

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

Annual Report

01 April 2015 - 31 March 2016



Part 1 – Committee Membership and Training

Name of REC:	North West - Greater Manchester South Research Ethics Committee
Type of REC:	Recognised Type III
Type of Flag:	Medical Devices, MCA, IRB, Phase 1 in patients
Chair:	Professor Sobhan Vinjamuri
Vice-Chair:	Mr Richard Hovey
Alternate Vice-Chair:	Mrs Lesley Thornton
REC Manager:	Mrs Kieran Hall (from March 2016) Mrs Margaret Hutchinson (up to March 2016) Miss Helen Penistone (up to August 2015)
REC Assistant:	Miss Ewa Grzegorska
Committee Address:	3rd Floor, Barlow House 4 Minshull Street Manchester M1 3DZ
Telephone:	0207 104 8128
Email:	nrescommittee.northwest-gmsouth@nhs.net

Chair's overview of the past year:

The GM South committee continues to perform well with 100% of decisions decided and communicated within the allotted time.

-Attendance at the meetings has been consistent and there has been good interaction within the committee and with researchers.

-All members have declared their interests and have attended their mandated training sessions as required by our terms of reference

-It is nice to notice continuous and persistent good performance within the context of changes to committee structure and administration

North West - Greater Manchester South Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Dr Anne Armstrong	Consultant Medical Oncologist	Expert	06/11/2008	
Mr Ed Brightman	Research Executive	Lay Plus	02/06/2014	30/03/2015
Mrs Rosalyn Chandler	Clinical Project Manager	Lay	01/10/2015	
Miss Kathryn Fellows	CRO Monitor	Expert	11/07/2013	
Mrs Christine Holly	Retired Librarian	Lay Plus	09/09/2012	
Mr Richard Hovey	Business Analyst	Lay Plus	31/01/2007	
Dr Paul Mortimer	Retired Executive Principal of Academy school group	Lay	01/01/2015	31/12/2015
Mrs Anne O'Brien	Senior Specialist Haematology Pharmacist	Expert	01/02/2014	
Mr David Ryder	Medical Statistician	Expert	01/06/2006	
Ms Joanne Skellern	Lecturer in Learning Disabilities	Expert	13/09/2012	
Dr Jacques SinFat Tamin	Honorary Senior Lecturer in Occupational Medicine	Expert	02/06/2014	
Mrs Lesley Thornton	Retired Clinical Delivery Director	Lay	04/09/2012	
Dr Nader Touqan	Speciality Training Registrar - Surgery	Expert	01/10/2015	
Professor Sobhan Vinjamuri (Chair)	Consultant in Nuclear Medicine	Expert	01/06/2012	

North West - Greater Manchester South Research Ethics Committee: Deputy Members

Name	Profession	Status	Meeting date attended
Dr Nathalie Abou-Zeid	Pharmacovigilance Pharmacist	Expert	n/a On a Break in Service up to 15/10/2015 then since resigned.

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

Name	Profession	Status	Meeting date attended
Mr John Addison	Retired Librarian	Lay	11/06/2015
Mr James Burns	Retired Housing Consultant	Lay	11/06/2016
Mr Frank Killen	Retired Engineer	Lay Plus	11/02/2016
Dr Lorraine Lighton	Consultant in Communicable Diseases	Expert	11/02/2016
Miss Kimberley Saint	Clinical Scientist	Expert	08/10/2015

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

Name	Declaration of Interest	Date
Dr Anne Armstrong	Consultancy fees from Pfizer and Roche from attending advisory board. Expert member to NICE Breast Cancer Standards Committee. Invited Reviewer to European Journal Cancer.	25/01/2016
Miss Kathryn Fellows	Employed by Chiltern Clinical Research Organisation.	14/01/2016
Mrs Christine Holly	None declared.	13/01/2016
Mr Richard Hovey	Own shares in various publicly quoted generalist unit/investment trusts which at any point in time may or may not have holdings in companies engaging in medical research. He does not have any direct shareholdings in companies that engage in medical research, nor any holdings in trusts specialising in companies that may undertake medical research.	13/01/2016
Mrs Anne O'Brien	None declared	14/01/2016
Mr David Ryder	NHS employee (statistician). Involved in grant applications and occasionally peer review of others applications	14/01/2016
Ms Joanne Skellern	None declared	16/12/2015
Dr Jacques SinFat Tamin	Honorary senior lecturer in occupational medicine, University of Manchester. Chair, Independent Ethics Committee, Unilever R&D.	14/01/2016
Mrs Lesley Thornton	Directorship/Trustee of 2 charities; none of private companies.200 shares in AZ. Trustee for Counselling & Family Centre. Provides mental health services support. Member of public advisory committee for Trafford CCG.	14/01/2016
Dr Nader Touqan	None declared	14/01/2016
Professor Sobhan Vinjamuri	President Elect of British Nuclear Medicine Society. Appointed member of ARSAC (DoH). Member of trust's Techniques & Medical Devices Associate Medical Director for Clinical Audit in Trust	11/01/2016
Rosalyn Chandler	Project Manager, Hematology Lab Service, Alderley Park, Macclesfield Trustee of Autistic Society GMA, Manchester	01/04/2015

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

Month	Date	Number of Members Present at Meeting
April	09/04/2015	9
May	14/05/2015	8
June	11/06/2015	9
July	09/07/2015	10
August	13/08/2015	8
October	08/10/2015	8
November	12/11/2015	9
January	14/01/2016	10
February	11/02/2016	7
March	10/03/2016	10

10 full committee meetings were held during the reporting period.

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

Month	Date	Number of Members Present at Meeting
April	27/04/2015	3
June	12/06/2015	4
July	20/07/2015	4
August	24/08/2015	3
September	28/09/2015	5
October	26/10/2015	4
December	07/12/2015	3
January	14/01/2016	3
February	18/02/2016	3
March	17/03/2016	3

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

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

Month	Date	Number of Members Present at Meeting
April	10/04/2015	2
April	24/04/2015	2
May	08/05/2015	2
May	22/05/2015	2
June	05/06/2015	2
June	19/06/2015	2
July	03/07/2015	2
July	17/07/2015	2
July	31/07/2015	3
August	14/08/2015	2
August	28/08/2015	3
September	11/09/2015	2

September	25/09/2015	2
October	09/10/2015	2
October	23/10/2015	2
November	06/11/2015	2
November	20/11/2015	2
December	04/12/2015	2
December	18/12/2015	3
January	01/01/2016	2
January	15/01/2016	2
January	29/01/2016	2
February	12/02/2016	2
February	26/02/2016	2
March	11/03/2016	2
March	25/03/2016	2

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

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

Date	Reason	Action taken
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No inquorate meetings were held

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

Name	Number of Meetings Attended
Dr Anne Armstrong	7
Mrs Rosalyn Chandler	1
Miss Kathryn Fellows	6
Mrs Christine Holly	8
Mr Richard Hovey	10
Dr Paul Mortimer	5
Mrs Anne O'Brien	9
Mr David Ryder	10
Ms Joanne Skellern	5
Dr Jacques SinFat Tamin	8
Mrs Lesley Thornton	8
Dr Nader Touqan	2
Professor Sobhan Vinjamuri	4

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

Name	Number of Meetings Attended
Dr Anne Armstrong	1
Miss Kathryn Fellows	2
Mrs Christine Holly	3
Mr Richard Hovey	9
Dr Paul Mortimer	3
Mrs Anne O'Brien	1
Mr David Ryder	1
Dr Jacques SinFat Tamin	2
Mrs Lesley Thornton	4
Professor Sobhan Vinjamuri	9

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

Name	Number of Meetings Attended
Mr Richard Hovey	26
Dr Paul Mortimer	1
Mrs Lesley Thornton	5
Professor Sobhan Vinjamuri	23

Training 01 April 2015 - 31 March 2016

Name of Member	Date	Event(s) attended
Miss Kathryn Fellows	08/04/2015	Ethics & GCP Forum ICR
Mrs Christine Holly	23/04/2015	Equality and Diversity
Mrs Christine Holly	30/06/2015	Human Tissue Act (Use of Human Samples in Research) - An Introductory Level
Mr Richard Hovey	12/07/2015	Equality and Diversity
Mr Richard Hovey	09/12/2015	National Training Day for Committee Chairs
Dr Paul Mortimer	15/06/2015	Members Induction
Mrs Anne O'Brien	16/03/2016	National Members Training Day
Mr David Ryder	23/04/2015	Research Information for Minors: Suitable Formats and Readability
Mr David Ryder	01/08/2015	The Journal of the Association of Research Ethics Committees - Vol 8
Mr David Ryder	01/09/2015	The Journal of the Association of Research Ethics Committees
Ms Joanne Skellern	29/04/2015	Equality and Diversity Online
Dr Jacques SinFat Tamin	23/04/2015	Equality and Diversity
Dr Jacques SinFat Tamin	15/10/2015	Assessing the Consequences (benefits and harm) of Research: A Health Research Authority Workshop
Mrs Lesley Thornton	19/11/2015	Personal Data in Research - A Workshop
Mrs Lesley Thornton	05/02/2016	Local Training Day - Social Care REC
Professor Sobhan Vinjamuri	03/02/2016	Training - Handling Health-Related Findings in Research (Joint MRC/HRA)

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	21	38.18
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	0	0.00
Others	34	61.82
Total Applications Reviewed	55	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	1
Number of student applications reviewed	16
Number of paediatric applications reviewed	3
Number of device applications reviewed	6
Number of prisoner applications reviewed	1
Number of applications involving adults unable consent reviewed	9
Number of applications reviewed that are funded by the US DHHS	2
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	3.64
Favourable Opinion with Additional Conditions	1	1.82
Unfavourable Opinion	0	0.00
Provisional Opinion	52	94.55
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	55	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	45	81.82
Further Information Favourable Opinion with Additional Conditions	3	5.45
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	2	3.64
Favourable Opinion with Additional Conditions	1	1.82
Unfavourable Opinion	0	0.00
Provisional Opinion	2	3.64
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	2	3.64
Total	55	100

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

Total Applications Reviewed	30
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Table 6: Breakdown of PRS applications and other activity during reporting period:

Number of applications made invalid by the REC Manager	6
Number of studies withdrawn prior to the meeting	0
Number of student applications reviewed	14
Number of paediatric applications reviewed	3
Number of device applications reviewed	1
Number of qualitative applications reviewed	6

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

Decisions taken at proportionate review sub-committee meetings	Number	%
Favourable Opinion with Standard Conditions	9	30.00
Favourable Opinion with Additional Conditions	6	20.00
No Opinion transfer to full committee for review	1	3.33
Provisional Opinion	14	46.67
Unfavourable Opinion	0	0.00
Total	30	100

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

Average number of applications reviewed per full meeting	5.50
Number of completed applications for full ethical review	53
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	3.64%
Number of days taken to final decision – average (mean)	31
Number of completed proportionate review applications for ethical review	29
Number of completed proportionate review applications for ethical review over 14 days	0
Number of completed proportionate review applications over 14 days as a % of total	0.00%
Number of SSAs (non-Phase 1) reviewed	34
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	0
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	147
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	4
Number of completed substantial amendments over 28 days as a % of total substantial amendments	2.72%
Number of modified amendments reviewed	4
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	95
Number of substantial amendments received for information	0
Number of substantial amendments received for new sites/Pis	32
Number of annual progress reports received	102
Number of safety reports received	36
Number of Serious Adverse Events received	18
Number of final reports received	39

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

Further Information Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
15/NW/0229	WRAP-IT Study Version 1.0 29 July 2014	27
15/NW/0262	Immune biomarkers and clinical outcome in trauma patients	28
15/NW/0275	Open label phase 4 study of a new formulation of Calcichew D3	38
15/NW/0279	Improving the coordination of children with DCD	33
15/NW/0296	Mobile phone use in the neurological examination	37
15/NW/0354	(duplicate) Memory training in individuals with Fragile X Syndrome: a pilot study	38
15/NW/0359	U-SLEEP: Experimental Study	38
15/NW/0382	Pembrolizumab (MK-3475) vs Paclitaxel in 2L Subjects with Advanced Gastric Adenocarcinoma	33
15/NW/0408	Fulranumab as adjunctive therapy for OA of hip or knee (3001)	37
15/NW/0410	Fulranumab as monotherapy for OA of hip or knee (3002)	31
15/NW/0420	BLT Study: Bloodbank Led Thromboelastography.	17
15/NW/0478	Breast Cancer - Anti-Progestin Prevention Study 1	39
15/NW/0481	Safety and Efficacy of Ceftolozane/Tazobactam - ASPECT	24
15/NW/0483	SFAST	24
15/NW/0493	SAMS Longitudinal	20
15/NW/0505	Switch to MK-1439A from Ritonavir-boosted Protease Inhibitor regimen in HIV-1 infected subjects	24
15/NW/0546	Hip Injection Trial (HIT)	28
15/NW/0548	Vascular Function in Obesity	28
15/NW/0582	The role of biochemical markers in the pathogenesis of kidney failure	27
15/NW/0599	Drug use and austerity (v2)	32
15/NW/0602	Optimum Use of Tympanometry in Adults with Down Syndrome	39
15/NW/0616	AWARD Study	30
15/NW/0618	CA209-358 Nivolumab in virus positive and virus negative tumors	25
15/NW/0622	BIOWOMEN Study, v1.0, 03.Dec.2014	33
15/NW/0756	The decision making process of ECT administration	38
15/NW/0773	Effects of CKD and haemodialysis on hepatic drug metabolism	33
15/NW/0775	Cross-sectional study antipsychotic-induced cardiometabolic toxicity	38
15/NW/0776	Characterisation of myocardial inflammation in cardiomyopathies	37
15/NW/0818	Salford Kidney Study	25
15/NW/0827	0301 – Phase 3 study of ASP2215 vs salvage chemotherapy in AML patient	29

15/NW/0831	Trigger_V1_03Aug2015	28
15/NW/0832	Trimaran_V1_03Aug2015	28
15/NW/0834	Bioimpedance Spectroscopy and Estimated Energy Requirements in ICU-1.0	22
15/NW/0839	Leukaemia chemotherapy research study	28
16/NW/0004	Lidocaine levels In DLTBs Study (LID Study)	34
16/NW/0008	Goal setting in stroke rehabilitation	41
16/NW/0009	Niemann Pick Type C gait analysis study	25
16/NW/0011	Oral BI 1026706 and placebo in patients with COPD.	36
16/NW/0082	Breast Reconstruction Outcomes With and without StratticE [BROWSE]	41
16/NW/0084	Pembrolizumab vs chemotherapy in Subjects with Oesophageal Cancer	39
16/NW/0085	ActION-PD	34
16/NW/0086	Study of Avelumab in pts with previously treated Hodgkin's Lymphoma	32
16/NW/0126	Deaf life-stories project	34
16/NW/0140	A drug drug interaction study of ceritinib with warfarin and midazolam	30
16/NW/0153	Comparison of 2D US to tUS for conduit mapping	31

Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/NW/0381	Fulranumab as Adjunctive Therapy for OA of Hip or Knee (3007)	35
15/NW/0383	Effects of dietary nitrate in hypertensive pregnant women (version 1)	28
16/NW/0005	Neuromodulation Therapy for Faecal Incontinence	39

Further Information Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
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Favourable Opinion with Standard Conditions

REC Reference	Title	Number of Days on Clock
15/NW/0255	Rempex 506	26
15/NW/0393	Breath Analysis in ICU for Diagnosis of Ventilator Associated Pneumonia	26

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
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15/NW/0769	Feasibility Study of the ReCell Device in Diabetic Foot Ulcers	32
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Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
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Provisional Opinion

REC Reference	Title	Number of Days on Clock
16/NW/0018	The role of troponin I measurement in non cardiac aortic surgery	n/a
16/NW/0162	Phase 2 trial of Axitinib and TRC105 versus Axitinib alone	n/a

Provisional Opinion Pending Consultation with Referee

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

REC Reference	Title	Number of Days on Clock
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Withdrawn after the meeting

REC Reference	Title	Number of Days on Clock
15/NW/0459	Does steroid during hydrodilatation make a difference?	21
16/NW/0161	15VR8 Long-Term Extension Study of the Safety & Efficacy of Somavartan	27

Table 9.2: Breakdown of current status of all PRS applications reviewed within the reporting period

Further Information Favourable Opinion with Standard Conditions

REC Reference	Title	Number of Days on Clock
15/NW/0378	Sensory processing and anxiety characteristics in NSCLBP patients	12
15/NW/0379	Burden of Infection in Primary Antibody Deficiency (BIPAD) Study	13
15/NW/0528	Adult onset type 1 diabetes - the PROCEED study	13
15/NW/0529	Clinical effects of radiofrequency based therapy. Version 1.	10

15/NW/0621	Patients' decision-making regarding breast cancer surgery (Version 1)	13
15/NW/0692	Obtaining antibodies from kidney transplants. Version 1	13
15/NW/0694	Qualitative Exploration of Perceptions of Patient Safety and Patient Involvement	14
15/NW/0794	Mothers Experiences of Public Breastfeeding in London	13
15/NW/0965	Surgical management of Axillary hyperhidrosis (questionnaire)	7
16/NW/0043	VIPP with adoptive families in the UK: A pilot study	11
16/NW/0053	Measurement of CO levels following Gas Transfer Measurement	12
16/NW/0212	Immunohistochemistry of the synovium, PCL and pMFLs Ver:1.0 10/02/2016	12
16/NW/0214	RHAM - Phase 2	11
16/NW/0215	Screening and Diagnosis of Familial Hypercholesterolemia by NGS.	14

Further Information Favourable Opinion with Additional Conditions

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

REC Reference	Title	Number of Days on Clock
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Favourable Opinion with Standard Conditions

REC Reference	Title	Number of Days on Clock
15/NW/0530	RETROSPECTIVE ANALYSIS OF UNCEMENTED CMCJ ARTHROPLASTY OF THUMB	7
15/NW/0625	Evaluating practices for initiating decision making in neurology	10
15/NW/0798	Evaluation of fine needle aspiration samples in podoconiosis.	12
15/NW/0812	Developing an outcome measure for dry mouth.	14
15/NW/0857	Evaluating the health visiting service for children with Autism 1	11
15/NW/0860	Remote care of cochlear implant users	9
15/NW/0865	Reducing Unplanned Hospital Admissions Study (RUHAS) v1.0	9
15/NW/0966	Control samples for T1D genotype & T-cell phenotype study (Version 1)	11
16/NW/0211	Self-Management App for young people with chronic rheumatic disease	10

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/NW/0623	A study of diabetic retinopathy screening in older people. v1	8

15/NW/0861	TKI response rate	8
15/NW/0963	Focus Groups aimed at Device Development	11
16/NW/0044	Assessing patient outcomes following radioiodine	14
16/NW/0139	Real world effects of three-curve rocker sole shoe	9
16/NW/0142	Early PROMPT Study	11

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
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Provisional Opinion

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

REC Reference	Title	Number of Days on Clock
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Withdrawn after the meeting

REC Reference	Title	Number of Days on Clock
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Table 10.1: Breakdown of current status of all substantial amendments reviewed within the reporting period

Favourable opinion				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
04/Q1403/37/AM18	Predictors of Etanercept response.	Substantial Amendment 12	18/05/2015	20
04/Q1403/37/AM20	Predictors of Etanercept response.	Substantial Amendment 13	29/07/2015	12
04/Q1403/37/AM21	Predictors of Etanercept response.	Substantial Amendment 14	25/02/2016	34
05/Q1403/159/AM03	Breast tissue gene expression and stem cells in breast cancer patients	Amendment - Version 6	13/01/2016	25
05/Q1403/98/AM12	Prion surveillance in primary immunodeficiency. (Version 2.0)	Substantial Amendment 10	25/02/2016	28
06/Q1403/156/AM12	Bronchoscopy studies in patients with asthma and COPD	Substantial Amendment 8	14/12/2015	20
6/Q1403/156/AM13	Bronchoscopy studies in patients with asthma and COPD	(Amendment 9)	29/02/2016	6
07/H1003/161+5/AM06	Manchester Cancer Research Centre Biobank - collection of biological	Substantial Amendment 5	27/10/2015	10
07/H1004/160/AM05	Genetics of Pernicious anaemia	Substantial Amendment 4	09/05/2015	11
08/H1003/224/AM10	Detection of Bronchial Preneoplasia	Substantial Amendment 5	16/12/2015	12
10/H1003/105/AM02	Emotional learning	Substantial Amendment 02	08/09/2015	6
10/H1003/105/AM03	Emotional learning	Substantial Amendment 3	18/11/2015	25
10/H1003/37/AM10	Low frequency administration of 40mg GA in RRMS subjects (GALA study)	Local UK Amendment 3 for Proto	16/04/2015	1
10/H1003/7/AM09	The Use of Silicone Gel in the Treatment of Stretch Marks	Amendment 6	21/11/2015	7
10/H1003/96/AM02	Novel biomarkers of acute coronary syndromes using metabolomics	Substantial Amendment 3	22/02/2016	17
11/NW/0244/AM05	Validation of potential markers of disease in systemic sclerosis	Substantial Amendment 5	26/11/2015	31
11/NW/0390/AM07	SC IL-1Ra in SAH	Substantial Amendment 5	27/04/2015	4

11/NW/0782/AM11	POUT	Substantial Amendment 4	25/06/2015	11
11/NW/0798/AM67	The Salford Lung Study (COPD)	Substantial Amendment 58 -	19/11/2015	25
12/NW/0255/AM04	Efficacy comparison of Ipilimumab vs Etoposide in ED-SCLC patients	SA IB v17	20/01/2015	12
12/NW/0255/AM05	Efficacy comparison of Ipilimumab vs Etoposide in ED-SCLC patients	Ipilimumab Investigator Brochure	10/03/2015	21
12/NW/0311/AM10	Varicella Zoster vaccine in autologous stem cell transplant subjects	Protocol Amendment 7	08/09/2015	7
12/NW/0425/AM11	ARTSS-2	Substantial Amendment	13/04/2015	1
12/NW/0455/AM35	The Salford Lung Study (Asthma)	SA 28 - Temporary Halt to Recruitment	16/04/2015	1
12/NW/0455/AM37	The Salford Lung Study (Asthma)	Substantial Amendment 30	29/05/2015	12
12/NW/0455/AM41	The Salford Lung Study (Asthma)	Substantial Amendment 32	26/06/2015	10
12/NW/0455/AM45	The Salford Lung Study (Asthma)	36	20/08/2015	4
12/NW/0455/AM49	The Salford Lung Study (Asthma)	Substantial Amendment 38	11/11/2015	11
12/NW/0455/AM53	The Salford Lung Study (Asthma)	Substantial Amendment 39	06/01/2016	12
12/NW/0455/AM55	The Salford Lung Study (Asthma)	SA40	10/02/2016	26
12/NW/0722/AM08	Subjects with chronic moderate to severe pain related to cancer	Substantial Amendment 5	01/07/2015	5
12/NW/0722/AM10	Subjects with chronic moderate to severe pain related to cancer	Substantial Amendment 07	15/09/2015	9
12/NW/0790/AM14	BASICS	SA07	10/08/2015	1
12/NW/0811/AM03	Feasibility of intra-gastric balloon treatment for obesity in CKD v5.1	Substantial Amendment 2	30/04/2015	15
13/NW/0003/AM07	3-001:Study of ART-123 in Subjects with Severe Sepsis and Coagulopathy	Substantial Amendment - IB v7	12/05/2015	7
13/NW/0003/AM08	3-001:Study of ART-123 in Subjects with Severe Sepsis and Coagulopathy	ART-123 IB 7 - Addendum 1	27/07/2015	22
13/NW/0003/AM09	3-001:Study of ART-123 in Subjects with Severe Sepsis and	SA - Protocol V4	17/11/2015	18

	Coagulopathy	dated 23/10/2		
13/NW/0184/AM07	FAST - Four-fold asthma study	SA02_15	11/11/2015	25
13/NW/0241/AM05	Investigating methods of transdermal fluid extraction	Substantial Amendment 2	26/02/2016	22
13/NW/0270/AM10	Brexpiprazole in patients with major depressive disorder	Substantial Amendment version 5	07/04/2015	4
13/NW/0270/AM11	Brexpiprazole in patients with major depressive disorder	Substantial Amendment 6	04/11/2015	19
13/NW/0384/AM02	CIMI-DENT Pilot Trial, Version 1, 01May13	Substantial Amendment 2	10/07/2015	7
13/NW/0463/AM05	Risk of SCC on skin treated with Ingenol Mebutate or Imiquimod Cream	Substantial Amendment 5	30/10/2015	5
13/NW/0674/AM08	The effects of multiple doses of QBM076 in COPD patients	Seven	02/04/2015	25
13/NW/0674/AM11	The effects of multiple doses of QBM076 in COPD patients	Substantial Amendment 8	12/05/2015	7
13/NW/0830/AM07	A Phase I study of Human Pharmacokinetics and Safety of ORY-1001	Substantial Amendment 4	10/11/2015	13
13/NW/0835/AM01	ARTFORCE PET Boost Study	Substantial Amendment 2	11/11/2015	22
13/NW/0836/AM02	Influence of Expressed Emotion on dementia sufferers' adjustment	Substantial Amendment 2	27/04/2015	10
13/NW/0836/AM03	Influence of Expressed Emotion on dementia sufferers' adjustment	Substantial Amendment 3	27/11/2015	14
13/NW/0837/AM03	REFRESHED Version 1.0	Substantial Amendment 3	04/03/2016	12
13/NW/0869/AM03	Left ventricular hypertrophy and fibrosis in aortic stenosis	Substantial Amendment 2.3	03/05/2015	3
14/NW/0005/AM03	Efficacy of Gevokizumab in polymyositis/dermatomyositis	Three	04/02/2015	13
14/NW/0010/AM07	LEE011 + BYL719 with Letrozole in patients with ER+ breast cancer	Six	09/04/2015	18
14/NW/0010/AM09	LEE011 + BYL719 with Letrozole in patients with ER+ breast cancer	Substantial Amendment 4 -	22/06/2015	3
14/NW/0010/AM11	LEE011 + BYL719 with Letrozole in patients with ER+ breast cancer	LEE011X2107 Patient dosing	21/12/2015	28
14/NW/0063/AM01	Cochlear CBAS5477	Substantial Amendment 1	24/11/2015	16

14/NW/0183/AM03	REFINE ICD	Substantial Amendment 2	01/07/2015	10
14/NW/0303/AM01	Person-centred care: meaning and measurement	Substantial Amendment 1	24/07/2015	12
14/NW/1027/AM03	SORAMIC	3	30/03/2015	11
14/NW/1053/AM02	ISIS 494372-CS3	Protocol Amendment 2	26/06/2015	12
14/NW/1068/AM04	GO28888 Neoadjuvant Letrozole and GDC-0032 in ER+/HER2- Breast Cancer	Substantial Amendment 3 - Protocol	28/09/2015	21
14/NW/1068/AM05	GO28888 Neoadjuvant Letrozole and GDC-0032 in ER+/HER2- Breast Cancer	Substantial Amendment 4 - PIS/	24/11/2015	20
14/NW/1068/AM06	GO28888 Neoadjuvant Letrozole and GDC-0032 in ER+/HER2- Breast Cancer	Amendment 05 (substantial)	25/02/2016	11
14/NW/1072/AM02	Antibiotic consumption & Klebsiella colonisation in hospital patients	Substantial Amendment 2	03/03/2016	15
14/NW/1084/AM03	CA209-205	Three	17/04/2015	24
14/NW/1084/AM05	CA209-205	Substantial Amendment 4	06/07/2015	7
14/NW/1084/AM06	CA209-205	Substantial Amendment 5	17/11/2015	21
14/NW/1088/AM02	Myocardial involvement in pulmonary disease	Substantial Amendment 1	25/09/2015	4
14/NW/1088/AM03	Myocardial involvement in pulmonary disease	Substantial Amendment 2	09/03/2016	12
14/NW/1258/AM03	Phase 3 efficacy&safety study of ODM-201 in high risk non-met CRPC	Sponsorship Transfer Amendment	11/06/2015	4
14/NW/1258/AM05	Phase 3 efficacy&safety study of ODM-201 in high risk non-met CRPC	CMC Amendment	26/01/2016	24
14/NW/1294/AM01	4-stage LCI699 study with optional extension in Cushing's Disease	Protocol Amendment 2 & Change	30/04/2015	11
14/NW/1294/AM02	4-stage LCI699 study with optional extension in Cushing's Disease	(Protocol CLCI699C2301 v2	08/01/2016	18
14/NW/1393/AM02	PANasta	Substantial	06/08/2015	11

		Amendment 2		
15/NW/0004/AM03	MO29112 Biomarker Driven Maintenance Treatment of Metastatic CRC	Two	09/04/2015	18
15/NW/0004/AM04	MO29112 Biomarker Driven Maintenance Treatment of Metastatic CRC	Substantial Amendment 03	08/07/2015	5
15/NW/0004/AM05	MO29112 Biomarker Driven Maintenance Treatment of Metastatic CRC	Substantial Amendment 4	15/01/2016	31
15/NW/0005/AM03	MRK Poly Vs Metal	Substantial Amendment 1	05/11/2015	17
15/NW/0080/AM01	Pulmonary Embolism Removal with the AngioJet 6F Ultra SystEm (PERFUSE)	Substantial Amendment 1	28/07/2015	1
15/NW/0111/AM01	Biomarkers associated with known phenotypes across asthma severities.	Substantial Amendment 01	21/04/2015	4
15/NW/0111/AM04	Biomarkers associated with known phenotypes across asthma severities.	Substantial Amendment 2	19/05/2015	8
15/NW/0184/AM03	National investigation into suicide in children and young people	Substantial Amendment 1	14/10/2015	8
15/NW/0184/AM04	National investigation into suicide in children and young people	Substantial Amendment 2	11/03/2016	28
15/NW/0185/AM02	A clinical evaluation of a CVC securement device	Substantial Amendment 1	15/10/2015	5
15/NW/0185/AM03	A clinical evaluation of a CVC securement device	Substantial Amendment 2	24/02/2016	14
15/NW/0187/AM01	Oral ZPL3893787 on pruritus in adults with atopic dermatitis	Substantial Amendment - UK Specific	27/04/2015	14
15/NW/0229/AM02	WRAP-IT Study Version 1.0 29 July 2014	Substantial Amendment – Patient info	03/08/2015	12
15/NW/0229/AM03	WRAP-IT Study Version 1.0 29 July 2014	Substantial Amendment 2	30/10/2015	27
15/NW/0255/AM01	Rempex 506	Substantial Amendment - Protocol	11/06/2015	21
15/NW/0255/AM02	Rempex 506	Substantial Amendment - Update	07/10/2015	16

15/NW/0275/AM03	Open label phase 4 study of a new formulation of Calcichew D3	Substantial Amendment – patient info	12/08/2015	8
15/NW/0275/AM04	Open label phase 4 study of a new formulation of Calcichew D3	2	24/08/2015	9
15/NW/0275/AM05	Open label phase 4 study of a new formulation of Calcichew D3	Substantial Amendment - Country	04/09/2015	14
15/NW/0359/AM01	U-SLEEP: Experimental Study	1	17/07/2015	18
15/NW/0359/AM02	U-SLEEP: Experimental Study	Two	18/08/2015	8
15/NW/0359/AM03	U-SLEEP: Experimental Study	Substantial Amendment 3	03/02/2016	25
15/NW/0379/AM02	Burden of Infection in Primary Antibody Deficiency (BIPAD) Study	Substantial Amendment 1	17/02/2016	6
15/NW/0381/AM01	Fulranumab as Adjunctive Therapy for OA of Hip or Knee (3007)	Substantial Amendment 01	02/07/2015	28
15/NW/0381/AM02	Fulranumab as Adjunctive Therapy for OA of Hip or Knee (3007)	Substantial Amendment 2	19/10/2015	21
15/NW/0381/AM03	Fulranumab as Adjunctive Therapy for OA of Hip or Knee (3007)	Substantial Amendment 3	23/11/2015	21
15/NW/0381/AM05	Fulranumab as Adjunctive Therapy for OA of Hip or Knee (3007)	Substantial Amendment 4	22/12/2015	28
15/NW/0381/AM06	Fulranumab as Adjunctive Therapy for OA of Hip or Knee (3007)	Substantial Amendment 5	07/01/2016	15
15/NW/0382/AM01	Pembrolizumab (MK-3475) vs Paclitaxel in 2L Subjects with Advanced Gastric Adenocarcinoma	Mrec SA01	30/06/2015	5
15/NW/0382/AM02	Pembrolizumab (MK-3475) vs Paclitaxel in 2L Subjects with Advanced Gastric Adenocarcinoma	MREC SA02	27/07/2015	20
15/NW/0382/AM03	Pembrolizumab (MK-3475) vs Paclitaxel in 2L Subjects with Advanced Gastric Adenocarcinoma	MREC SA03	10/11/2015	22
15/NW/0382/AM04	Pembrolizumab (MK-3475) vs Paclitaxel in 2L Subjects with Advanced Gastric Adenocarcinoma	MREC SA4	05/02/2016	28
15/NW/0382/AM05	Pembrolizumab (MK-3475) vs Paclitaxel in 2L Subjects with Advanced Gastric Adenocarcinoma	Notification of a Halt	21/03/2016	13
15/NW/0383/AM01	Effects of dietary nitrate in hypertensive pregnant women (version 1)	Substantial Amendment 1	08/10/2015	15
15/NW/0393/AM01	Breath Analysis in ICU for Diagnosis of Ventilator Associated	Substantial	04/06/2015	18

	Pneumonia	Amendment 1		
15/NW/0393/AM02	Breath Analysis in ICU for Diagnosis of Ventilator Associated Pneumonia	Substantial Amendment 2	05/10/2015	17
15/NW/0393/AM04	Breath Analysis in ICU for Diagnosis of Ventilator Associated Pneumonia	Substantial Amendment 3	12/11/2015	17
15/NW/0408/AM03	Fulranumab as adjunctive therapy for OA of hip or knee (3001)	Substantial Amendment 1 (Amend	14/08/2015	6
15/NW/0408/AM06	Fulranumab as adjunctive therapy for OA of hip or knee (3001)	Substantial Amendment 3	19/10/2015	22
15/NW/0408/AM08	Fulranumab as adjunctive therapy for OA of hip or knee (3001)	Substantial Amendment 5	15/12/2015	20
15/NW/0408/AM10	Fulranumab as adjunctive therapy for OA of hip or knee (3001)	Substantial Amendment 6	11/01/2016	15
15/NW/0410/AM01	Fulranumab as monotherapy for OA of hip or knee (3002)	Substantial Amendment 1	21/07/2015	14
15/NW/0410/AM02	Fulranumab as monotherapy for OA of hip or knee (3002)	Substantial Amendment 2	20/11/2015	24
15/NW/0410/AM03	Fulranumab as monotherapy for OA of hip or knee (3002)	Substantial Amendment 3	18/12/2015	17
15/NW/0410/AM04	Fulranumab as monotherapy for OA of hip or knee (3002)	Substantial Amendment 4	11/01/2016	11
15/NW/0478/AM01	Breast Cancer - Anti-Progestin Prevention Study 1	UHSM0315 Version 1.1	07/07/2015	5
15/NW/0478/AM02	Breast Cancer - Anti-Progestin Prevention Study 1	UHSM0315 Version 1.2	09/10/2015	21
15/NW/0478/AM04	Breast Cancer - Anti-Progestin Prevention Study 1	UHSM0315 1.4	05/02/2016	26
15/NW/0481/AM01	Safety and Efficacy of Ceftolozane/Tazobactam - ASPECT	Substantial Amendment 1	07/09/2015	23
15/NW/0493/AM01	SAMS Longitudinal	One	17/08/2015	16
15/NW/0493/AM02	SAMS Longitudinal	Substantial Amendment 02 - 05/	05/09/2015	13
15/NW/0493/AM03	SAMS Longitudinal	Substantial Amendment 3	11/09/2015	18
15/NW/0505/AM01	Switch to MK-1439A from Ritonavir-boosted Protease Inhibitor regimen in HIV-1 infected subjects	SA01 - Updated Protocol	06/08/2015	2

15/NW/0505/AM02	Switch to MK-1439A from Ritonavir-boosted Protease Inhibitor regimen in HIV-1 infected subjects	Substantial Amendment 2	06/01/2016	14
15/NW/0505/AM03	Switch to MK-1439A from Ritonavir-boosted Protease Inhibitor regimen in HIV-1 infected subjects	SA03	01/03/2016	5
15/NW/0505/AM04	Switch to MK-1439A from Ritonavir-boosted Protease Inhibitor regimen in HIV-1 infected subjects	SA04	22/03/2016	13
15/NW/0546/AM01	Hip Injection Trial (HIT)	Substantial Amendment 1	08/10/2015	7
15/NW/0618/AM01	CA209-358 Nivolumab in virus positive and virus negative tumors	Substantial Amendment 01	02/09/2015	14
15/NW/0618/AM02	CA209-358 Nivolumab in virus positive and virus negative tumors	Substantial Amendment 2	13/11/2015	25
15/NW/0618/AM03	CA209-358 Nivolumab in virus positive and virus negative tumors	Substantial Amendment 3	08/01/2016	18
15/NW/0694/AM01	Qualitative Exploration of Perceptions of Patient Safety and Patient Involvement	Substantial Amendment 1	10/02/2016	24
15/NW/0756/AM01	The decision making process of ECT administration	Amendment 3	29/12/2015	14
15/NW/0756/AM02	The decision making process of ECT administration	Amendment 4	22/02/2016	11
15/NW/0769/AM01	Feasibility Study of the ReCell Device in Diabetic Foot Ulcers	Substantial Amendment 1	18/11/2015	11
15/NW/0775/AM01	Cross-sectional study antipsychotic-induced cardiometabolic toxicity	Substantial Amendment 1	19/01/2016	24
15/NW/0827/AM02	0301 – Phase 3 study of ASP2215 vs salvage chemotherapy in AML patient	Protocol Amendment 04	22/02/2016	27
15/NW/0831/AM01	Trigger_V1_03Aug2015	Substantial Amendment 1	14/12/2015	4
15/NW/0832/AM01	Trimaran_V1_03Aug2015	Substantial Amendment 1	14/12/2015	4
15/NW/0834/AM01	Bioimpedance Spectroscopy and Estimated Energy Requirements in ICU-1.0	Substantial Amendment 1	17/02/2016	26
16/NW/0043/AM01	VIPP with adoptive families in the UK: A pilot study	Substantial Amendment	16/02/2016	8
ERP/96/136/AM15	National Confidential Enquiry	Substantial Amendment 15	18/06/2015	14

Unfavourable opinion				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
14/NW/1009/AM05	Managing short sightedness using glasses/contact lenses	Substantial Amendment 2	22/09/2015	27
14/NW/1027/AM04	SORAMIC	Four	28/07/2015	29

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
11/NW/0541/AM04/1	Assessment of levodopa-induced dyskinesia using a novel device- V2	Modified Amendment	15/04/2015	5
14/NW/1009/AM05/1	Managing short sightedness using glasses/contact lenses	Modified Amendment 2 - Protocol	02/11/2015	7
14/NW/1027/AM04/2	SORAMIC	Modification of the amendment	08/12/2015	7

Unfavourable opinion timeline				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
14/NW/1027/AM04/1	SORAMIC	Patient Information	12/11/2015	13

Table 11: Items exceeding timelines

Full applications for ethical review over 60 day timeline

REC Reference	Title	Number of Days on Clock
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Proportionate review applications for ethical review over 14 day timeline

REC Reference	Title	Number of Days on Clock
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SSAs (non Phase 1) over 25 day timeline

REC Reference	Title	Number of Days on Clock
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SSAs (Phase 1) over 14 day timeline

REC Reference	Title	Number of Days on Clock
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Substantial Amendments over 35 day timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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Modified Amendments over 14 day timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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