

**North West - Greater Manchester Central
Research Ethics Committee**

Annual Report

01 April 2015 - 31 March 2016



Part 1 – Committee Membership and Training

Name of REC:	North West - Greater Manchester Central Research Ethics Committee
Type of REC:	Type 1 and Type III
Type of Flag:	Paediatrics and Research Tissue Banks and Phase 1 studies in Patients and Phase 1 Studies in Healthy Volunteers
Chair:	Professor S J Mitchell
Vice-Chair:	Dr R G Rawbone
Alternate Vice-Chair:	Dr J Ormrod
REC Manager:	Mrs K Osborne
REC Assistant:	Miss Diane Catterall until 24 July 2015 Miss Jenna Woodburn from 19 October 2015
Committee Address:	3rd Floor Barlow House 4 Minshull Street Manchester M1 3DZ
Telephone:	02071 048022
Email:	nrescommittee.northwest-gmcentral@nhs.net

Chair's overview of the past year:

The members of GM Central continue to have a high commitment to the work of the Committee.

During the reporting period, April 2015 to March 2016, 10 committee meetings took place and the total number of applications reviewed was 57. Sub-committee meetings take place on a regular basis, usually by telephone conference.

During the year, due to work commitments, one member transferred to another committee, one new member was appointed and it was necessary to co-opt a member for one meeting. Due to other commitments some members were unable to meet the requirements regarding attendance at meetings. The training requirements have been met by the majority of members.

As Chairman of GM Central I would like to thank the REC Manager, REC Assistant, Vice Chair, Alternate Vice Chair and members for their continued support and commitment.

North West - Greater Manchester Central Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Mr J Addison	Retired Librarian	Lay Plus	01/05/2013	
Mrs J Budd	Lead Research Midwife for MiNESS	Expert	01/07/2014	
Mrs R Chandler	Project Manager	Lay	02/06/2014	30/09/2015
Mr K Cook	Qi Gong Teacher	Lay	01/05/2013	
Dr B Duran-Jimenez	Paediatric Clinical Trials Pharmacist	Expert	01/01/2012	
Dr G Gkimpas	Honorary Clinical Fellow	Expert	01/02/2016	
Mrs D Hamburger	Retired Social Worker	Lay Plus	01/05/2013	
Dr F Hartley	Student Physician Associate	Expert	01/12/2015	
Dr P Klimiuk	Consultant Rheumatologist	Expert	01/08/2013	
Mr R Lighton	Retired Software Engineer	Lay Plus	01/05/2013	
Mrs F E Maders	Retired Clinical Trials Co-ordinator for Radiology	Expert	01/07/2012	
Professor S J Mitchell	Consultant Neonatologist	Expert	15/10/2004	
Dr J Ormrod	Lecturer / Staff Support Counsellor	Expert	06/09/2006	
Dr B Potrata	Research Fellow	Lay Plus	17/11/2008	
Dr R G Rawbone	Retired Occupational Physician	Expert	06/11/2008	
Dr P Stanford	Lecturer	Expert	09/01/2012	
Mr I A T Taylor	Consulting Engineer	Lay Plus	04/09/2012	

North West - Greater Manchester Central Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended
Mr R Hovey	Business Analyst	Lay Plus	08/06/2015

North West - Greater Manchester Central Research Ethics Committee: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Mr J Addison	None	09/02/2016
Mrs J Budd	Lead Research Midwife Maternal and Fetal Health Research Dept St Marys Hospital CMFT. Action Medical Research and SANDS fund the study I am employed to work on. However I do not have any contact with the funders. Works specifically on the Midland and North of England Stillbirth Study (MiNESS) which has ethical approval from GM Central REC. Amendments have also been put through the committee. The study is due to start closing in March therefore there is considered to be no conflicts of interest. Works in the Maternal and Fetal Health Research Centre at St Marys Hospital CMFT which often puts applications through REC and GM Central REC. It may be that I know the PI on a study but am not directly involved in any other study in the department.	10/02/2016
Mrs R Chandler	Clinical Project Manager at GAEA Clinical. Trustee at Autistic Society Greater Manchester.	02/04/2015
Mr K Cook	None	09/02/2016
Dr B Duran-Jimenez	Lead Clinical Trials Pharmacist in UHSM. Member of Sponsor Oversight Committee in UHSM.	12/04/2016
Dr G Gkimpas	Member of the Junior member Board in the European Academy of Allergy and Clinical Immunology, and the board's representative in the interest group of Occupational Allergy of the Academy.	10/03/2016
Mrs D Hamburger	None	09/02/2016
Dr F Hartley	Senate Assembly	09/02/2016
Dr P Klimiuk	None	09/02/2016
Mr R Lighton	None.	09/02/2016
Mrs F E Maders	None	09/02/2016
Professor S J Mitchell	Membership of Surfactant Administration Advisory Board, Chiesi Pharmaceuticals, November 2015. Received honorarium.	09/02/2016
Dr J Ormrod	None	11/01/2016
Dr B Potrata	None.	09/02/2016
Dr R G Rawbone	None	11/01/2016
Dr P Stanford	Epilepsy Action - Lay Adviser. Royal College of Nursing member - forum committee member. British Pain Society. Committee member - University of Manchester Ethics Committee.	09/02/2016
Mr I A T Taylor	None	09/02/2016

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

Month	Date	Number of Members Present at Meeting
April	13/04/2015	12
May	11/05/2015	10
June	08/06/2015	9
August	10/08/2015	8
September	14/09/2015	12
October	12/10/2015	9
December	14/12/2015	12
January	11/01/2016	10
February	01/02/2016	8
March	14/03/2016	9

10 full 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	03/04/2015	2
April	13/04/2015	2
April	17/04/2015	2
April	24/04/2015	2
April	28/04/2015	2
May	11/05/2015	2
May	29/05/2015	2
May	29/05/2015	2
June	12/06/2015	2
June	12/06/2015	2
June	19/06/2015	3
June	19/06/2015	2
June	19/06/2015	2
July	01/07/2015	2
July	13/07/2015	2
July	20/07/2015	2
August	10/08/2015	2
September	02/09/2015	2
September	14/09/2015	2
October	02/10/2015	2
October	12/10/2015	2
October	27/10/2015	2
November	10/11/2015	2
December	01/12/2015	2
December	14/12/2015	2
December	24/12/2015	2
January	11/01/2016	2
February	01/02/2016	2
February	19/02/2016	2

March	04/03/2016	2
March	21/03/2016	2

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

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

0

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

Name	Number of Meetings Attended
Mr J Addison	8
Mrs J Budd	6
Mrs R Chandler	2
Mr K Cook	5
Dr B Duran-Jimenez	2
Mrs D Hamburger	4
Dr F Hartley	3
Dr P Klimiuk	10
Mr R Lighton	7
Mrs F E Maders	8
Professor S J Mitchell	9
Dr J Ormrod	8
Dr B Potrata	7
Dr R G Rawbone	9
Dr P Stanford	5
Mr I A T Taylor	5

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

Name	Number of Meetings Attended
Mr J Addison	1
Mr K Cook	1
Professor S J Mitchell	28
Dr J Ormrod	6
Dr R G Rawbone	27

Training 01 April 2015 - 31 March 2016

Name of Member	Date	Event(s) attended
Mrs J Budd	06/10/2015	Quantitative Research Methods and Statistics: A Health Research Authority Workshop
Mrs J Budd	19/11/2015	Equality, Diversity and Human Rights
Mr K Cook	03/12/2015	HRA Workshop - Pragmatic or Point of Care Trials
Dr B Duran-Jimenez	30/10/2015	Introduction to GCP for IMP Management (Pharmacy)
Dr G Gkimpas	21/09/2015	Researcher Training Day
Dr G Gkimpas	06/10/2015	Quantitative Research Methods and Statistics
Mrs D Hamburger	30/06/2015	Human Tissue Act (Use of Human Samples in Research) - An Introductory Level
Mrs D Hamburger	16/03/2016	National Member's Training Day
Dr P Klimiuk	20/05/2015	CTIMP Training Day
Mr R Lighton	30/06/2015	Human Tissue Act (Use of Human Samples in Research) - An Introductory Level
Mr R Lighton	15/03/2016	Equality and Diversity
Mrs F E Maders	24/07/2015	Personal Data in Research
Professor S J Mitchell	19/11/2015	Personal Data in Research - A Workshop
Dr B Potrata	31/03/2016	Undertook self-study of main issues in visual research and ethics. Self-study of analysis of visual images and secondly, ethical issues involved in visual research. Self-study on visual analysis of objects and ethical issues that such research engenders.
Dr R G Rawbone	31/03/2016	During late 2014, early 2015 completed a review/report of all Manchester University Faculty/departmental ethics screening panels. Following this the University decided to develop an electronic ethics application form to cover all research (including proportionate review). In November/December 2015 chaired a University departmental ethics panel. In addition to chairing meetings this involved meeting with COEH staff, student lectures; and the assessment and

		feedback to students, on a one to one basis, of ethical considerations in their research.
--	--	---

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	20	35.09
Phase 1	10	17.54
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	4	7.02
Research Database (including renewals)	0	0.00
Others	23	40.35
Total Applications Reviewed	57	100

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

Number of applications made invalid by the REC Manager	2
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	13
Number of paediatric applications reviewed	15
Number of device applications reviewed	1
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

Decisions taken at meetings following review of applications	Number	%
Favourable Opinion with Standard Conditions	2	3.51
Favourable Opinion with Additional Conditions	9	15.79
Unfavourable Opinion	1	1.75
Provisional Opinion	45	78.95
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	57	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	43	75.44
Further Information Favourable Opinion with Additional Conditions	1	1.75
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	2	3.51
Favourable Opinion with Additional Conditions	9	15.79
Unfavourable Opinion	1	1.75
Provisional Opinion	1	1.75
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
Total	57	100

Table 5: Other Management Information based on the number of completed applications for the reporting period:

Average number of applications reviewed per full meeting	5.70
Number of completed applications for full ethical review	57
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	2
Number of completed applications over 40 days as a % of total	3.51%
Number of days taken to final decision – average (mean)	26
Number of SSAs (non-Phase 1) reviewed	22
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	10
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	128
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	12
Number of completed substantial amendments over 28 days as a % of total substantial amendments	9.38%
Number of modified amendments reviewed	6
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	90
Number of substantial amendments received for information	1
Number of substantial amendments received for new sites/PIs	68
Number of annual progress reports received	96
Number of safety reports received	93
Number of Serious Adverse Events received	0
Number of final reports received	29

Table 6: 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/NW/0239	A Sheffield Ophthalmology Research Tissue Bank	26
15/NW/0242	The effect of CYP3A inhibition on the PK of RO5186582	25
15/NW/0253	VELOCITY	23
15/NW/0260	Device robustness study after dosing MGR001 in asthma & COPD Subjects	30
15/NW/0301	Cardiac myocytes derived from skin fibroblasts	20
15/NW/0338	Rejection, Immune Response and Timing of Kidney and Pancreas Transplant	23
15/NW/0350	Exploring the Patient Experience of Transgender People	29
15/NW/0385	MBS2320 - SAD/MAD/Food Effect/Relative Bioavailability and DDI Study	24
15/NW/0404	Understanding Attitudes towards Seeking Psychological Help	30
15/NW/0405	Evaluate 2 doses of LND101001 in Mild-Moderate Alzheimer's patients	30
15/NW/0428	WA29249 - Lebrikizumab in mild to moderate Asthma - STRETTO	27
15/NW/0431	Open-label phase II trial with a pan_FGFR Tyrosine Kinase Inhibitor	21
15/NW/0433	Independent Prescribing Optometrists in Acute Ophthalmic Services	24
15/NW/0440	234HV101 - SAD	14
15/NW/0454	PKU: Parenting experiences and wellbeing	22
15/NW/0468	ACP-196 as mono and combination therapy in untreated CLL patients	22
15/NW/0514	A Mass Balance Study	26
15/NW/0574	Phase I, SAD study of IV doses	42
15/NW/0584	Treatment preferences of cannabis users with psychosis (v1.1)	30
15/NW/0585	Angiogenesis as a target in psoriasis management	25
15/NW/0638	A Smart COPD-SPOC monitor for interactive management of COPD	27
15/NW/0663	Tomographic ultrasound angiographic assessment in PAD - V1	28
15/NW/0672	Women with BRCA1/2 and choices for breast/ovarian cancer prevention	35
15/NW/0684	Imaging measurement of early brain development (I-MED study) V1	28
15/NW/0691	Phase 1 OL study of AZD0156 monotherapy or with combination therapies	25
15/NW/0720	Ivabradine and PCI related microcirculatory dysfunction	21
15/NW/0751	Pneumacare SLP validation in infants and in clinical bronchiolitis	23
15/NW/0779	ALXN1210-PNH-201: ALXN1210 Phase 2 study in patients with PNH	23
15/NW/0802	SAD/MAD Study of MTP-131 in Healthy Subjects (QCL117652)	23
15/NW/0854	IV Administration of 14C-LY2606368	27
15/NW/0858	PB01 in an inhaled LPS challenge study in healthy subjects	31
15/NW/0899	Does Pancreatic Transplantation Reverse Cardiovascular Damage in DM	22

15/NW/0912	PACT-G	26
15/NW/0918	A study to confirm equivalence between Z7200 and Symbicort in asthma	28
16/NW/0002	A Phase I, Single and Multiple Dose Study	24
16/NW/0003	215HV102 - SAD+MAD	27
16/NW/0007	A study to look at the effects of secukinumab in paediatric psoriasis	48
16/NW/0012	HOMAGE	28
16/NW/0033	Correlation of Rectal Prolapse with AAR Parameters	32
16/NW/0041	SOLAR-1: alpelisib + fulvestrant in advanced breast cancer	35
16/NW/0060	UltraSound Evaluation For mUsculoskeletal Lupus (USEFUL)	31
16/NW/0062	Peer to Peer service intervention in primary care mental health	28
16/NW/0164	Biomarkers Of Lynch syndrome Tumours (BOLT)	27

Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/NW/0045	Plasma Ammonia Stability Study (PASS)	27

Favourable Opinion with Standard Conditions

REC Reference	Title	Number of Days on Clock
15/NW/0748	Clients' experiences of the St Marys SARC: A qualitative study	17
16/NW/0199	Bringing compassion to self-criticism: understanding client experience	22

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/NW/0240	Ratifying dosage and duration of levo-bupivacaine infusion in infants.	18
15/NW/0391	TOPTAM V1.0	22
15/NW/0573	NP25737 PK & Safety Study of TCZ in patients <2 years with active sJIA	22
15/NW/0685	Nottingham Health Science Biobank (NHSB)	31
15/NW/0713	GTx G200802 - GTx-024(Enobosarm) on ER+/AR+ Breast Cancer	17
15/NW/0932	Manchester Eye Tissue Repository - ETR Biobank	18
16/NW/0149	K1-70 – Safety Study in Subjects with Graves' Disease.	22
16/NW/0151	Study of the Effect of AUT00206 in healthy male - ketamine challengeV1	22
16/NW/0169	First line treatment of metastatic bowel cancer with S95005 & Avastin	22

Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock
16/NW/0063	Outcome of elderly patients admitted to critical care as an emergency.	24

Provisional Opinion		
REC Reference	Title	Number of Days on Clock
16/NW/0119	Manchester Renal Biobank 2016 - 2021	n/a

Table 7.1 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
06/Q1407/94/AM10	Study of Clinical and Genetic Risk Factors for Encapsulating Peritone	11	29/05/2015	10
08/H1008/25/AM11	Predicting Response to Methotrexate in Rheumatoid Arthritis	8	08/01/2016	25
09/H1008/40/AM21	Extension Study of ENB-0040 in Severely Affected Infants and Young Children	10	10/04/2015	30
09/H1008/40/AM22	Extension Study of ENB-0040 in Severely Affected Infants and Young Children	11	29/10/2015	13
09/H1008/81/AM44	Breast cancer risk assessment and validation in The NHSBSP (PROCAS)	23	05/01/2016	27
10/H1008/73/AM11	HGT-SAN-067	6.1	27/04/2015	25
11/NW/0021/AM04	Investigation of the genetic basis of renal tract abnormalities	4	24/08/2015	25
11/NW/0021/AM05	Investigation of the genetic basis of renal tract abnormalities	5	12/10/2015	16
11/NW/0080/AM10	Masitinib vs Imatinib in first line metastatic GIST - AB04030 v4.0 UK2	9	16/02/2016	28
11/NW/0731/AM03	Paraoxonase and HDL qualities in glycaemia and inflammation	4	26/05/2015	9
12/NW/0014/AM12	FOCUS FH	8	07/05/2015	26
12/NW/0044/AM11	Study of Anaceptrapib in Heterozygous Familial Hypercholesterolemia	11	29/04/2015	15
12/NW/0044/AM13	Study of Anaceptrapib in Heterozygous Familial Hypercholesterolemia	13	29/01/2016	24
12/NW/0149/AM13	CHF5633 To Treat Respiratory Failure in Premature Babies V2.0 16/11/11	13	30/03/2015	22
12/NW/0157/AM08	Ipilimumab dose comparison study in Metastatic Melanoma	EC07	27/04/2015	17
12/NW/0321/AM14	Extended BMN 701 treatment in patients with late-onset Pompe disease	7	03/09/2015	15
12/NW/0694/AM06	A0221047 Paediatric NDO study	6	01/04/2015	20
12/NW/0719/AM05	Effect of LCQ908 in subjects with FCS - Extension Study	4	06/04/2015	24
12/NW/0766/AM14	PREDNOS 2	7	29/04/2015	11
12/NW/0766/AM17	PREDNOS 2	9	07/09/2015	17
12/NW/0794/AM04	Southampton Research Biorepository (SRB)	2	05/06/2015	20
12/NW/0794/AM05	Southampton Research Biorepository (SRB)	3	21/08/2015	18

12/NW/0827/AM08	Euro Ewing 2012	6	04/03/2016	13
12/NW/0868/AM01	Adverse Drug Reactions to Antiepileptic Drugs (v1.0)	2	26/05/2015	10
13/NW/0006/AM08	Phase III study of Brentuximab vedotin in T-cell lymphoma patients	3	02/04/2015	17
13/NW/0006/AM11	Phase III study of Brentuximab vedotin in T-cell lymphoma patients	9	20/08/2015	29
13/NW/0006/AM14	Phase III study of Brentuximab vedotin in T-cell lymphoma patients	SA11	17/11/2015	20
13/NW/0017/AM04	Quality in Organ Donation	2	27/08/2015	10
13/NW/0032/AM13	AZD9291 in patients with advanced NSCLC, following EGFR TKI therapy	5	18/05/2015	14
13/NW/0068/AM04	OUTPASS - OUTcomes of Treatment in Psoriatic Arthritis Study Syndicate	1	01/06/2015	13
13/NW/0068/AM05	OUTPASS - OUTcomes of Treatment in Psoriatic Arthritis Study Syndicate	2	22/10/2015	19
13/NW/0068/AM06	OUTPASS - OUTcomes of Treatment in Psoriatic Arthritis Study Syndicate	2a	01/12/2015	28
13/NW/0081/AM04	Feasibility study: The Manchester Acute Coronary Syndromes rule	2	22/02/2016	18
13/NW/0199/AM06	AMG 145 in patients with Severe Familial Hypercholesterolemia	5	13/07/2015	15
13/NW/0291/AM04	Investigation of a therapeutic vaccine (ACIT-1) in late stage cancer	Code number 02 version 1	18/03/2015	29
13/NW/0297/AM06	Hypertriglyceridaemia - cause and effects	4	26/03/2015	21
13/NW/0297/AM07	Hypertriglyceridaemia - cause and effects	4	17/08/2015	19
13/NW/0321/AM11	WA28118 Study of Tocilizumab in sJIA	05	15/07/2015	13
13/NW/0321/AM12	WA28118 Study of Tocilizumab in sJIA	6	03/09/2015	19
13/NW/0321/AM13	WA28118 Study of Tocilizumab in sJIA	7	17/12/2015	33
13/NW/0321/AM16	WA28118 Study of Tocilizumab in sJIA	9	16/03/2016	14
13/NW/0698/AM06	LDK378 vs Chemo in newly diagnosed untreated ALK+ NSCLC patients	Protocol Amendment 02	17/06/2015	8
13/NW/0698/AM07	LDK378 vs Chemo in newly diagnosed untreated ALK+ NSCLC patients	3	11/12/2015	19
13/NW/0727/AM09	The effects of SEP-363858 on high or low schizotype characteristics	Version 4.0	13/03/2015	28

13/NW/0730/AM04	Neuroinflammation and serotonergic change in HD gene carriers	2	27/08/2015	26
13/NW/0811/AM10	PK Study in Adolescents and Young Adults Treated with Glucocorticoids	8	27/01/2016	26
13/NW/0838/AM01	Predictive Accuracy of Risk Tools for Repeat Self-Harm. VERSION 1	1	27/07/2015	26
13/NW/0874/AM05	The Midlands and North of England Stillbirth Study - MiNESS	5	10/02/2016	30
14/NW/0006/AM04	Calcipotriol + Betamethasone Dipropionate Gel scalp/body psoriasis 12-16yr	2	15/04/2015	15
14/NW/0006/AM07	Calcipotriol + Betamethasone Dipropionate Gel scalp/body psoriasis 12-16yr	4	20/10/2015	14
14/NW/0006/AM09	Calcipotriol + Betamethasone Dipropionate Gel scalp/body psoriasis 12-16yr	5	13/11/2015	14
14/NW/0006/AM10	Calcipotriol + Betamethasone Dipropionate Gel scalp/body psoriasis 12-16yr	6	15/01/2016	12
14/NW/0060/AM02	Reproducibility of Cardiac MRI Spectroscopy	2	24/04/2015	16
14/NW/0071/AM01	Imaging in Transforming Gilomas	1	15/07/2015	23
14/NW/0130/AM20	RESPONSE	IB V4.0	10/07/2015	18
14/NW/0176/AM03	The Paediatric EVICEL ® Bleeding Study	3	29/09/2015	16
14/NW/0193/AM04	Neurodevelopment of Babies Born to Mothers with Epilepsy (NaME)Study	1	11/02/2015	21
14/NW/0194/AM07	Phase 1 Single Ascending Dose Study	2	02/12/2015	15
14/NW/0194/AM08	Phase 1 Single Ascending Dose Study	3	22/01/2016	15
14/NW/0200/AM11	Dupilumab for adult patients with moderate to severe atopic dermatitis	3	08/05/2015	26
14/NW/0200/AM12	Dupilumab for adult patients with moderate to severe atopic dermatitis	3	28/07/2015	16
14/NW/0200/AM14	Dupilumab for adult patients with moderate to severe atopic dermatitis	4	02/10/2015	25
14/NW/0270/AM03	Near infra-red fluorescence imaging in thyroid/parathyroid surgery	1	02/04/2015	18
14/NW/0294/AM05	Study of REGN1908-1909 in volunteers with allergic rhinitis	05	23/02/2015	18
14/NW/0321/AM10	Sebelipase Alfa in Infants with Rapidly Progressive LAL Deficiency	3.0	24/11/2015	24
14/NW/0321/AM11	Sebelipase Alfa in Infants with Rapidly Progressive LAL Deficiency	One	22/01/2016	11

14/NW/1008/AM03	Collaborative case management to aid return to work	2	26/08/2015	30
14/NW/1008/AM04	Collaborative case management to aid return to work	3	16/02/2016	20
14/NW/1041/AM01	Asbestos Workers Survey (v1)	1	15/07/2015	21
14/NW/1042/AM01	The Pesticide Users' Health Study (v1)	1	29/06/2015	7
14/NW/1042/AM02	The Pesticide Users' Health Study (v1)	2	07/10/2015	14
14/NW/1057/AM01	Assessing the effects of mechanical unloading on repair - version 1	1	28/03/2015	21
14/NW/1057/AM02	Assessing the effects of mechanical unloading on repair - version 1	2		30
14/NW/1067/AM05	PROteKT	3	02/04/2015	28
14/NW/1067/AM06	PROteKT	4	10/06/2015	15
14/NW/1067/AM07	PROteKT	5	10/07/2015	18
14/NW/1067/AM10	PROteKT	7	18/11/2015	16
14/NW/1092/AM03	Cellular Immunotherapy Treatment Antigen-Directed for EBV Lymphoma	2	05/01/2016	10
14/NW/1344/AM02	The BEST study	2	04/08/2015	21
14/NW/1344/AM03	The BEST study	3	22/02/2016	26
14/NW/1353/AM03	Impression 3	3	15/05/2015	14
14/NW/1353/AM04	Impression 3	4	28/10/2015	14
14/NW/1373/AM03	DS-5565 in pain associated with fibromyalgia (FM)	2	08/04/2015	34
14/NW/1373/AM07	DS-5565 in pain associated with fibromyalgia (FM)	4	04/11/2015	6
14/NW/1374/AM03	DS-5565 for 52 weeks in pain associated with fibromyalgia (FM)	2	08/04/2015	34
14/NW/1374/AM05	DS-5565 for 52 weeks in pain associated with fibromyalgia (FM)	4	17/08/2015	22
14/NW/1374/AM06	DS-5565 for 52 weeks in pain associated with fibromyalgia (FM)	5	23/09/2015	22
14/NW/1374/AM07	DS-5565 for 52 weeks in pain associated with fibromyalgia (FM)	6	04/11/2015	6
14/NW/1452/AM04	A Phase I, Single Oral Dose Study	3	17/06/2015	14
14/NW/1454/AM03	1237.19 Tiotropium + olodaterol vs tiotropium in severe COPD	2	12/11/2015	26
15/NW/0009/AM01	Denosumab in Children With Osteogenesis Imperfecta	1	13/04/2015	18
15/NW/0009/AM03	Denosumab in Children With Osteogenesis Imperfecta	3	04/08/2015	34
15/NW/0009/AM04	Denosumab in Children With Osteogenesis Imperfecta	4	18/02/2016	23
15/NW/0015/AM03	MEDI4736 in NSCLC (D4191C00001, PACIFIC Study)	3	06/05/2015	8
15/NW/0015/AM05	MEDI4736 in NSCLC (D4191C00001, PACIFIC Study)	5	11/11/2015	27

15/NW/0051/AM04	Assessing the benefits of acclidinium bromide in COPD patients	4	11/01/2016	22
15/NW/0067/AM01	ASCEND- Peds	1	24/08/2015	27
15/NW/0067/AM02	ASCEND- Peds	2	26/11/2015	22
15/NW/0077/AM01	The behavioural phenotype in MPS IH	1	16/07/2015	31
15/NW/0153/AM01	MeMoSa: The effects of Morphine Sulphate	1	25/06/2015	29
15/NW/0153/AM05	MeMoSa: The effects of Morphine Sulphate	2	03/02/2016	20
15/NW/0172/AM02	REmote MONitoring in Rheumatoid Arthritis (REMORA) v1.0	1	18/02/2016	27
15/NW/0240/AM01	Ratifying dosage and duration of levo-bupivacaine infusion in infants.	1	26/05/2015	7
15/NW/0338/AM01	Rejection, Immune Response and Timing of Kidney and Pancreas Transplant	1	24/08/2015	16
15/NW/0338/AM02	Rejection, Immune Response and Timing of Kidney and Pancreas Transplant	2	16/12/2015	14
15/NW/0385/AM02	MBS2320 - SAD/MAD/Food Effect/Relative Bioavailability and DDI Study	1	11/09/2015	21
15/NW/0385/AM03	MBS2320 - SAD/MAD/Food Effect/Relative Bioavailability and DDI Study	2	27/10/2015	15
15/NW/0385/AM04	MBS2320 - SAD/MAD/Food Effect/Relative Bioavailability and DDI Study	4	17/11/2015	14
15/NW/0428/AM02	WA29249 - Lebrikizumab in mild to moderate Asthma - STRETTO	2	16/09/2015	16
15/NW/0431/AM01	Open-label phase II trial with a pan_FGFR Tyrosine Kinase Inhibitor	1	25/06/2015	22
15/NW/0431/AM02	Open-label phase II trial with a pan_FGFR Tyrosine Kinase Inhibitor	2	26/09/2015	19
15/NW/0440/AM01	234HV101 - SAD	Protocol version 2	06/07/2015	9
15/NW/0440/AM04	234HV101 - SAD	2	19/11/2015	15
15/NW/0454/AM01	PKU: Parenting experiences and wellbeing	1	11/12/2015	19
15/NW/0468/AM01	ACP-196 as mono and combination therapy in untreated CLL patients	2.1	10/07/2015	18
15/NW/0514/AM02	A Mass Balance Study	1	02/10/2015	28
15/NW/0573/AM01	NP25737 PK & Safety Study of TCZ in patients <2 years with active sJIA	1	22/02/2016	22
15/NW/0574/AM01	Phase I, SAD study of IV doses	One	30/09/2015	13
15/NW/0751/AM02	Pneumacare SLP validation in infants and in clinical bronchiolitis	1	07/01/2016	21

15/NW/0854/AM01	IV Administration of 14C-LY2606368	I4D-EW-JTJG(a)	08/03/2016	19
-----------------	------------------------------------	----------------	------------	----

Unfavourable opinion				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
11/NW/0016/AM16	SBC-102 in children with growth failure due to LAL deficiency	12	03/11/2015	19
13/NW/0874/AM03	The Midlands and North of England Stillbirth Study - MiNESS	3	05/05/2015	7
14/NW/1353/AM02	Impression 3	2 Halt of recruitment	13/04/2015	18
14/NW/1454/AM02	1237.19 Tiotropium + olodaterol vs tiotropium in severe COPD	1	08/09/2015	14
15/NW/0015/AM04	MEDI4736 in NSCLC (D4191C00001, PACIFIC Study)	3	20/08/2015	15
15/NW/0147/AM01	How do perceptions of sleep quality relate to suicidality	1	03/03/2016	26
15/NW/0385/AM06	MBS2320 - SAD/MAD/Food Effect/Relative Bioavailability and DDI Study	1	15/01/2016	18
15/NW/0684/AM01	Imaging measurement of early brain development (I-MED study) V1	1	26/02/2016	28

Table 7.2: 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
09/H1008/81/AM43/1	Breast cancer risk assessment and validation in The NHSBSP (PROCAS)	22 (modified 21.04.2015)	23/04/2015	6
11/NW/0016/AM16/1	SBC-102 in children with growth failure due to LAL deficiency	12	24/11/2015	12
12/NW/0795/AM05/2	The Lipid Efficacy and Safety Add-On Study.	03#	18/03/2015	13
13/NW/0874/AM03/1	The Midlands and North of England Stillbirth Study - MiNESS	4	16/07/2015	8
14/NW/1454/AM02/1	1237.19 Tiotropium + olodaterol vs tiotropium in severe COPD	2.0	15/07/2015	12
15/NW/0015/AM04/1	MEDI4736 in NSCLC (D4191C00001, PACIFIC Study)	4	16/09/2015	7