

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

**Annual Report**

**01 April 2016 - 31 March 2017**



## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	North West - Greater Manchester Central Research Ethics Committee
<b>Type of REC:</b>	RECs recognised to review CTIMPS in Healthy Volunteers - Type i, RECs recognised to review CTIMPS in Patients - Type iii
<b>Type of Flag:</b>	Establishing Research Tissue Banks, Phase 1 Studies in Healthy Volunteers, Phase 1 Studies in Patients, Research Involving Children
<b>Chair:</b>	Dr Barbara Potrata
<b>Vice-Chair:</b>	Dr George Gkimpas
<b>Alternate Vice-Chair:</b>	None
<b>REC Manager:</b>	Miss Amber Ecclestone Miss Katherine Ashley (From 03/04/2017)
<b>REC Assistant:</b>	Jenna Woodburn (to January 2017) Ms Harriet Wood (From March 2017)
<b>Committee Address:</b>	3rd Floor Barlow House 4 Minshull Street Manchester M1 3DZ
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## Chair's overview of the past year:

The Committee has continued to work well together this year despite major changes, both in regards to the HRA processes and procedures, and the Committee's membership. We thanked previous Chair (Simon Mitchell) and Vice-Chair (Roger Rawbone) for all their hard work over the years. These roles have now been taken on by Barbara Potrata as Chair and Georgios Gkimpas as Vice-Chair.

We wished all the best to three more Committee members (Fran Maders, Beatriz Duran Jimenez and Judith Ormrod). We have also said goodbye to our excellent REC Manager Kath Osborne and have welcomed both Amber Ecclestone who is now on maternity leave, and Katherine Ashley as our new REC managers.

We are delighted to now have a new Anesthetist, Dr Bernadette Lomas, who is at the beginning of her role on the ethics committee and has been offered full support from the experienced members. We are finding productive ways of working optimally together, and we are looking forward to supporting researchers in their work while guarding safety, dignity and well-being of research participants.

## 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	12/09/2016
Mr K Cook	Qi Gong Teacher	Lay	01/05/2013	
Dr B Duran-Jimenez	Paediatric Clinical Trials Pharmacist	Expert	01/01/2012	08/08/2016
Dr George Gkimpas	Clinical Fellow	Expert	01/02/2016	
Mrs D Hamburger	Retired Social Worker	Lay Plus	01/05/2013	
Dr Fay Hartley	Student Physician Associate	Expert	01/12/2015	18/05/2016
Dr P Klimiuk	Consultant Rheumatologist	Expert	01/08/2013	
Mr Rodney Lighton	Retired Software Engineer	Lay Plus	01/05/2013	
Dr Bernadette Lomas	Doctor, ST6 in Anaesthesia	Expert	01/03/2017	
Professor S J Mitchell	Consultant Neonatologist	Expert	15/10/2004	16/10/2016
Dr J Ormrod	Lecturer / Staff Support Counsellor	Expert	06/09/2006	30/09/2016
Dr Barbara Potrata	Research Fellow	Lay Plus	17/11/2008	
Dr R G Rawbone	Retired Occupational Physician	Expert	06/11/2008	12/09/2016
Dr Penelope 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
Dr Lorraine Lighton	Retired Consultant in Communicable Disease Control	Expert	12/12/2016
Professor Basil Sharrack	Consultant Neurologist	Expert	13/02/2017
Dr Lorraine Murphy	Pharmaceutical Consultant	Expert	13/02/2017

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

<b>Name</b>	<b>Declaration of Interest</b>	<b>Date</b>
Mr K Cook	None	31/03/2017
Dr B Duran-Jimenez	UHSM Lead Clinical Trial Pharmacist, Clinical Trial Pharmacist on Sponsor Oversight Committee (UHSM).	26/04/2016
Dr P Klimiuk	None	30/03/2017
Mr Rodney Lighton	None	31/03/2017
Mrs F E Maders	None	31/03/2017
Dr Barbara Potrata	None	30/03/2017
Dr Penelope Stanford	Royal College of Nursing Committee Member  Lay Member Epilepsy Action Committee Member Royal College of Nursing	31/03/2017
Mr I A T Taylor	Involved in assisting companies who are also involved in R&D activities. To secure financial benefit from the Governments R&D tax credit scheme	31/03/2017
Mr John Addison	None	31/03/2017
Mrs Debbie Hamburger	None	09/03/2017
Dr George Gkimpas	None	31/03/2017

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

Month	Date	Number of Members Present at Meeting
April	11/04/2016	8
May	09/05/2016	13
June	13/06/2016	7
August	08/08/2016	11
September	12/09/2016	8
October	10/10/2016	8
December	12/12/2016	8
January	09/01/2017	9
February	13/02/2017	11
March	13/03/2017	8

10 full committee meetings were held during the reporting period.

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

Month	Date	Number of Members Present at Meeting
April	11/04/2016	2
April	27/04/2016	2
May	09/05/2016	2
May	13/05/2016	2
May	20/05/2016	2
May	27/05/2016	2
May	27/05/2016	2
June	03/06/2016	2
June	13/06/2016	2
June	24/06/2016	2
July	01/07/2016	2
July	06/07/2016	2
July	29/07/2016	2
August	08/08/2016	2
August	12/08/2016	2
August	19/08/2016	2
September	02/09/2016	2
September	12/09/2016	2
September	30/09/2016	2
October	19/10/2016	2
November	04/11/2016	2
November	17/11/2016	2
December	12/12/2016	2
December	29/12/2016	2
January	11/01/2017	2
January	25/01/2017	2
February	08/02/2017	2
February	22/02/2017	2
March	08/03/2017	2
March	22/03/2017	2

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

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

0

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Mr J Addison	8
Mrs J Budd	2
Mr K Cook	5
Dr B Duran-Jimenez	1
Dr George Gkimpas	8
Mrs D Hamburger	8
Dr P Klimiuk	8
Mr Rodney Lighton	8
Mrs F E Maders	8
Professor S J Mitchell	6
Dr J Ormrod	3
Dr Barbara Potrata	9
Dr R G Rawbone	2
Dr Penelope Stanford	5
Mr I A T Taylor	7

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Mr J Addison	10
Mr K Cook	1
Dr George Gkimpas	7
Mrs D Hamburger	1
Mr Rodney Lighton	3
Professor S J Mitchell	18
Dr Barbara Potrata	7
Dr R G Rawbone	12
Dr Penelope Stanford	1



**Training 01 April 2016 - 31 March 2017**

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Mr J Addison	06/04/2016	Quantitative Research
Dr George Gkimpas	06/04/2016	Quantitative Research Methods and Statistics
Dr George Gkimpas	08/06/2016	Committee Members Induction
Dr George Gkimpas	29/06/2016	Handling Health-Related Findings
Dr George Gkimpas	22/08/2016	Equality, Diversity & Human Rights
Dr Fay Hartley	08/06/2016	Committee Members Induction
Dr P Klimiuk	24/08/2016	Equality and Diversity
Dr P Klimiuk	30/01/2017	Information Governance
Dr P Klimiuk	30/01/2017	Mental Capacity Act
Dr P Klimiuk	30/01/2017	Safeguarding Adults 2017
Dr P Klimiuk	30/01/2017	Safeguarding Children
Mr Rodney Lighton	29/06/2016	Handling Health-Related Findings in Research (Joint MRC/HRA)
Mrs F E Maders	16/02/2017	National Members Training Day
Mr I A T Taylor	06/07/2016	Local Training Day - York Regional Day
Mr K Cook	22/03/2017	National Members Training Day
Dr Barbara Potrata	28/03/2017	Chairs Review Programme Workshop

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

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

<b>Applications for full ethical review – Study Type</b>	<b>Number</b>	<b>%</b>
Clinical Trial of Investigational Medicinal Product	13	27.66
Phase 1	8	17.02
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	1	2.13
Research Database (including renewals)	1	2.13
Others	24	51.06
<b>Total Applications Reviewed</b>	<b>47</b>	<b>100</b>

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

Number of applications made invalid by the REC Manager	1
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	11
Number of paediatric applications reviewed	8
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	4

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

<b>Decisions taken at meetings following review of applications</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	3	6.38
Favourable Opinion with Additional Conditions	7	14.89
Unfavourable Opinion	1	2.13
Provisional Opinion	36	76.60
Provisional Opinion Pending Consultation with Referee	0	0.00
<b>Total</b>	<b>47</b>	<b>100</b>
Number of studies sent back to full committee meeting for final opinion	0	

**Table 4: Summary of current status of applications reviewed during the reporting period**

<b>Status of applications at date of generation of report</b>	<b>Number</b>	<b>%</b>
Further Information Favourable Opinion with Standard Conditions	31	65.96
Further Information Favourable Opinion with Additional Conditions	3	6.38
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	3	6.38
Favourable Opinion with Additional Conditions	7	14.89
Unfavourable Opinion	1	2.13
Provisional Opinion	1	2.13
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	2.13
<b>Total</b>	<b>47</b>	<b>100</b>

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

<b>Average number of applications reviewed per full meeting</b>	4.70
<b>Number of completed applications for full ethical review</b>	46
<b>Number of completed applications for full ethical review over 60 days</b>	0
<b>Number of completed applications over 60 days as a % of total</b>	0.00%
<b>Number of completed applications for full ethical review over 40 days</b>	11
<b>Number of completed applications over 40 days as a % of total</b>	23.40%
<b>Number of days taken to final decision – average (mean)</b>	34
<b>Number of SSAs (non-Phase 1) reviewed</b>	31
<b>Number of completed applications for SSA review over 25 days</b>	3
<b>Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs</b>	9.68%
<b>Number of SSAs (Phase 1) reviewed</b>	7
<b>Number of completed applications for SSA review over 14 days</b>	0
<b>Number of completed applications for SSA review over 14 days as % of all Phase 1 SSAs</b>	0.00%
<b>Number of substantial amendments reviewed</b>	152
<b>Number of completed substantial amendments over 35 days</b>	5
<b>Number of completed substantial amendments over 35 days as a % of total substantial amendments</b>	3.29%
<b>Number of completed substantial amendments over 28 days</b>	33
<b>Number of completed substantial amendments over 28 days as a % of total substantial amendments</b>	21.71%
<b>Number of modified amendments reviewed</b>	10
<b>Number of completed modified amendments over 14 days</b>	3
<b>Number of completed modified amendments over 14 days as a % of total modified amendments</b>	30.00%
<b>Number of non substantial amendments received</b>	123
<b>Number of substantial amendments received for information</b>	0
<b>Number of substantial amendments received for new sites/PIs</b>	36
<b>Number of annual progress reports received</b>	78
<b>Number of safety reports received</b>	43
<b>Number of Serious Adverse Events received</b>	2
<b>Number of final reports received</b>	32

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

<b>Further Information Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
16/NW/0217	Young Persons Chlamydia Screening Survey	36
16/NW/0219	Phase III with Octreotide capsules in acromegaly patients	38
16/NW/0228	R475-PN-1523 Fasinumab in patients with knee or hip osteoarthritis	41
16/NW/0263	Dementia Care Mapping (DCM) and Person Centred Care (PCC).Version 1.	41
16/NW/0304	DIRMP	22
16/NW/0306	Manchester anti-VEGF vs anti-VEGF & Laser (MarVEL) Study	32
16/NW/0314	Experience of psychological therapy for postnatal depression	23
16/NW/0324	EDEN - Early DEvelopment in Neurofibromatosis type 1	40
16/NW/0408	A phase 1 study of GWN323 in combination with PDR001	55
16/NW/0453	Frailty and Advanced Chronic Kidney Disease	50
16/NW/0459	The ELDERS Study - Immunotherapy in Elderly Cancer Patients	51
16/NW/0498	EPZ-6438: IV microtracer and ADME Study	38
16/NW/0530	GWP42003-P (CBD) Relative Bioavailability Study	30
16/NW/0571	Synovial Pathology of Treatment response in Inflammatory Arthritis	44
16/NW/0576	Evaluate efficacy and safety of 4 doses of CHF6001DPI in COPD patients	42
16/NW/0592	Next Level: Method of Levels for Psychosis	21
16/NW/0602	Protocol 9785-CL-0335	28
16/NW/0643	ACP Experiences Project	37
16/NW/0686	CR-BD-001	37
16/NW/0693	SAD/MAD PK and PD Study in Healthy Male Subjects	20
16/NW/0798	Study on the effect of theobromine in suppression of cough	40
16/NW/0862	Bioavailability of BMS-986141 (QCL117808)	35
16/NW/0876	The effects of RPL554 in addition to tiotropium in COPD patients	43
17/NW/0012	LILACS	40
17/NW/0022	Post-Authorization Study of HyQvia in Pediatric PIDD subjects	40
17/NW/0058	MAPS-2: Metoclopramide and SOD mouth paste to prevent pneumonia vs 1	32
17/NW/0082	Comparison of mesh fixation techniques in elective laparoscopic repair	28
17/NW/0112	Communication about the psychosexual consequences of breast cancer	45
17/NW/0145	Longitudinal study of chronic wounds using novel measurement tech v01	30
17/NW/0165	Children with SVCHD; considering the parent experience	27
17/NW/0168	CA209-744: Nivolumab and brentuximab vedotin for cHL	59

<b>Further Information Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
16/NW/0587	VESPA study	28
16/NW/0694	An evaluation of a pilot digital-based, pain-management intervention	36
17/NW/0008	Natural History Study of CBSDH	51

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

<b>Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
16/NW/0593	Imaging carotid plaque inflammation using GE180-PET/MRI	26
16/NW/0627	MAHSC Cardiovascular Diseases Biobank (CVD-Biobank)	25
17/NW/0076	A study examining the effects of RGH-706 in healthy male volunteers	20

<b>Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
16/NW/0260	Investigation of low-sound-level auditory processing deficits	28
16/NW/0351	Preoperative teaching for urgent cardiac surgery patients	18
16/NW/0430	Safety and PK of VX-440 with VX-661/Ivacaftor in Healthy Adults	20
16/NW/0448	Platelet function in preeclampsia: ROTEM Assessment V2	29
16/NW/0718	Respiratory Distress Symptom Intervention (RDSI)	25
17/NW/0011	ZPL389/103	28
17/NW/0084	A Phase I study of Y14 in adult subjects	23

<b>Unfavourable Opinion</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
16/NW/0328	MRI Cardio-pulmonary Exercise Testing Database	18

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

<b>Provisional Opinion Pending Consultation with Referee</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>

<b>Further information response not complete</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>

<b>Withdrawn after the meeting</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
16/NW/0390	Placebo- and Active-Controlled Study of DS-5565 in fibromyalgia	29

**Table 10.1: Breakdown of current status of all substantial amendments reviewed within the reporting period**

<b>Favourable opinion</b>				
<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>
08/H1008/25/AM13	Predicting Response to Methotrexate in Rheumatoid Arthritis	9.0	04/04/2016	23
08/H1008/25/AM17	Predicting Response to Methotrexate in Rheumatoid Arthritis	10	22/12/2016	18
08/H1008/25/AM18	Predicting Response to Methotrexate in Rheumatoid Arthritis	11	14/02/2017	6
08/H1008/32/AM28	HOPON version 1	24	18/03/2016	19
08/H1008/32/AM30	HOPON version 1	Substantial Amendment 26	14/04/2016	11
08/H1008/32/AM31	HOPON version 1	23	06/12/2016	16
08/H1008/32/AM32	HOPON version 1	Protocol Version 9, 11/01/2017	07/02/2017	21
09/H1008/137/AM11	Safety and effectiveness of biologic treatments in children	5	07/04/2016	25
09/H1008/40/AM23	Extension Study of ENB-0040 in Severely Affected Infants and Young Chil	12	03/05/2016	14
09/H1008/40/AM24	Extension Study of ENB-0040 in Severely Affected Infants and Young Chil	Substantial Amendment 13	20/03/2017	17
09/H1008/81/AM46	Breast cancer risk assessment and validation in The NHSBSP (PROCAS)	24 02.02.2017	02/03/2017	26
10/H1008/73/AM13	HGT-SAN-067	7	29/03/2016	20
10/H1008/74/AM04	Genetics of Schwannomas and Meningiomas	Substantial Amendment 5	15/11/2016	20
10/H1008/74/AM05	Genetics of Schwannomas and Meningiomas	Amendment 6, 1st February 2017	13/02/2017	10
11/NW/0016/AM20	SBC-102 in children with growth failure due to LAL deficiency	Substantial Amendment 15	21/09/2016	20
11/NW/0080/AM12	Masitinib vs Imatinib in first line metastatic GIST - AB04030 v4.0 UK2	Substantial Amendment 8	13/09/2016	21
11/NW/0080/AM13	Masitinib vs Imatinib in first line metastatic GIST - AB04030 v4.0 UK2	Combined Investigators Brochure V1.0 Oct 2016	04/01/2017	21
11/NW/0428/AM02	Off-the-shelf use of toric IOLs (Version 2)	2	01/01/2016	24
11/NW/0659/AM12	PK comparison of Advagraf and Prograf in children	Substantial Amendment 6	04/08/2016	17



11/NW/0659/AM13	PK comparison of Advagraf and Prograf in children	APL Amendment S - Part C (GP L	25/01/2017	26
11/NW/0731/AM04	Paraoxonase and HDL qualities in glycaemia and inflammation	5	03/05/2016	28
11/NW/0773/AM13	Intrathecal Enzyme Replacement Therapy for MPS II Extension Study	Substantial Protocol Amendment 8	17/03/2016	18
12/NW/0044/AM14	Study of Anaceptrapib in Heterozygous Familial Hypercholesterolemia	REC & MHRA : Updated MK-0859 I	23/09/2016	24
12/NW/0157/AM09	Ipilimumab dose comparison study in Metastatic Melanoma	EC08	01/03/2017	27
12/NW/0694/AM08	A0221047 Paediatric NDO study	Substantial Amendment 4	21/09/2016	5
12/NW/0794/AM06	Southampton Research Biorepository (SRB)	Substantial Amendment 4	01/09/2016	42
13/NW/0006/AM16	Phase III study of Brentuximab vedotin in T-cell lymphoma patients	12	23/11/2016	29
13/NW/0032/AM15	AZD9291 in patients with advanced NSCLC, following EGFR TKI therapy	12	20/06/2016	16
13/NW/0068/AM07	OUTPASS - OUtcomes of Treatment in Psoriatic Arthritis Study Syndicate	Substantial Amendment 2b	23/08/2016	23
13/NW/0068/AM08	OUTPASS - OUtcomes of Treatment in Psoriatic Arthritis Study Syndicate	Substantial Amendment 3	31/08/2016	15
13/NW/0199/AM07	AMG 145 in patients with Severe Familial Hypercholesterolemia	Substantial Amendment 6	14/04/2016	15
13/NW/0199/AM08	AMG 145 in patients with Severe Familial Hypercholesterolemia	7	19/05/2016	31
13/NW/0297/AM11	Hypertriglyceridaemia - cause and effects	6	19/10/2016	36
13/NW/0320/AM10	WA28117 Study of Tocilizumab in pcJIA	Substantial Amendment 4	21/03/2016	28
13/NW/0496/AM08	Pregabalin in subjects with Primary Generalised Tonic-Clonic seizures	3	19/07/2016	14
13/NW/0698/AM10	LDK378 vs Chemo in newly diagnosed untreated ALK+ NSCLC patients	05	18/11/2016	7
13/NW/0778/AM10	ProCervix vs placebo in women with HPV 16 & HPV 18 infection	5	19/05/2016	14
13/NW/0778/AM11	ProCervix vs placebo in women with HPV 16 & HPV 18	6	13/05/2016	24

	infection			
14/NW/0001/AM09	Continuation Study of Prophylactic BAX 855 in PTP with Haemophilia A	6	31/05/2016	24
14/NW/0001/AM13	Continuation Study of Prophylactic BAX 855 in PTP with Haemophilia A	Substantial Amendment 8	04/08/2016	11
14/NW/0001/AM14	Continuation Study of Prophylactic BAX 855 in PTP with Haemophilia A	9	23/11/2016	29
14/NW/0055/AM07	Pregabalin Open Label Follow up study of A0081105	Substantial Amendment 2	20/10/2016	35
14/NW/0069/AM13	PK & Safety of Naloxegol in Paediatric Patients Receiving Opioids	SA05	14/10/2016	26
14/NW/0176/AM07	The Paediatric EVICELÂ® Bleeding Study	5	06/05/2016	27
14/NW/0193/AM05	Neurodevelopment of Babies Born to Mothers with Epilepsy (NaME) Study	Substantial Amendment 2	16/08/2016	34
14/NW/0321/AM17	Sebelipase Alfa in Infants with Rapidly Progressive LAL Deficiency	Substantial Amendment 21/07/2016	21/07/2016	55
14/NW/0321/AM18	Sebelipase Alfa in Infants with Rapidly Progressive LAL Deficiency	Parents ICF Version 6.0	16/11/2016	28
14/NW/0335/AM01	Experiences of Leaving Early Intervention	SA1	28/09/2016	17
14/NW/0335/AM02	Experiences of Leaving Early Intervention	2 - 02/02/017	07/02/2017	27
14/NW/0351/AM03	GENIALL	1,14Nov2016	14/11/2016	30
14/NW/1008/AM06	Collaborative case management to aid return to work	Substantial Amendment 5	10/08/2016	30
14/NW/1057/AM03	Assessing the effects of mechanical unloading on repair - version 1	3	20/04/2016	26
14/NW/1067/AM14	PROteKT	9	29/04/2016	27
14/NW/1067/AM18	PROteKT	10	21/02/2017	31
14/NW/1092/AM04	Cellular Immunotherapy Treatment Antigen-Directed for EBV Lymphoma	Substantial Amendment 3	23/09/2016	11
14/NW/1110/AM06	rEECur	6	03/06/2016	15
14/NW/1110/AM08	rEECur	SA08	29/11/2016	33
14/NW/1331/AM01	Argus II Retinal Prosthesis System Dry AMD Feasibility Study	Substantial Amendment 1	16/09/2016	15
14/NW/1373/AM09	DS-5565 in pain associated with fibromyalgia (FM)	Substantial Amendment 5	18/04/2016	10

14/NW/1373/AM10	DS-5565 in pain associated with fibromyalgia (FM)	6	05/08/2016	17
14/NW/1374/AM09	DS-5565 for 52 weeks in pain associated with fibromyalgia (FM)	Substantial Amendment 7	18/04/2016	10
14/NW/1374/AM10	DS-5565 for 52 weeks in pain associated with fibromyalgia (FM)	8	18/07/2016	30
14/NW/1374/AM11	DS-5565 for 52 weeks in pain associated with fibromyalgia (FM)	9	20/10/2016	23
14/NW/1374/AM12	DS-5565 for 52 weeks in pain associated with fibromyalgia (FM)	Substantial Amendment 10	28/02/2017	28
14/NW/1374/AM13	DS-5565 for 52 weeks in pain associated with fibromyalgia (FM)	Substantial Amendment 11	16/03/2017	19
14/NW/1397/AM02	CoSMIC: Colorectal ca & Synchronous liver Metastases Inception Cohort.	Substantial Amendment 2	05/09/2016	8
15/NW/0009/AM05	Denosumab in Children With Osteogenesis Imperfecta	5	28/04/2016	19
15/NW/0009/AM06	Denosumab in Children With Osteogenesis Imperfecta	Substantial Amendment 6	04/08/2016	18
15/NW/0009/AM10	Denosumab in Children With Osteogenesis Imperfecta	Substantial Amendment 7	17/01/2017	30
15/NW/0009/AM12	Denosumab in Children With Osteogenesis Imperfecta	Substantial Amendment 8 - PIS	21/02/2017	13
15/NW/0010/AM03	SLUMBRS (Version 1)	1. 12th September 2016	18/09/2016	24
15/NW/0011/AM04	Transplant BRaVE Version 1	Protocol amendment 2, protocol	04/10/2016	31
15/NW/0015/AM06	MEDI4736 in NSCLC (D4191C00001, PACIFIC Study)	SA06 (protocol amendment, updated PIS, updated IB)	23/03/2016	26
15/NW/0015/AM08	MEDI4736 in NSCLC (D4191C00001, PACIFIC Study)	SA07	31/01/2017	28
15/NW/0022/AM03	Bone anchored maxillary protraction (BAMP)RCT	Substantial Amendment 1	19/09/2016	19
15/NW/0067/AM04	ASCEND- Peds	SA-003	29/03/2016	20
15/NW/0077/AM02	The behavioural phenotype in MPS IH	2	28/04/2016	12
15/NW/0152/AM08	MetaPHer	2	22/10/2016	40

15/NW/0152/AM09	MetaPHer	Substantial Amendment 3	22/02/2017	14
15/NW/0153/AM06	MeMoSa: The effects of Morphine Sulphate	3	01/12/2016	34
15/NW/0154/AM01	Immediate loading of bone anchored hearing devices. Version 1	1 - 19/12/2016	05/01/2017	19
15/NW/0172/AM03	REmote MOnitoring in Rheumatoid Arthritis (REMORA) v1.0	2	08/06/2016	25
15/NW/0301/AM01	Cardiac myocytes derived from skin fibroblasts	1	02/06/2016	12
15/NW/0385/AM12	MBS2320 - SAD/MAD/Food Effect/Relative Bioavailability and DDI Study	5	20/05/2016	13
15/NW/0385/AM13	MBS2320 - SAD/MAD/Food Effect/Relative Bioavailability and DDI Study	6	14/07/2016	46
15/NW/0385/AM18	MBS2320 - SAD/MAD/Food Effect/Relative Bioavailability and DDI Study	Substantial Amendment 8	02/12/2016	20
15/NW/0405/AM09	Evaluate 2 doses of LND101001 in Mild-Moderate Alzheimer's patients	4	27/06/2016	9
15/NW/0431/AM04	Open-label phase II trial with a pan_FGFR Tyrosine Kinase Inhibitor	Substantial Amendment 3	31/08/2016	7
15/NW/0431/AM06	Open-label phase II trial with a pan_FGFR Tyrosine Kinase Inhibitor	4	16/12/2016	23
15/NW/0440/AM05	234HV101 - SAD	Substantial Amendment 3	12/04/2016	10
15/NW/0468/AM05	ACP-196 as mono and combination therapy in untreated CLL patients	3	29/04/2016	18
15/NW/0468/AM08	ACP-196 as mono and combination therapy in untreated CLL patients	4	23/06/2016	19
15/NW/0573/AM02	NP25737 PK & Safety Study of TCZ in patients <2 years with active sJIA	2	10/02/2016	18
15/NW/0691/AM02	Phase 1 OL study of AZD0156 monotherapy or with combination therapies	1	19/05/2016	14
15/NW/0713/AM02	GTx G200802 - GTx-024(Enobosarm) on ER+/AR+ Breast Cancer	1	26/05/2016	5
15/NW/0713/AM03	GTx G200802 - GTx-024(Enobosarm) on ER+/AR+ Breast Cancer	3	28/09/2016	30
15/NW/0713/AM04	GTx G200802 - GTx-024(Enobosarm) on ER+/AR+ Breast Cancer	(Legal Rep Change)	24/01/2017	27
15/NW/0748/AM01	Clients' experiences of the St Marys SARC: A qualitative study	1 05/01/2017	21/01/2017	34

15/NW/0779/AM04	ALXN1210-PNH-201: ALXN1210 Phase 2 study in patients with PNH	Substantial Amendment 2		20
15/NW/0779/AM05	ALXN1210-PNH-201: ALXN1210 Phase 2 study in patients with PNH	Substantial Amendment 3	14/09/2016	20
15/NW/0854/AM03	IV Administration of 14C-LY2606368	2	31/05/2016	19
15/NW/0854/AM04	IV Administration of 14C-LY2606368	4	29/07/2016	17
15/NW/0899/AM01	Does Pancreatic Transplantation Reverse Cardiovascular Damage in DM	1	01/06/2016	14
15/NW/0899/AM03	Does Pancreatic Transplantation Reverse Cardiovascular Damage in DM	2	18/01/2017	28
15/NW/0912/AM01	PACT-G	1	04/05/2016	27
15/NW/0912/AM02	PACT-G	2	14/09/2016	34
15/NW/0912/AM03	PACT-G	3	18/11/2016	22
15/NW/0912/AM05	PACT-G	Amendment number 4 02.02.2017	02/02/2017	32
16/NW/0007/AM01	A study to look at the effects of secukinumab in paediatric psoriasis	Substantial Amendment 1	17/03/2016	33
16/NW/0012/AM01	HOMAGE	Substantial Amendment 1	03/08/2016	7
16/NW/0033/AM04	Correlation of Rectal Prolapse with AAR Parameters	3	15/05/2016	29
16/NW/0041/AM02	SOLAR-1: alpelisib + fulvestrant in advanced breast cancer	1	16/06/2016	19
16/NW/0041/AM04	SOLAR-1: alpelisib + fulvestrant in advanced breast cancer	4	21/10/2016	34
16/NW/0041/AM06	SOLAR-1: alpelisib + fulvestrant in advanced breast cancer	CBYL719C2301 PA03 substantial	07/02/2017	22
16/NW/0060/AM02	UltraSound Evaluation For mUsculoskeletal Lupus (USEFUL)	Substantial Amendment 1	29/04/2016	24
16/NW/0149/AM01	K1-70 – Safety Study in Subjects with Graves' Disease.	1	02/06/2016	22
16/NW/0149/AM03	K1-70 – Safety Study in Subjects with Graves' Disease.	2	12/10/2016	16
16/NW/0151/AM01	Study of the Effect of AUT00206 in healthy male - ketamine challengeV1	1	12/07/2016	29
16/NW/0151/AM04	Study of the Effect of AUT00206 in healthy male - ketamine challengeV1	AUT021206	14/02/2017	19
16/NW/0164/AM01	Biomarkers Of Lynch syndrome Tumours (BOLT)	Amendment 1, 09/01/2017	24/01/2017	29
16/NW/0169/AM03	First line treatment of metastatic bowel cancer with S95005 & Avastin	3	30/11/2016	22

16/NW/0169/AM04	First line treatment of metastatic bowel cancer with S95005 & Avastin	Substantial Amendment No4 to the clinical study protocol final version dated 25th January 2017	02/02/2017	22
16/NW/0219/AM02	Phase III with Octreotide capsules in acromegaly patients	2	01/07/2016	29
16/NW/0219/AM05	Phase III with Octreotide capsules in acromegaly patients	Amendment 3: Temporary Hold on Study Enrolment	10/01/2017	15
16/NW/0228/AM02	R475-PN-1523 Fasinumab in patients with knee or hip osteoarthritis	2	20/06/2016	33
16/NW/0228/AM04	R475-PN-1523 Fasinumab in patients with knee or hip osteoarthritis	Substantial Amendment 3	21/09/2016	12
16/NW/0228/AM07	R475-PN-1523 Fasinumab in patients with knee or hip osteoarthritis	R475-PN-1523 Protocol	17/01/2017	30
16/NW/0228/AM09	R475-PN-1523 Fasinumab in patients with knee or hip osteoarthritis	Change of Principle investigator at 2x non-NHS sites	22/02/2017	12
16/NW/0314/AM01	Experience of psychological therapy for postnatal depression	1	07/09/2016	31
16/NW/0430/AM01	Safety and PK of VX-440 with VX-661/Ivacaftor in Healthy Adults	1	30/06/2016	6
16/NW/0430/AM02	Safety and PK of VX-440 with VX-661/Ivacaftor in Healthy Adults	Amendment 2, Protocol 3.0, 5th July 2016		19
16/NW/0430/AM03	Safety and PK of VX-440 with VX-661/Ivacaftor in Healthy Adults	Substantial Amendment 3	04/08/2016	18
16/NW/0498/AM01	EPZ-6438: IV microtracer and ADME Study	SA 1	23/09/2016	24
16/NW/0498/AM02	EPZ-6438: IV microtracer and ADME Study	SA2 (Protocol V3)	21/03/2017	15
16/NW/0530/AM01	GWP42003-P (CBD) Relative Bioavailability Study	Substantial Amendment 1	16/09/2016	7
16/NW/0530/AM02	GWP42003-P (CBD) Relative Bioavailability Study	2	08/09/2016	21
16/NW/0587/AM01	VESPA study	Substantial amendment 1, 29/11/16	01/12/2016	32

16/NW/0592/AM01	Next Level: Method of Levels for Psychosis	Substantial amendment 1, 27.09.2016	27/09/2016	7
16/NW/0592/AM02	Next Level: Method of Levels for Psychosis	2	01/11/2016	18
16/NW/0693/AM01	SAD/MAD PK and PD Study in Healthy Male Subjects	SA1 Protocol V2	23/01/2017	28
16/NW/0718/AM01	Respiratory Distress Symptom Intervention (RDSI)	1 23.12.2016	19/01/2017	25
17/NW/0022/AM01	Post-Authorization Study of HyQvia in Pediatric PIDD subjects	Substantial Amendment 01	16/03/2017	15

### Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
13/NW/0297/AM09	Hypertriglyceridaemia - cause and effects	5	05/05/2016	12
13/NW/0385/AM05	Cognitive remediation for first episode of psychosis patients	Amendment 4, 18/03/2016	18/03/2016	25
14/NW/0321/AM16	Sebelipase Alfa in Infants with Rapidly Progressive LAL Deficiency	Amendment 3.1	29/03/2016	20
14/NW/1008/AM05	Collaborative case management to aid return to work	4	31/05/2016	20
14/NW/1110/AM05	rEECur	SA04	23/03/2016	18
15/NW/0013/AM05	PEGS: Patients experiences of Genetic Conditions & Services	1	16/11/2016	18
15/NW/0077/AM04	The behavioural phenotype in MPS IH	3. 03/01/2017	09/01/2017	24
15/NW/0385/AM19	MBS2320 - SAD/MAD/Food Effect/Relative Bioavailability and DDI Study	UKCTG early-adopters	31/01/2017	34
15/NW/0685/AM01	Nottingham Health Science Biobank (NHSB)	1.0	02/11/2016	28
16/NW/0169/AM02	First line treatment of metastatic bowel cancer with S95005 & Avastin	Amendment 2 to the clinical study protocol, final version dated 17 May 2016	24/06/2016	8

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

### Favourable opinion timeline

<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>
13/NW/0297/AM09/1	Hypertriglyceridaemia - cause and effects	5 (modified)	09/06/2016	15
13/NW/0385/AM05/1	Cognitive remediation for first episode of psychosis patients	4 modified	10/05/2016	11
14/NW/0321/AM16/1	Sebelipase Alfa in Infants with Rapidly Progressive LAL Deficiency	Modified Amendment 3.1	03/05/2016	15
14/NW/1008/AM05/1	Collaborative case management to aid return to work	4 (modified)	03/08/2016	9
14/NW/1110/AM05/1	rEECur	Modified Amendment SA04	29/02/2016	2
15/NW/0013/AM05/1	PEGS: Patients experiences of Genetic Conditions & Services	Substantial amendment 1 - modified, 19th Dec 2016	20/12/2016	6
15/NW/0147/AM01/1	How do perceptions of sleep quality relate to suicidality	Modified Substantial Amendment 1	31/03/2016	11
15/NW/0385/AM06/1	MBS2320 - SAD/MAD/Food Effect/Relative Bioavailability and DDI Study	Modified Diary Card - Part D	30/03/2016	12
15/NW/0684/AM01/1	Imaging measurement of early brain development (I-MED study) V1	Modified Substantial Amendment 1	04/04/2016	13
16/NW/0169/AM02/1	First line treatment of metastatic bowel cancer with S95005 & Avastin	2 modified	12/07/2016	17

#### **Unfavourable opinion timeline**

<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>
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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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**SSAs (non Phase 1) over 25 day timeline**

REC Reference	Title	Number of Days on Clock
16/NW/0336	A randomised, double-blind, placebo-controlled study to demonstrate the efficacy and long-term safety of Dupilumaab in adult patients with moderate-to-severe Atopic Dermatitis	31
16/NW/0337	A randomised, double-blind, placebo-controlled study to demonstrate the efficacy and long-term safety of Dupilumaab in adult patients with moderate-to-severe Atopic Dermatitis	31
16/NW/0345	A randomised, double-blind, placebo-controlled study to demonstrate the efficacy and long-term safety of Dupilumaab in adult patients with moderate-to-severe Atopic Dermatitis	49

**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
12/NW/0794/AM06	Southampton Research Biorepository (SRB)	Substantial Amendment 4	01/09/2016	42
13/NW/0297/AM11	Hypertriglyceridaemia - cause and effects	6	19/10/2016	36
14/NW/0321/AM17	Sebelipase Alfa in Infants with Rapidly Progressive LAL Deficiency	Substantial Amendment 21/07/20	21/07/2016	55
15/NW/0152/AM08	MetaPHer	2	22/10/2016	40
15/NW/0385/AM13	MBS2320 - SAD/MAD/Food Effect/Relative Bioavailability and DDI Study	6	14/07/2016	46

**Modified Amendments over 14 day timeline**

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
	Hypertriglyceridaemia - cause and effects	5 (modified)	09/06/2016	15

13/NW/0297/AM09/1				
14/NW/0321/AM16/1	Sebelipase Alfa in Infants with Rapidly Progressive LAL Deficiency	03/05/2016	03/05/2016	15
16/NW/0169/AM02/1	First line treatment of metastatic bowel cancer with S95005 & Avastin	2 modified	12/07/2016	17