx: Understanding how frontline staff use patient experience data	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
15/NE/0157	Use of human biological material for drug discovery	8
15/NE/0189	CWL-CT-001	7
15/NE/0265	Exploring pain in the CP population: Piloting a big data approach.	8
15/NE/0267	Variability of temperature during chemotherapy treatment	7
15/NE/0289	TT-TG distance in different positions of the leg	10
15/NE/0291	Philips Study - remote cough monitoring in COPD	10
15/NE/0343	ALN-AAT-NT-002 Retrospective chart review	12
15/NE/0363	Corneal imaging to monitor disease progression and/or treatments	8
15/NE/0365	Predictive Genetic Testing in Young Adults: A Qualitative Study	9
15/NE/0366	Immune responses in perinephric fat	8
15/NE/0426	Validating and piloting the ACHE Tool	7
15/NE/0427	Parental adjustment following paediatric burn injury - version 1	7
16/NE/0103	FCR Pilot Study	5
16/NE/0104	Qualitative Study: Understanding recruitment processes	7
16/NE/0105	Improving the diagnosis of myeloid malignancies	7

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
15/NE/0160	Dicrotic notch and hypotension at caesarean under spinal anaesthesia.	8
15/NE/0417	Ultrasound assessment of Bladder Sphericity in diagnosis of OAB	8
16/NE/0072	Psychological effects of a Behcet's diagnosis	13

Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock
15/NE/0186	Acoustic emission assessment of knee joint degeneration	7

Provisional Opinion		
REC Reference	Title	Number of Days on Clock
15/NE/0416	Evaluation of toe pressure PPG measurement in diabetics with PAD	n/a

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
15/NE/0187	Umbilical cord Cell Model of Inflammation and Disease	5

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
01/3/022/AM05	UK and Ireland JDM Registry and Repository	Substantial Amendment 9, 17/06	23/06/2015	17
01/3/022/AM06	UK and Ireland JDM Registry and Repository	Substantial Amendment 10 - 15/	15/11/2015	12
05/MRE03/17/AM06	VIM	Substantial Amendment 7, 24/08	10/11/2015	27
06/MRE03/3/AM12	VORTEX - version 1	Substantial Amendment 5 - 19/8	20/08/2015	22
06/MRE03/9/AM03	United Kingdom Paediatric Chronic ITP Registry version 1.0	Substantial Amendment 2 - 10/6	10/06/2015	32
07/MRE03/23/AM05	Quality of low rectal cancer surgery - version 1	Substantial Amendment5: Protoc	19/01/2016	14
07/MRE03/24/AM05	Quality of colonic cancer surgery - version 1	Substantial Amendment 5: Proto	19/01/2016	14
10/H0903/29/AM17	Eslicarbazepine acetate monotherapy in newly diagnosed focal epilepsy	Substantial Amendment 2 - Clin	05/05/2015	18
10/H0903/42/AM01	Dialectical Behaviour Therapy for Female offenders: A Single Case Study	Substantial Amendment 1, March	15/05/2015	16
10/H0903/7/AM14	Daclizumab Long-Term Safety and Efficacy Extension Study in MS	Substantial Amendment 4: IB11,	15/05/2015	17
11/H0903/6/AM02	Investigating variations in colorectal anatomy	Substantial Amendment 2 Feb2	26/02/2016	16
11/NE/0022/AM21	BABY (Born and Bred in Yorkshire)	Substantial	15/05/2015	17

		Amendment 10, 14/0		
11/NE/0022/AM22	BABY (Born and Bred in Yorkshire)	Substantial Amendment 11, 29/0	03/02/2016	16
11/NE/0174/AM07	TRYTON IDE	Substantial Amendment 7 Protoc	18/03/2015	10
11/NE/0245/AM02	Responding to diversity in 3 Yorkshire prisons: an Appreciative Inquiry	Substantial Amendment 2, 18/05	20/05/2015	12
12/NE/0010/AM04	Study of Brentuximab Vedotin in Pediatric Patients with Lymphoma	Substantial Amendment Investig	30/04/2015	12
12/NE/0010/AM05	Study of Brentuximab Vedotin in Pediatric Patients with Lymphoma	Substantial Amendment Investig	03/02/2016	15
12/NE/0186/AM02	Observational Study of Patients administered Cinryze for HAE	Substantial Amendment 2 - Prot	02/09/2015	20
12/NE/0228/AM07	TiLTS-cc	Substantial Amendment 6, 30/06	27/07/2015	7
12/NE/0385/AM02	Arthrodesis v Proximal Phalanx Hemiarthroplasty for Hallux Rigidus	Substantial Amendment 2 v5.4	10/09/2015	14
12/NE/0388/AM07	The AMICI trial	Substantial Amendment - Update	17/06/2015	21
13/NE/0005/AM03	Product Surveillance Registry Base Protocol, Version 2.	Substantial Amendment 2, 19/06	01/07/2015	9
13/NE/0182/AM04	Volume Guarantee [®] or Volume-Controlled Ventilation, version 6	Substantial Amendment 2	08/06/2015	22
13/NE/0292/AM07	Cardiac MRI in HF-PEF	Substantial Amendment 2 (CD13/	25/02/2016	25
13/NE/0323/AM05	VLA009 Systemic Treatment of Resistant Metastatic Disease	Substantial	04/09/2015	10

	(STORM)	Amendment 4: Update		
14/NE/0004/AM03	The Prevalence of Non-Communicable Diseases in Prisons	Substantial Amendment 2, 15/01	26/01/2016	9
14/NE/0114/AM12	Mind-mindedness Intervention	Substantial Amendment 3	19/03/2015	19
14/NE/0114/AM13	Mind-mindedness Intervention	Substantial Amendment 4, 01/04	02/04/2015	18
14/NE/0114/AM14	Mind-mindedness Intervention	Substantial Amendment 5	26/05/2015	22
14/NE/0115/AM01	Cardiac MRI in Prediction of Myocardial Hibernation Recovery - Pilot	Substantial Amendment 1, 08/04	14/04/2015	21
14/NE/0115/AM02	Cardiac MRI in Prediction of Myocardial Hibernation Recovery - Pilot	Substantial Amendment 2, 12/05	20/05/2015	12
14/NE/1001/AM02	ReActiv8-A	Substantial Amendment 2, 20/07	23/07/2015	11
14/NE/1011/AM01	Participants' Experiences of a 'Friends and Family Day' (v.2)	Substantial Amendment 1, 26/01	18/02/2016	9
14/NE/1013/AM01	LLJ_Version 1.0	Substantial Amendment 1, 04/02	12/02/2016	24
14/NE/1037/AM01	Parkinson's pen project 1	Substantial Amendment 1 - 4/12	04/12/2015	9
14/NE/1037/AM02	Parkinson's pen project 1	Substantial Amendment 2, 22/01	27/01/2016	22
14/NE/1049/AM03	Einstein Junior Phase II: Paediatric oral rivaroxaban (BAY59- 7939)	Substantial amendment 3 study	03/06/2015	16
14/NE/1049/AM04	Einstein Junior Phase II: Paediatric oral rivaroxaban (BAY59- 7939)	Substantial Amendment 4,	27/08/2015	11

		14/04		
14/NE/1049/AM05	Einstein Junior Phase II: Paediatric oral rivaroxaban (BAY59-7939)	Substantial Amendment 5	24/09/2015	13
14/NE/1087/AM02	Development and Validation of a PROM for PNI of the Hand	Substantial Amendment 1: Proto	11/09/2015	7
14/NE/1087/AM03	Development and Validation of a PROM for PNI of the Hand	Substantial Amendment 2, 02/03	03/03/2016	16
14/NE/1103/AM06	Pfizer A3921187- Phase 3b/4 Tofacitinib (CP-690,550-10)for RA	Substantial Amendment 6 - Addi	30/04/2015	12
14/NE/1103/AM07	Pfizer A3921187- Phase 3b/4 Tofacitinib (CP-690,550-10)for RA	Substantial Amendment 7 - Out	01/09/2015	20
14/NE/1129/AM02	PICSO as an adjunct to PCI in acute coronary syndrome	Substantial Amendment1	28/01/2016	21
14/NE/1169/AM03	Impact of RA characteristics on outcome of study drug dose tapering	Substantial Amendment 2, 03/06	20/07/2015	24
14/NE/1178/AM02	NEO6860 SAD, MAD Study	Substantial Amendment 3, 29/05	04/06/2015	13
14/NE/1189/AM05	Single ascending dose study for Two Glucagon compounds	Substantial Amendment 3 - 17U-	22/06/2015	24
14/NE/1189/AM06	Single ascending dose study for Two Glucagon compounds	Substantial Amendment 4	05/08/2015	8
14/NE/1189/AM07	Single ascending dose study for Two Glucagon compounds	Substantial Amendment 1 Tempor	15/09/2015	14
14/NE/1246/AM01	CUT*HIVTHER 001	Substantial Amendment 1, 12/06	15/06/2015	14
14/NE/1249/AM03	Phase 2 study of Cobimetinib in TNBC	Substantial Amendment 2 -10/6	10/06/2015	21
14/NE/1249/AM05	Phase 2 study of Cobimetinib in TNBC	Substantial Amendment 4,	28/10/2015	24

		27/10		
15/NE/0006/AM01	ADSTEM	Substantial Amendment 1, 05/10	12/10/2015	18
15/NE/0006/AM02	ADSTEM	Substantial Amendment 2, 14/12	18/12/2015	20
15/NE/0030/AM01	Assessment of the impact of records access on health	Substantial Amendment 1, 07/09	18/09/2015	17
15/NE/0040/AM02	Accessibility and acceptability of HIV services to older adults	Substantial Amendment 1, 10/09	11/09/2015	15
15/NE/0042/AM01	Peer led interventions to address NCD risk factors in prisons	Substantial Amendment 1	01/05/2015	8
15/NE/0071/AM01	The effect of itraconazole dosing on the PK of the Study Drug	Substantial Amendment - update	26/03/2015	25
15/NE/0104/AM01	MYOPROSP	Substantial Amendment 1, 12/01	19/01/2016	15
15/NE/0106/AM01	Community intervention to increase early uptake of antenatal care	Substantial Amendment 1, 22/01	01/02/2016	9
15/NE/0109/AM01	TIKA TB	Substantial Amendment 1, 08/01	26/02/2016	25
15/NE/0111/AM03	Phase I study to determine the BE of TA-8995 in healthy males	Substantial Amendment 1	26/08/2015	27
15/NE/0162/AM01	Describing the management of fibromyalgia by community pain clinic-V1	Updated Substantial Amendment	29/10/2015	14
15/NE/0163/AM01	ADjuST study	Substantial Amendment 1, 23/06	25/06/2015	14
15/NE/0167/AM03	MLN9708 in Multiple Myeloma Not Treated with Stem Cell transplantation	Substantial Amendment 2 - 4/8	04/08/2015	28

15/NE/0167/AM08	MLN9708 in Multiple Myeloma Not Treated with Stem Cell transplantation	Substantial Amendment 5, 14/01	19/01/2016	16
15/NE/0167/AM09	MLN9708 in Multiple Myeloma Not Treated with Stem Cell transplantation	Substantial Amendment 6, 01/03	01/03/2016	21
15/NE/0168/AM01	CA2014OUS CM Rev A 26 February 2015	Substantial Amendment 1, 12/10	16/10/2015	10
15/NE/0189/AM03	CWL-CT-001	Substantial Amendment 1	13/10/2015	17
15/NE/0204/AM01	PROSPER - Hepatic Encephalopathy Observational Study ZZ2014GL03	Substantial Amendment 1 - 12/8	12/08/2015	14
15/NE/0219/AM01	PCF and the perceived care of older people on MH inpatient wards.	Substantial Amendment 1	04/09/2015	14
15/NE/0219/AM02	PCF and the perceived care of older people on MH inpatient wards.	Substantial Amendment 2	05/10/2015	8
15/NE/0219/AM03	PCF and the perceived care of older people on MH inpatient wards.	Substantial Amendment 3, 04/01	04/01/2016	7
15/NE/0241/AM01	TAK-094 First in Human Study	Substantial Amendment 1 - 29/4	30/07/2015	19
15/NE/0299/AM01	MoRE: Models of Reablement Evaluation (Version 1)	Substantial amendment 1	05/08/2015	24
15/NE/0299/AM02	MoRE: Models of Reablement Evaluation (Version 1)	Substantial Amendment 2, 08/02	09/02/2016	13
15/NE/0365/AM01	Predictive Genetic Testing in Young Adults: A Qualitative Study	Substantial Amendment 1, 02/11	03/11/2015	7
15/NE/0375/AM01	Advanced solid tumours Phase 1 safety & tolerability study U3-1784	Substantial Amendment 1 - 8/12	08/12/2015	14

Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
15/NE/0389/AM01	ABY-035 - Phase I study in healthy subjects and psoriasis patients	Substantial Amendment 1, 01/02	03/02/2016	35

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
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Unfavourable opinion timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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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 14 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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