NHS
Health Research Authority

Research Ethics Service

RES Committee North West - Greater Manchester Central

Annual Report

01 April 2014 - 31 March 2015

Part 1 – Committee Membership and Training

Name of REC:	RES Committee North West - Greater Manchester Central
Type of REC:	Type I and Type III
Type of Flag:	Paediatrics, Research Tissue Banks, Phase I studies in healthy volunteers, Phase I studies in patients.
Chair:	Professor S J Mitchell
Vice-Chair:	Dr R G Rawbone
Alternate Vice-Chair:	Dr J Ormrod
REC Manager:	Mrs K Osborne
REC Assistant:	Ms Sîan Goodwin (from 01/04/2014 – 30/04/2014) Miss Diane Catterall (from 01/10/2014 – 31/03/2015)
Committee Address:	3rd Floor Barlow House 4 Minshull Street Manchester M1 3DZ
Telephone:	0161 625 7825
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Chair's overview of the past year:

During the last year the members of GM Central have continued to have a high level of commitment to the work of the Committee.

From April 2014 to March 2015 11 committee meetings took place and the total number of applications reviewed was 57. Although this number is lower than last year by 6, the work of the sub-committee has increased.

Membership during the year has remained the same and there was only one meeting to which members were co-opted to ensure a quorum.

In June 2014 GM Central achieved accreditation for the fourth time without any additional comments or action plan.

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

RES Committee North West - Greater Manchester Central Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Mr J Addison	Retired Librarian	Lay Plus	01/05/2013	
Mrs J Budd (nee Platts)	Lead Research Midwife for MiNESS	Expert	01/07/2014	
Mrs R Chandler	Project Manager	Lay	02/06/2014	
Mr K Cook	Qi Gong Teacher	Expert	01/05/2013	
Dr B Duran-Jimenez	Paediatric Clinical Trials Pharmacist	Expert	01/01/2012	
Mrs D Hamburger	Retired Social Worker	Lay Plus	01/05/2013	
Dr P Klimiuk	Consultant Rheumatologist	Expert	01/08/2013	
Mr R Lighton	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	

RES Committee North West - Greater Manchester Central: Co-opted Members

Name	Profession	Status	Meeting date attended
Mr J Burns	Retired	Lay Plus	14/10/2014
Mr R Hovey	Business Analyst	Lay Plus	14/10/2014

RES Committee North West - Greater Manchester Central: Members' Declarations of

Name	Declaration of Interest	Date
Mr J Addison	None	05/03/2015
Mrs J Budd (nee Platts)	Employed by CMFT and works within the maternal and fetal health research facility. Specifically employed as lead research midwife for the Midland and North of England Stillbirth Study (MiNESS) which is a multi-centred study currently recruiting across the UK.	05/03/2015
Mrs R Chandler	Clinical Project Manager at GAEA Clinical (a small CRO mainly involved in European clinical research, does very little UK research).Hold a small number of AstraZeneca shares. Hold post on board of trustees of Autistic Society Greater Manchester area. Occasionally approached by research students seeking studies in Autism.	02/09/2014
Mr K Cook	None	24/04/2015
Dr B Duran-Jimenez	Lead Clinical Trials Pharmacist in UHSM. Member of Sponsor Oversight Committee in UHSM, support CT pharmacy for Southern Sector Research Alliance.	09/03/2015
Mrs D Hamburger	None	05/03/2015
Dr P Klimiuk	None	09/04/2014
Mr R Lighton	None	31/03/2015
Mrs F E Maders	None	31/03/2015
Professor S J Mitchell	Member of MHRA Independent Scientific Advisory Committee (ISAC) for database research.	31/03/2015
Dr J Ormrod	None	31/03/2015
Dr B Potrata	None	31/03/2015
Dr R G Rawbone	None	31/03/2015
Dr P Stanford	Lay Adviser: Patient Information Epilepsy Action. British Pain Society. Collaborative Action Research Network. Royal College of Nursing. Ad hoc review of NIHR project bids for funding. CI for NRS reviewed University of Manchester sponsored research study.	31/03/2015
Mr I A T Taylor	None	31/03/2015

Meetings for Full Ethical Review 01 April 2014 - 31 March 2015:

Month	Date	Number of Members Present at Meeting
April	14/04/2014	11
May	12/05/2014	10
June	09/06/2014	10
July	14/07/2014	11
August	11/08/2014	10
October	13/10/2014	9
November	10/11/2014	12
December	08/12/2014	9
January	12/01/2015	13
February	09/02/2015	10
March	09/03/2015	11

11 full committee meetings were held during the reporting period.

Sub-Committee Meetings held during 01 April 2014 - 31 March 2015:

Month	Date	Number of Members Present at Meeting
April	09/04/2014	2
April	14/04/2014	2
May	01/05/2014	2
May	12/05/2014	2
May	29/05/2014	2
June	09/06/2014	2
June	16/06/2014	2
July	01/07/2014	2
July	14/07/2014	2
July	25/07/2014	2
July	28/07/2014	2
August	08/08/2014	2
August	11/08/2014	2
August	13/08/2014	2
August	15/08/2014	2
August	29/08/2014	2
September	04/09/2014	2
September	12/09/2014	2
September	26/09/2014	2
October	13/10/2014	2
October	24/10/2014	2
October	31/10/2014	2
November	04/11/2014	2
November	06/11/2014	2
November	07/11/2014	2
November	10/11/2014	2
November	21/11/2014	2
November	25/11/2014	2

December	08/12/2014	2
December	19/12/2014	2
January	12/01/2015	2
January	28/01/2015	2
February	06/02/2015	2
February	09/02/2015	2
February	26/02/2015	2
March	06/03/2015	2
March	09/03/2015	2
March	24/03/2015	2

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

Details of inquorate meeting held:01 April 2014 - 31 March 2015

Date	Reason	Action taken

None

Attendance of Members at full committee meetings:01 April 2014 - 31 March 2015

Name	Number of Meetings Attended
Mr J Addison	8
Mrs J Budd (nee Platts)	7
Mrs R Chandler	4
Mr K Cook	5
Dr B Duran-Jimenez	2
Mrs D Hamburger	7
Dr P Klimiuk	10
Mr R Lighton	10
Mrs F E Maders	9
Professor S J Mitchell	11
Dr J Ormrod	7
Dr B Potrata	7
Dr R G Rawbone	11
Dr P Stanford	7
Mr I A T Taylor	9

Attendance of Members at sub-committee meetings: 01 April 2014 - 31 March 2015

Name	Number of Meetings Attended
Professor S J Mitchell	38
Dr J Ormrod	2
Dr R G Rawbone	36

Training 01 April 2014 - 31 March 2015

Name of Member	Date	Event(s) attended
Mr J Addison	16/06/2014	Equality & Human Rights
Mr J Addison	21/01/2015	Internet/Web-based research
Mrs J Budd (nee Platts)	25/11/2014	NRES Committee Members Induction
Mrs R Chandler	25/11/2014	NRES Committee Members Induction
Mr K Cook	24/03/2015	National Members Training Day
Mrs D Hamburger	31/07/2014	Ethical Issues in Phase One Research: An Advanced Training Course
Dr P Klimiuk	24/03/2015	National Members Training Day
Mr R Lighton	16/10/2014	Reviewing CTIMPs
Mrs F E Maders	09/10/2014	Medical Devices Training Day
Mrs F E Maders	15/12/2014	Quantitative Research Methods and Statistics
Professor S J Mitchell	10/12/2014	National Training Day for NRES Committee Chairs
Dr J Ormrod	27/11/2014	Diversity in the Workplace Training
Dr J Ormrod	08/01/2015	Training for new REC Chairs
Dr R G Rawbone	24/06/2014	Human Tissue Act (Advanced Training in the use of Tissues in Research)
Dr R G Rawbone	09/10/2014	Medical Devices Training Day
Dr P Stanford	24/03/2015	National Members Training Day
Mr I A T Taylor	14/06/2014	Equality and Diversity (e-learning module)
Mr I A T Taylor	24/03/2015	National Members Training Day

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	18	31.58
Phase 1	7	12.28
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	0	0.00
Others	32	56.14
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	0
Number of applications withdrawn prior to the meeting	2
Number of student applications reviewed	17
Number of paediatric applications reviewed	12
Number of device applications reviewed	2
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	1

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	7	12.28
Unfavourable Opinion	0	0.00
Provisional Opinion	48	84.21
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	48	84.21
Further Information Favourable Opinion with Additional Conditions	0	0.00
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	2	3.51
Favourable Opinion with Additional Conditions	7	12.28
Unfavourable Opinion	0	0.00
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	0	0.00
Total	**57**	**100**

Table 8: **Other Management Information for the reporting period:**

Average number of applications reviewed per full meeting	5.18
Number of applications for full ethical review	57
Number of applications for full ethical review over 60 days	0
Number of applications over 60 days as a % of total	0.00%
Number of applications for full ethical review over 40 days	4
Number of applications over 40 days as a % of total	7.02%
Number of days taken to final decision – average (mean)	28

Number of SSAs (non-Phase 1) reviewed	18
Number of applications for SSA review over 25 days	0
Number of applications for SSA review over 25 days as % of all non- Phase 1 SSAs	0.00%

Number of SSAs (Phase 1) reviewed	5
Number of applications for SSA review over 14 days	0
Number of applications for SSA review over 14 days as % of all Phase 1 SSAs	0.00%

Number of substantial amendments reviewed	160
Number of substantial amendments over 35 days	0
Number of substantial amendments over 35 days as a % of total substantial amendments	0.00%
Number of substantial amendments over 28 days	10
Number of substantial amendments over 28 days as a % of total substantial amendments	6.25%

Number of modified amendments reviewed	19
Number of modified amendments over 14 days	2
Number of modified amendments over 14 days as a % of total modified amendments	10.53%

Number of minor amendments received	109
Number of substantial amendments received for information	1
Number of substantial amendments received for new sites/PIs	35
Number of annual progress reports received	113
Number of safety reports received	91
Number of Serious Adverse Events received	0
Number of final reports received	34

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**
14/NW/0176	The Paediatric EVICEL® Soft Tissue Bleeding Study	29
14/NW/0194	Phase 1 Single Ascending Dose Study	28
14/NW/0200	Dupilumab for adult patients with moderate to severe atopic dermatitis	30
14/NW/0207	Momentary Interventions in Suicidality	30
14/NW/0220	Does personality type influence attentional bias?	39
14/NW/0264	Three dimensional analysis of periodontal healing post-surgery	40
14/NW/0270	Near infra-red fluorescence imaging in thyroid/parathyroid surgery	29
14/NW/0278	The Role of the Baby in Recovery From Psychosis After Childbirth	18
14/NW/0281	Bioequivalence	26
14/NW/0294	Study of REGN1908-1909 in volunteers with allergic rhinitis	36
14/NW/0321	Sebelipase Alfa in Infants with Rapidly Progressive LAL Deficiency	23
14/NW/0335	Experiences of Leaving Early Intervention	27
14/NW/0351	GENIALL	40
14/NW/0354	Prospect	37
14/NW/1008	Collaborative case management to aid return to work	37
14/NW/1010	A Comparison of MCT Group Therapy versus MM Group Therapy in GAD	44
14/NW/1041	Asbestos Workers Survey (v1)	34
14/NW/1045	Hypoglycaemia And Neonatal Neurodevelopment, HANND	25
14/NW/1046	TEP versus open minimal suture repair for the Sportsman's groin.	28
14/NW/1067	PROteKT	30
14/NW/1092	Cellular Immunotherapy Treatment Antigen-Directed for EBV Lymphoma	57
14/NW/1110	rEECur	48
14/NW/1118	JPBS: Absolute Bioavailability Study of LY2835219 in Healthy Subjects	30
14/NW/1119	GRC 27864-102: MAD Study	22
14/NW/1308	Analysis of sub-optimal dosing in methadone maintenance treatment	28
14/NW/1344	The BEST study	23
14/NW/1352	The body clock effects in Asthma	21
14/NW/1353	Impression 3	26
14/NW/1373	DS-5565 in pain associated with fibromyalgia (FM)	26
14/NW/1374	DS-5565 for 52 weeks in pain associated with fibromyalgia (FM)	27
14/NW/1375	SAMS - Reliability and Proof of Concept study	32
14/NW/1397	CoSMIC: Colorectal ca & Synchronous liver Metastases Inception Cohort.	19

14/NW/1422	A Phase 1 Study with a Novel Oral Fulvestrant Formulation.	18
14/NW/1452	A Phase I, Single Oral Dose Study	23
14/NW/1454	1237.19 Tiotropium + olodaterol vs tiotropium in severe COPD	19
15/NW/0009	Denosumab in Children With Osteogenesis Imperfecta	20
15/NW/0011	Transplant BRaVE Version 1	25
15/NW/0013	PEGS: Patients experiences of Genetic Conditions & Services	26
15/NW/0015	MEDI4736 in NSCLC (D4191C00001, PACIFIC Study)	24
15/NW/0022	Bone anchored maxillary protraction (BAMP)RCT	21
15/NW/0051	Assessing the benefits of aclidinium bromide in COPD patients	29
15/NW/0061	Outcomes of adolescents transitioning from children's ADHD services	30
15/NW/0067	ASCEND- Peds	23
15/NW/0073	What works in CRHT? A 2-phase exploratory study	30
15/NW/0077	The behavioural phenotype in MPS IH	20
15/NW/0147	How do perceptions of sleep quality relate to suicidality	33
15/NW/0152	MetaPHer	30
15/NW/0153	MeMoSa: The effects of Morphine Sulphate	19

Favourable Opinion with Standard Conditions		
REC Reference	**Title**	**Number of Days on Clock**
14/NW/0222	What are the long-term health outcomes in psoriasis?	49
14/NW/1042	The Pesticide Users' Health Study (v1)	22

Favourable Opinion with Additional Conditions		
REC Reference	**Title**	**Number of Days on Clock**
14/NW/0193	Neurodevelopment of Babies Born to Mothers with Epilepsy (NaME)Study	22
14/NW/1057	Assessing the effects of mechanical unloading on repair - version 1	22
14/NW/1331	Argus II Retinal Prosthesis System Dry AMD Feasibility Study	19
15/NW/0010	SLUMBRS (Version 1)	18
15/NW/0099	Evaluation of taste profiles of JNJ-53718678 formulations (QCL117534)	16
15/NW/0154	Immediate loading of bone anchored hearing devices. Version 1	18
15/NW/0172	REmote MOnitoring in Rheumatoid Arthritis (REMORA) v1.0	18

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**
06/Q1407/94/AM09	Study of Clinical and Genetic Risk Factors for Encapsulating Peritone	10	09/06/2014	25
07/H1008/112/AM23	Short Chemo RadioImmunotherapy Phase II Trial. Version 1.1	22	18/02/2015	23
07/H1008/153/AM04	Secondary Screening for Early Pancreatic cancer in HP (v.1)	2	19/12/2014	18
09/H1008/137/AM09	Safety and effectiveness of biologic treatments in children	4	23/09/2014	12
09/H1008/40/AM18	Extension Study of ENB-0040 in Severely Affected Infants and Young Children	10.0	29/07/2014	15
09/H1008/76/AM15	SGN-35 in the treatment of Anaplastic Large Cell Lymphoma	11	14/04/2014	18
09/H1008/81/AM38	Breast cancer risk assessment and validation in The NHSBSP (PROCAS)	17	09/04/2014	29
09/H1008/81/AM39	Breast cancer risk assessment and validation in The NHSBSP (PROCAS)	Substantial Amendment 18	12/09/2014	4
09/H1008/81/AM40	Breast cancer risk assessment and validation in The NHSBSP (PROCAS)	19	17/10/2014	10
09/H1008/81/AM41	Breast cancer risk assessment and validation in The NHSBSP (PROCAS)	20	28/11/2014	19
09/H1008/81/AM42	Breast cancer risk assessment and validation in The NHSBSP (PROCAS)	21	10/12/2014	12
09/H1008/93/AM06	Northern Ireland Caries Prevention in Practice Trial (NIC-PIP)	5	15/05/2014	17
09/H1008/93/AM07	Northern Ireland Caries Prevention in Practice Trial (NIC-PIP)	Amendment Number 6	07/04/2014	17
10/H1008/105/AM06	Extension Study of Ferumoxytol for Iron Deficiency Anaemia in CKD	4	28/07/2014	25
10/H1008/122/AM19	PREDnisolone in NephrOtic Syndrome: The PREDNOS study	15	04/07/2014	14
10/H1008/122/AM23	PREDnisolone in NephrOtic Syndrome: The PREDNOS study	16	16/12/2014	14
10/H1008/72/AM14	Nottingham Research Biorepository (NRB)	14	11/08/2014	26
10/H1008/73/AM09	HGT-SAN-067	6	05/09/2014	10
10/H1008/74/AM03	Genetics of Schwannomas and Meningiomas	4	19/12/2014	27
10/H1008/88/AM05	Ferumoxytol for Iron Deficiency Anaemia in Dialysis-dependent	4	28/07/2014	26

	CKD			
11/NW/0016/AM13	SBC-102 in children with growth failure due to LAL deficiency	10	25/03/2014	16
11/NW/0016/AM14	SBC-102 in children with growth failure due to LAL deficiency	11	08/10/2014	19
11/NW/0016/AM15	SBC-102 in children with growth failure due to LAL deficiency	11	19/12/2014	27
11/NW/0080/AM05	Masitinib vs Imatinib in first line metastatic GIST - AB04030 v4.0 UK2	6	08/08/2014	28
11/NW/0080/AM06	Masitinib vs Imatinib in first line metastatic GIST - AB04030 v4.0 UK2	05	03/02/2015	16
11/NW/0080/AM07	Masitinib vs Imatinib in first line metastatic GIST - AB04030 v4.0 UK2	6	26/02/2015	15
11/NW/0731/AM02	Paraoxonase and HDL qualities in glycaemia and inflammation	2	27/03/2014	25
11/NW/0737/AM05	Approach and avoidance motivation in adolescent clinical anxiety	1	03/09/2014	22
11/NW/0772/AM07	E7050-701 - Phase Ib/II Study of E7050 Hepatocellular Carcinoma	Updated Patient Information Sheet	19/09/2014	26
11/NW/0772/AM08	E7050-701 - Phase Ib/II Study of E7050 Hepatocellular Carcinoma	5	06/03/2015	21
11/NW/0773/AM10	Intrathecal Enzyme Replacement Therapy for MPS II Extension Study	7a	21/10/2014	14
12/NW/0044/AM09	Study of Anaceptrapib in Heterozygous Familial Hypercholesterolemia	06	17/11/2014	11
12/NW/0044/AM10	Study of Anaceptrapib in Heterozygous Familial Hypercholesterolemia	020-03	30/01/2015	15
12/NW/0149/AM12	CHF5633 To Treat Respiratory Failure in Premature Babies V2.0 16/11/11	11	10/04/2014	25
12/NW/0157/AM06	Ipilimumab dose comparison study in Metastatic Melanoma	4 (EC05-CA06)	25/04/2014	16
12/NW/0157/AM07	Ipilimumab dose comparison study in Metastatic Melanoma	6	23/08/2014	22
12/NW/0160/AM09	Gastrointestinal care for patients undergoing pelvic chemoradiotherapy	3	26/01/2015	23
12/NW/0180/AM05	Evaluation of low sodium PDF in hypertensive PD patients	3	22/08/2014	22
12/NW/0321/AM13	Extended BMN 701 treatment in patients with late-onset Pompe disease	5	21/11/2014	21
12/NW/0386/AM21	A two-part, phase 1 single-dose study to assess doses of IL-31 mAb	15.0	05/05/2014	19
12/NW/0386/AM22	A two-part, phase 1 single-dose study to assess doses of IL-31 mAb	14.0	10/04/2014	26

12/NW/0411/AM05	Effect of LCQ908 in Subjects with Familial Chylomicronemia Syndrome	3	06/05/2014	29
12/NW/0694/AM04	A0221047 Paediatric NDO study	5.0	08/08/2014	23
12/NW/0719/AM02	Effect of LCQ908 in subjects with FCS - Extension Study	1	18/08/2014	22
12/NW/0719/AM03	Effect of LCQ908 in subjects with FCS - Extension Study	REC Amendment 3 - IN v9 4 Marc	16/09/2014	10
12/NW/0766/AM11	PREDNOS 2	6	10/06/2014	17
12/NW/0827/AM02	Euro Ewing 2012	SA01	17/03/2014	26
12/NW/0827/AM05	Euro Ewing 2012	SA02	23/01/2015	16
13/NW/0006/AM06	Phase III study of Brentuximab vedotin in T-cell lymphoma patients	4	26/03/2014	28
13/NW/0006/AM07	Phase III study of Brentuximab vedotin in T-cell lymphoma patients	5	24/06/2014	13
13/NW/0009/AM09	Medication and Memory in Parkinson's Disease (MeMory PaD)	4	11/04/2014	25
13/NW/0009/AM10	Medication and Memory in Parkinson's Disease (MeMory PaD)	5	11/04/2014	25
13/NW/0009/AM11	Medication and Memory in Parkinson's Disease (MeMory PaD)	6	23/06/2014	17
13/NW/0009/AM13	Medication and Memory in Parkinson's Disease (MeMory PaD)	7	03/10/2014	18
13/NW/0009/AM14	Medication and Memory in Parkinson's Disease (MeMory PaD)	8	03/10/2014	13
13/NW/0009/AM16	Medication and Memory in Parkinson's Disease (MeMory PaD)	9	18/11/2014	10
13/NW/0032/AM09	AZD9291 in patients with advanced NSCLC, following EGFR TKI therapy	4	20/03/2014	22
13/NW/0032/AM12	AZD9291 in patients with advanced NSCLC, following EGFR TKI therapy	10	19/02/2015	22
13/NW/0111/AM03	SimvAstatin in Neurofibromatosis Type 1-Autism (SANTA)	2	30/05/2014	17
13/NW/0131/AM02	Imaging Biomarkers for NF2 and VS	2	11/05/2014	22
13/NW/0199/AM05	AMG 145 in patients with Severe Familial Hypercholesterolemia	4	04/06/2014	33
13/NW/0208/AM01	ARROVEN - brentuximab vedotin PASS, version 1.1 dated on 14 June 2012	2	11/03/2014	18
13/NW/0291/AM02	Investigation of a therapeutic vaccine (ACIT-1) in late stage cancer	1	11/12/2014	12
13/NW/0297/AM05	Hypertriglyceridaemia - cause and effects	6	17/12/2014	5
13/NW/0320/AM05	WA28117 Study of Tocilizumab in pcJIA	2	23/05/2014	24
13/NW/0320/AM06	WA28117 Study of Tocilizumab in pcJIA	3	09/10/2014	18
13/NW/0321/AM05	WA28118 Study of Tocilizumab in sJIA	2	23/05/2014	25
13/NW/0321/AM06	WA28118 Study of Tocilizumab in sJIA	3	09/10/2014	18

13/NW/0350/AM04	Study to compare BE of Dutasteride & Tamsulosin HCI in male volunteers	2	08/04/2014	15
13/NW/0396/AM07	Fasted Study to compare BE of Dutasteride & Tamsulosin HCI in males	2	08/04/2014	15
13/NW/0477/AM03	Study of BYL719-LJM716 combination in patients with oesophageal cancer	4	14/05/2014	20
13/NW/0477/AM04	Study of BYL719-LJM716 combination in patients with oesophageal cancer	3	02/02/2015	22
13/NW/0477/AM05	Study of BYL719-LJM716 combination in patients with oesophageal cancer	4	04/03/2015	21
13/NW/0496/AM02	Pregabalin in subjects with Primary Generalised Tonic-Clonic seizures	1	19/08/2014	21
13/NW/0496/AM03	Pregabalin in subjects with Primary Generalised Tonic-Clonic seizures	3	29/10/2014	14
13/NW/0499/AM03	Safety, tolerability and PK of RV1162 in healthy and COPD patients.	2	22/07/2014	20
13/NW/0610/AM02	Study to examine safety, tolerability & PK of Baclofen and Memantine	2	17/04/2014	13
13/NW/0653/AM01	MEMO	1	28/10/2014	22
13/NW/0698/AM05	LDK378 vs Chemo in newly diagnosed untreated ALK+ NSCLC patients	v5	14/11/2014	10
13/NW/0723/AM01	A Comparison of atrophic and hypertrophic facial photoaged skin	1	22/09/2014	28
13/NW/0727/AM07	The effects of SEP-363858 on high or low schizotype characteristics	3.0	21/10/2014	16
13/NW/0741/AM04	The effects of XEN-D0501 on cough frequency in COPD patients	4	02/05/2014	10
13/NW/0741/AM05	The effects of XEN-D0501 on cough frequency in COPD patients	Amendment to Ethics Applicatio	22/09/2014	27
13/NW/0741/AM06	The effects of XEN-D0501 on cough frequency in COPD patients	6	09/12/2014	13
13/NW/0777/AM04	GWP42003 for treatment of schizophrenia or related psychotic disorders	Substantial Amendment 3	09/09/2014	9
13/NW/0777/AM05	GWP42003 for treatment of schizophrenia or related psychotic disorders	4	14/01/2015	9

13/NW/0778/AM02	ProCervix vs placebo in women with HPV 16 & HPV 18 infection	2	09/06/2014	34
13/NW/0778/AM06	ProCervix vs placebo in women with HPV 16 & HPV 18 infection	3	26/08/2014	20
13/NW/0778/AM08	ProCervix vs placebo in women with HPV 16 & HPV 18 infection	Investigator Brochure Ed6.0 /	25/09/2014	13
13/NW/0794/AM02	Influence of nitrates on bone and endothelial function in diabetes.	2	08/08/2014	25
13/NW/0805/AM05	1237.25 - Tiotropium/olodaterol vs tiotropium and placebo in COPD	1	27/10/2014	15
13/NW/0811/AM02	PK Study in Adolescents and Young Adults Treated with Glucocorticoids	1	15/05/2014	14
13/NW/0811/AM04	PK Study in Adolescents and Young Adults Treated with Glucocorticoids	3	28/07/2014	17
13/NW/0874/AM01	The Midlands and North of England Stillbirth Study - MiNESS	1	09/07/2014	29
13/NW/0874/AM02	The Midlands and North of England Stillbirth Study - MiNESS	2	27/11/2014	28
14/NW/0001/AM02	Continuation Study of Prophylactic BAX 855 in PTP with Haemophilia A	2	08/07/2014	14
14/NW/0001/AM03	Continuation Study of Prophylactic BAX 855 in PTP with Haemophilia A	UK EC SA#3 New CI & PI	30/09/2014	21
14/NW/0006/AM02	CalcipotriolBetamethasoneDipropionateGel scalp/body psoriasis 12-16yr	1	12/06/2014	29
14/NW/0055/AM01	Pregabalin Open Label Follow up study of A0081105	2	29/07/2014	14
14/NW/0069/AM02	PK & Safety of Naloxegol in Paediatric Patients Receiving Opioids	1	28/05/2014	19
14/NW/0069/AM03	PK & Safety of Naloxegol in Paediatric Patients Receiving Opioids	2	11/07/2014	24
14/NW/0069/AM05	PK & Safety of Naloxegol in Paediatric Patients Receiving Opioids	2		30
14/NW/0069/AM07	PK & Safety of Naloxegol in Paediatric Patients Receiving Opioids	3	24/12/2014	22
14/NW/0116/AM01	Phase III Paediatric CKD study in peritoneal dialysis or haemodialysis	1	19/05/2014	21
14/NW/0130/AM01	RESPONSE	1	10/04/2014	27
14/NW/0130/AM03	RESPONSE	4	07/07/2014	14
14/NW/0130/AM05	RESPONSE	5	20/08/2014	26

14/NW/0130/AM06	RESPONSE	6	12/09/2014	10
14/NW/0130/AM08	RESPONSE	7	15/12/2014	8
14/NW/0130/AM11	RESPONSE	Code number 9 version 3.0	15/08/2014	16
14/NW/0130/AM12	RESPONSE	10	05/03/2015	22
14/NW/0176/AM02	The Paediatric EVICELÂ® Soft Tissue Bleeding Study	SA02	10/02/2015	15
14/NW/0194/AM01	Phase 1 Single Ascending Dose Study	1	25/04/2014	18
14/NW/0194/AM02	Phase 1 Single Ascending Dose Study	3	17/07/2014	18
14/NW/0194/AM04	Phase 1 Single Ascending Dose Study	4 (SA0001)	15/09/2014	4
14/NW/0194/AM05	Phase 1 Single Ascending Dose Study	SA002	18/11/2014	10
14/NW/0200/AM04	Dupilumab for adult patients with moderate to severe atopic dermatitis	3	22/08/2014	24
14/NW/0200/AM05	Dupilumab for adult patients with moderate to severe atopic dermatitis	Amendment 4 - Updated Patient	24/09/2014	26
14/NW/0200/AM07	Dupilumab for adult patients with moderate to severe atopic dermatitis	5	06/01/2015	29
14/NW/0294/AM01	Study of REGN1908-1909 in volunteers with allergic rhinitis	1.0	18/08/2014	22
14/NW/0294/AM02	Study of REGN1908-1909 in volunteers with allergic rhinitis	3	22/08/2014	18
14/NW/0294/AM03	Study of REGN1908-1909 in volunteers with allergic rhinitis	Add adverts	31/10/2014	14
14/NW/0321/AM04	Sebelipase Alfa in Infants with Rapidly Progressive LAL Deficiency	3	13/08/2014	0
14/NW/0321/AM06	Sebelipase Alfa in Infants with Rapidly Progressive LAL Deficiency	4	30/10/2014	7
14/NW/0321/AM07	Sebelipase Alfa in Infants with Rapidly Progressive LAL Deficiency	2	02/12/2014	21
14/NW/1008/AM01	Collaborative case management to aid return to work	1	04/12/2014	19
14/NW/1010/AM01	A Comparison of MCT Group Therapy versus MM Group Therapy in GAD	#1	21/01/2015	15
14/NW/1067/AM01	PROteKT	1	18/12/2014	5
14/NW/1092/AM02	Cellular Immunotherapy Treatment Antigen-Directed for EBV Lymphoma		19/12/2014	32
14/NW/1110/AM01	rEECur	1	10/09/2014	19
14/NW/1118/AM01	JPBS: Absolute Bioavailability Study of LY2835219 in Healthy Subjects	1	11/12/2014	15
14/NW/1119/AM01	GRC 27864-102: MAD Study	V3	14/11/2014	10
14/NW/1344/AM01	The BEST study	1	27/02/2015	21

14/NW/1352/AM01	The body clock effects in Asthma	1	05/12/2014	27
14/NW/1352/AM02	The body clock effects in Asthma	2	10/03/2015	16
14/NW/1353/AM01	Impression 3	1	14/01/2015	21
14/NW/1373/AM01	DS-5565 in pain associated with fibromyalgia (FM)	1	21/10/2014	23
14/NW/1374/AM01	DS-5565 for 52 weeks in pain associated with fibromyalgia (FM)	1	21/10/2014	23
14/NW/1452/AM01	A Phase I, Single Oral Dose Study	Version 2	18/12/2014	28
14/NW/1452/AM02	A Phase I, Single Oral Dose Study	Version 2.1	07/01/2015	19

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Amendment REC Reference	Title	Version	Date	Number of Days on Clock
09/H1008/81/AM43	Breast cancer risk assessment and validation in The NHSBSP (PROCAS)	22	23/02/2015	18
10/H1008/72/AM13	Nottingham Research Biorepository (NRB)	11	22/04/2014	22
11/NW/0021/AM02	Investigation of the genetic basis of renal tract abnormalities	1	19/08/2014	21
12/NW/0160/AM08	Gastrointestinal care for patients undergoing pelvic chemoradiotherapy	2	14/07/2014	18
12/NW/0321/AM08	Extended BMN 701 treatment in patients with late-onset Pompe disease	4	19/08/2014	26
12/NW/0794/AM03	Southampton Research Biorepository (SRB)	1	06/11/2014	22
12/NW/0795/AM05	The Lipid Efficacy and Safety Add-On Study.	Substantial Amendment #03: IB	28/10/2014	15
13/NW/0058/AM03	The Amputation Surgical Site Infection Trial (ASSIT)	4	11/09/2014	4
13/NW/0727/AM06	The effects of SEP-363858 on high or low schizotype characteristics	1.0	05/06/2014	14
13/NW/0727/AM08	The effects of SEP-363858 on high or low schizotype characteristics	4	13/02/2015	14
13/NW/0730/AM01	Neuroinflammation and serotonergic change in HD gene carriers	1	11/04/2013	18
13/NW/0777/AM03	GWP42003 for treatment of schizophrenia or related psychotic disorders	2	27/06/2014	20
13/NW/0794/AM01	Influence of nitrates on bone and endothelial function in diabetes.	1	07/04/2014	19
13/NW/0811/AM05	PK Study in Adolescents and Young Adults Treated with	5	15/10/2014	30

	Glucocorticoids			
13/NW/0823/AM01	The SCRIBE (Social Cognition Research in Bonding and Emotions) study	1	30/04/2014	16
14/NW/0001/AM04	Continuation Study of Prophylactic BAX 855 in PTP with Haemophilia A	UK EC SA #2 - Protocol Amendme	10/10/2014	25
14/NW/0130/AM02	RESPONSE	2	13/05/2014	22
14/NW/0278/AM01	The Role of the Baby in Recovery From Psychosis After Childbirth	Version 1	22/09/2014	28
14/NW/0294/AM04	Study of REGN1908-1909 in volunteers with allergic rhinitis	Add adverts	23/12/2014	28
14/NW/0321/AM01	Sebelipase Alfa in Infants with Rapidly Progressive LAL Deficiency	01	29/05/2014	19

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**
10/H1008/72/AM13/1	Nottingham Research Biorepository (NRB)	11	11/08/2014	6
11/NW/0021/AM02/1	Investigation of the genetic basis of renal tract abnormalities	3	27/11/2014	9
12/NW/0014/AM11/1	FOCUS FH	7	14/04/2014	10
12/NW/0160/AM08/1	Gastrointestinal care for patients undergoing pelvic chemoradiotherapy	2	14/08/2014	12
12/NW/0321/AM08/1	Extended BMN 701 treatment in patients with late-onset Pompe disease	6	21/01/2015	13
12/NW/0794/AM03/1	Southampton Research Biorepository (SRB)	1	03/12/2014	7
13/NW/0058/AM03/1	The Amputation Surgical Site Infection Trial (ASSIT)	4	06/10/2014	14
13/NW/0477/AM01/1	Study of BYL719-LJM716 combination in patients with oesophageal cancer	02	11/02/2014	4

13/NW/0727/AM06/1	The effects of SEP-363858 on high or low schizotype characteristics	Final	05/08/2014	13
13/NW/0727/AM08/1	The effects of SEP-363858 on high or low schizotype characteristics	4	03/03/2015	9
13/NW/0730/AM01/1	Neuroinflammation and serotonergic change in HD gene carriers	Amendment 1	05/09/2014	7
13/NW/0777/AM03/1	GWP42003 for treatment of schizophrenia or related psychotic disorders	2	24/07/2014	10
13/NW/0811/AM05/1	PK Study in Adolescents and Young Adults Treated with Glucocorticoids	5	17/11/2014	1
13/NW/0823/AM01/1	The SCRIBE (Social Cognition Research in Bonding and Emotions) study	1	04/07/2014	7
14/NW/0001/AM04/1	Continuation Study of Prophylactic BAX 855 in PTP with Haemophilia A	2	24/11/2014	16
14/NW/0130/AM02/1	RESPONSE	2	13/05/2014	10
14/NW/0321/AM01/1	Sebelipase Alfa in Infants with Rapidly Progressive LAL Deficiency	1	29/05/2014	4

Unfavourable opinion timeline				
Amendment REC Reference	**Title**	**Version**	**Date**	**Number of Days on Clock**
12/NW/0795/AM05/1	The Lipid Efficacy and Safety Add-On Study.	3	24/11/2014	18
13/NW/0794/AM01/1	Influence of nitrates on bone and endothelial function in diabetes.	1	07/05/2014	7

Table 11: **Items exceeding timelines**

Modified Amendments over 14 day timeline				
Amendment REC Reference	**Title**	**Version**	**Date**	**Number of Days on Clock**
12/NW/0795/AM05/1	The Lipid Efficacy and Safety Add-On Study.	3	24/11/2014	18
14/NW/0001/AM04/1	Continuation Study of Prophylactic BAX 855 in PTP with Haemophilia A	2	24/11/2014	16