

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

Annual Report

01 April 2016 - 31 March 2017



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 01.04.2016 to 30.09.2016 Ms Gemma Warren from 01.03.2017
REC Assistant:	Miss Ewa Grzegorska
Committee Address:	3rd Floor, Barlow House 4 Minshull Street Manchester M1 3DZ
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Chair's overview of the past year:

Over the past year we have had a few members leave us and a few new members have joined us.

I am pleased to note that the majority of our members have attended regularly in spite of busy work commitments.

We have tried to reduce our consumption of paper as a committee, and I am pleased to report that the majority of our members have chosen to access the paperwork prior to meetings in an electronic format. We should be making more progress on this matter in the coming months.

Members have also availed of the training programmes offered by HRA and kept themselves updated with latest information in the area of ethical review of research projects for the NHS.

We continue to review CTIMPs on a regular basis and I hope this can continue going forwards. We have been a regular contributor to Proportionate Review with good contribution from members on a rotating basis.

We have been well supported by the HRA office in Manchester and our administrative support has been exceptional. We are still seeking to meet in South Manchester rather than at the HRA office in Manchester, and we will keep this under review

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 Robert Bedford	Senior Clinical Trials Coordinator	Lay	13/09/2016	
Mrs Rosalyn Chandler	Clinical Project Manager	Lay	01/10/2015	20/02/2017
Miss Kathryn Fellows	CRO Monitor	Expert	11/07/2013	
Mr Ian Harrison	Chief Scientific Officer	Expert	01/07/2016	
Mrs Christine Holly	Retired Librarian	Lay	09/09/2012	12/09/2016
Mr Richard Hovey	Business Analyst	Lay Plus	31/01/2007	
Dr Derrick Martin	Retired Consultant Radiologist	Expert	10/06/2016	
Mrs Anne O'Brien	Senior Specialist Haematology Pharmacist	Expert	01/02/2014	12/01/2017
Mr David Ryder	Medical Statistician	Expert	01/06/2006	01/06/2016
Dr Joel Sanderson	Medical Expert	Expert	01/07/2016	
Ms Joanne Skellern	Lecturer in Learning Disabilities	Expert	13/09/2012	05/07/2016
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	Consultant in Nuclear Medicine	Expert	01/06/2012	

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

Name	Profession	Status	Meeting date attended
Mrs F E Maders	Retired Clinical Trials Co-ordinator for Radiology	Expert	09/02/2017
Mrs Debbie Hamburger	Retired Social Worker	Lay Plus	09/03/2017
Dr Peter Owen	Retired Mathematics Lecturer	Lay Plus	09/03/2017

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

Name	Declaration of Interest	Date
Mr Robert Bedford	Clinical Studies Officer at Greater Manchester Clinical Research Network, National Institute for Health Research. Deliver research for NIHR portfolio studies in the field of dementia, neurodegeneration, neurology and mental health. Activities include study set-up/close out, data collection, recruitment and monitoring.	30/09/2016
Mr Ian Harrison	Is part owner and share holder in Private Company is Alchemy Pharmatech Limited	29/06/2016
Dr Derrick Martin	None declared	21/06/2016
Dr Joel Sanderson	None	05/07/2016
Dr Jacques SinFat Tamin	Honorary senior lecturer, University of Manchester. Chair, Unilever R&D Independent Ethics Committee	31/03/2017
Mrs Lesley Thornton	Trustee/Director of Northmoor Community Association (Charity).Trustee/Director of The Counselling and Family Centre, Altrincham (Charity).200 AstraZeneca shares.3 Pharma pensions	31/03/2017
Professor Sobhan Vinjamuri	President of British Nuclear Medicine Society, a charitable institution for professional members. Associate Medical Director for Clinical Audit in Trust. Peer reviewer for MRC/NIHR	31/03/2017

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

Month	Date	Number of Members Present at Meeting
April	14/04/2016	8
May	12/05/2016	8
June	09/06/2016	8
July	14/07/2016	10
August	11/08/2016	10
October	13/10/2016	11
November	10/11/2016	8
January	12/01/2017	10
February	09/02/2017	9
March	09/03/2017	9

10 full committee meetings were held during the reporting period.

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

Month	Date	Number of Members Present at Meeting
April	21/04/2016	3
May	19/05/2016	3
June	16/06/2016	3
July	21/07/2016	3
August	18/08/2016	3
September	15/09/2016	3
October	20/10/2016	3
November	17/11/2016	3
January	19/01/2017	3
February	24/02/2017	3

10 proportionate review sub-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	15/04/2016	2
April	29/04/2016	2
May	13/05/2016	2
May	27/05/2016	2
June	10/06/2016	2
June	24/06/2016	2
July	08/07/2016	2
July	22/07/2016	2
August	05/08/2016	2
August	19/08/2016	2
September	02/09/2016	2

September	16/09/2016	2
September	30/09/2016	2
October	14/10/2016	2
October	28/10/2016	2
November	11/11/2016	2
November	25/11/2016	2
December	09/12/2016	2
December	23/12/2016	2
January	13/01/2017	2
January	27/01/2017	2
February	10/02/2017	2
February	24/02/2017	2
March	10/03/2017	2
March	24/03/2017	2

25 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

Name	Number of Meetings Attended
Dr Anne Armstrong	6
Mr Robert Bedford	4
Miss Kathryn Fellows	5
Mr Ian Harrison	7
Mrs Christine Holly	4
Mr Richard Hovey	10
Dr Derrick Martin	7
Mrs Anne O'Brien	6
Mr David Ryder	3
Dr Joel Sanderson	5
Ms Joanne Skellern	3
Dr Jacques SinFat Tamin	8
Mrs Lesley Thornton	8
Dr Nader Touqan	6
Professor Sobhan Vinjamuri	6

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

Name	Number of Meetings Attended
Dr Anne Armstrong	3
Mrs Christine Holly	2
Mr Richard Hovey	8
Dr Jacques SinFat Tamin	3
Mrs Lesley Thornton	4
Dr Nader Touqan	1
Professor Sobhan Vinjamuri	9

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

Name	Number of Meetings Attended
Mr Richard Hovey	25
Professor Sobhan Vinjamuri	25

Training 01 April 2016 - 31 March 2017

Name of Member	Date	Event(s) attended
Mr Robert Bedford	10/01/2017	Committee Members Induction
Mr Ian Harrison	15/09/2016	Committee Members Induction
Mr Ian Harrison	26/10/2016	Qualitative Research and Ethical Review
Mr Ian Harrison	01/02/2017	Medical Devices
Mrs Christine Holly	29/06/2016	Handling Health-Related Findings in Research (Joint MRC/HRA)
Dr Derrick Martin	30/11/2016	Committee Members Induction
Dr Joel Sanderson	29/06/2016	Induction to Research Ethics Service
Dr Joel Sanderson	30/06/2016	Equality, Diversity and Human Rights
Dr Joel Sanderson	02/08/2016	Reviewing the Research Design of Clinical Trials
Dr Joel Sanderson	15/09/2016	Committee Members Induction
Dr Joel Sanderson	27/09/2016	HTA Training _Introductory Level
Dr Jacques SinFat Tamin	27/09/2016	HTA Training - An Introductory Level
Dr Nader Tougan	06/07/2016	HRA Regional Training Day
Professor Sobhan Vinjamuri	04/02/2017	Equality Diversity and Human Rights
Professor Sobhan Vinjamuri	09/02/2017	Training for Non-Commercial Studies
Professor Sobhan Vinjamuri	09/02/2017	Training for Commercial Studies
Professor Sobhan Vinjamuri	09/02/2017	Reviewing the Research Design of Clinical Trials

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	14	27.45
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	37	72.55
Total Applications Reviewed	51	100

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

Number of applications made invalid by the REC Manager	1
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	17
Number of paediatric applications reviewed	2
Number of device applications reviewed	5
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	7
Number of applications reviewed that are funded by the US DHHS	1
Number of qualitative applications reviewed	3

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

Decisions taken at meetings following review of applications	Number	%
Favourable Opinion with Standard Conditions	2	3.92
Favourable Opinion with Additional Conditions	8	15.69
Unfavourable Opinion	0	0.00
Provisional Opinion	41	80.39
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	51	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	37	72.55
Further Information Favourable Opinion with Additional Conditions	2	3.92
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	2	3.92
Favourable Opinion with Additional Conditions	8	15.69
Unfavourable Opinion	0	0.00
Provisional Opinion	1	1.96
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	1.96
Total	51	100

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

Total Applications Reviewed	29
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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	8
Number of studies withdrawn prior to the meeting	1
Number of student applications reviewed	14
Number of paediatric applications reviewed	5
Number of device applications reviewed	2
Number of qualitative applications reviewed	3

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	12	41.38
Favourable Opinion with Additional Conditions	4	13.79
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	13	44.83
Unfavourable Opinion	0	0.00
Total	29	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	5.10
Number of completed applications for full ethical review	50
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	9
Number of completed applications over 40 days as a % of total	17.65%
Number of days taken to final decision – average (mean)	34
Number of completed proportionate review applications for ethical review	29
Number of completed proportionate review applications for ethical review over 14 days (Please note the timeline for the review of PR applications was extended from 14 to 21 calendar days in December 2016)	4
Number of completed proportionate review applications for ethical review over 21 days	1
Number of completed proportionate review applications over 14 days as a % of total	13.79%
Number of SSAs (non-Phase 1) reviewed	10
Number of completed applications for SSA review over 25 days	1
Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs	10.00%
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	105
Number of completed substantial amendments over 35 days	1
Number of completed substantial amendments over 35 days as a % of total substantial amendments	0.95%
Number of completed substantial amendments over 28 days	8
Number of completed substantial amendments over 28 days as a % of total substantial amendments	7.62%
Number of modified amendments reviewed	2
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 non substantial amendments received	84
Number of substantial amendments received for information	4
Number of substantial amendments received for new	18

sites/PIs	
Number of annual progress reports received	89
Number of safety reports received	39
Number of Serious Adverse Events received	20
Number of final reports received	40

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
16/NW/0089	Linaclotide for abdominal distension V1	46
16/NW/0197	ASD2 Study	41
16/NW/0239	A prospective trial of DXM gel for early stage chronic low back pain	51
16/NW/0242	Phase I pharmacokinetics, safety and tolerability study of DITEST	37
16/NW/0262	Safety & Efficacy of VX-371 in CF patients Homozygous for F508del-CFTR	34
16/NW/0264	A pilot RCT on the Management of Term Pre labour Rupture of Membranes	35
16/NW/0371	Neuroimaging Markers for Atypical Brain Development in Autism v1	39
16/NW/0373	Capsule study	40
16/NW/0386	Additive Manufacture in Orthotics (AMinO)	36
16/NW/0387	Rehabilitation for Outdoor Activities and Mobility in Care Homes	40
16/NW/0398	Psychological Processes involved in voice-hearing	19
16/NW/0413	Healthcare behaviours in pregnancy - version 1	34
16/NW/0417	CA008-002 Phase I/II study of mesothelin directed ADC in solid tumours	35
16/NW/0497	The PFP-Inhibit study	48
16/NW/0499	Developing and validating a therapeutic alliance measure	40
16/NW/0506	CAIN457F3301 (ACHILLES) Secukinumab in patients with PsA and axSpA	34
16/NW/0510	A feasibility study of Baby Triple P for mothers with MH difficulties	40
16/NW/0517	Myeloma XII (ACCoRd trial) Version 1.0	35
16/NW/0533	Making sense of the patient experience on general medical wards vers 1	29
16/NW/0541	Care Home Acute Norovirus Gastroenteritis Study	36
16/NW/0548	TSPO PET Imaging in GBM	40
16/NW/0553	A study to evaluate the effect of inhaled CHF 6001 in adults with COPD	32
16/NW/0564	A study of BET Inhibitor BMS-986158 in advanced solid tumours	29
16/NW/0705	Pilot PET study of regional cerebral protein synthesis in Alzheimer's	47
16/NW/0729	Corneal Confocal Microscopy: A multinational study	34
16/NW/0730	CaSPPeR - Congenital cardiac surgery and parental perception of risk	41
16/NW/0781	An AMP challenge study of escalating repeat doses of FF, FP and BUD	33
16/NW/0805	Ph I dose escalation of INC280+food in cMET advanced solid tumors	30
16/NW/0812	Safety, tolerability, PK & PD effects of REGN3500 in Asthma Patients	35
17/NW/0003	REmLap	43
17/NW/0005	Investigating beliefs and goal appraisals in severe mental illness	41
17/NW/0030	Circadian Disruption on ICU - CADI	27

17/NW/0039	Are Spirituality Outcome Measures Acceptable in Mental Health Settings	23
17/NW/0055	Endocrine disrupting chemicals in adipose tissue of diabetics	32
17/NW/0111	UMANC	31
17/NW/0159	Being trans with ID: Experiences and perceptions.	31
17/NW/0163	A Study in Adult Patients with Allergic Asthma	39

Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/NW/0532	DevPROMsHaem	46
17/NW/0015	FLiP-GD2	40

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
16/NW/0566	ALZHEIMER'S OBSERVATIONAL INTERNATIONAL STUDY	21
16/NW/0727	Multi Centre RCT for postnatal depression in BSA women - ROSHNI-2	27

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/NW/0391	Challenge Ag 01	25
16/NW/0431	Can a disposable bronchoscope-ascope- be used as choledochoscope	25
16/NW/0721	Preferred future & resource through SFBT with people with LTCs	27
17/NW/0001	Cardiac Output Monitoring in Donation after Cardiac Death	14
17/NW/0002	BOLUS study	28
17/NW/0010	Pulmonary CT in pneumonia complicating stroke	28
17/NW/0089	CARMS v1	26
17/NW/0162	HER2CLIMB	26

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/0710	Endosonographically targeted injection of Botox for chronic fissure-in	n/a

Provisional Opinion Pending Consultation with Referee		
REC Reference	Title	Number of Days on Clock

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

Withdrawn after the meeting		
REC Reference	Title	Number of Days on Clock
16/NW/0393	64294178HPC2001 - Chronic Hepatitis C (OMEGA-1)	25

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
16/NW/0407	Store-operated calcium entry in the human sweat gland version 1	29
16/NW/0409	Validation study of SCG dietary questionnaire	20
16/NW/0568	ProstaMetric Clinical Study	14
16/NW/0639	Information Preferences in Ulcerative Colitis	10
16/NW/0640	Information Preference in Perianal Crohn's Disease	8
16/NW/0681	The Relevance of PTSD in Major Trauma Patients at UHCW (Version 1)	12
16/NW/0835	Positive antenatal parenting using a bespoke mobile music APP.	13
17/NW/0064	Illness appraisals in non-specific abdominal pain.	10
17/NW/0073	Perceptions of the purpose and value of health visitor baby clinics	16

17/NW/0132	Harnessing technological innovation to improve cardiac rehabilitation	13
17/NW/0133	Microbiome in Tendinopathy (MINT)	15
17/NW/0135	Perception of biologics/anti-tumour necrosis factor	11

Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/NW/0837	The effectiveness of functional appliance in Class II malocclusion	13

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
16/NW/0300	Physical activity in mental health	7
16/NW/0302	Effect of Two Breathing Methods on Cough Strength of Tetraplegics. V1	10
16/NW/0313	Long-term adverse outcomes associated with antenatal exposure to drugs	8
16/NW/0323	Analysis of plasma samples from Swedish COPD study	7
16/NW/0414	Magnetic Resonance Imaging of Patients with Knee Replacements	12
16/NW/0484	Use of blood cells in regenerative medicine	9
16/NW/0569	Natural History of Early Onset Stargardt Disease	12
16/NW/0679	Non-accidental and Neglectful Injuries	8
16/NW/0772	PAMDC version 1	8
16/NW/0780	determinants of adherence with mandibular appliances in sleep apnoea	13
16/NW/0839	Use of PAX8 in endometrial and endocervical adenocarcinomas	14
17/NW/0068	Cross Sectional Study of Audiology Patients; Employment and Outcomes	7

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/NW/0567	Otsuka non-interventional: Quality of life of ADPKD patients	8
16/NW/0570	Non-luer one way filter valve intravenous needle and the blood patch	7
16/NW/0638	Safety and efficacy of CFA endovascular treatment	11
16/NW/0838	Delivery of interventions in children with speech sound disorder	13

Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock

Provisional Opinion		
REC Reference	Title	Number of Days on Clock

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

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

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/AM22	Predictors of Etanercept response.	15	15/04/2016	16
04/Q1403/37/AM24	Predictors of Etanercept response.	Substantial Amendment 12a	09/11/2016	20
06/Q1403/256/AM02	A retrospective immunohistochemical study in sarcoma patients	Substantial Amendment 2	27/04/2016	8
10/H1003/77/AM03	Understanding the conditions of the RAS-MAPK pathway: version 1	3	28/04/2016	6
11/H1003/3/AM02	Manchester Gene Identification Consortium (MAGIC) Study	1	31/03/2016	14
11/NW/0244/AM06	Validation of potential markers of disease in systemic sclerosis	Amendment 6	09/09/2016	25
12/NW/0255/AM06	Efficacy comparison of Ipilimumab vs Etoposide in ED-SCLC patients	19	02/03/2016	35
12/NW/0378/AM13	The role of the medial temporal lobes in memory	Substantial Amendment 7	10/10/2016	24
12/NW/0455/AM58	The Salford Lung Study (Asthma)	Substantial Amendment 42	27/10/2016	4
12/NW/0790/AM15	BASICS	Substantial Amendment 8	10/08/2016	20
13/NW/0003/AM14	3-001:Study of ART-123 in Subjects with Severe Sepsis and Coagulopathy	Substantial Amendment 14	23/04/2016	17
13/NW/0241/AM06	Investigating methods of transdermal fluid extraction	Substantial Amendment 3	31/05/2016	14
13/NW/0460/AM03	SC IL-1Ra in Stroke Study	Substantial Amendment 3	05/04/2016	27
13/NW/0703/AM04	Cognitive behaviour therapy for voices and dissociation	Amendment 4	24/10/2016	26
13/NW/0830/AM08	A Phase I study of Human Pharmacokinetics and Safety of ORY-1001	Substantial Amendment 5	07/06/2016	8
13/NW/0835/AM02	ARTFORCE PET Boost Study	Substantial Amendment 3	30/08/2016	14
14/NW/0010/AM12	LEE011 + BYL719 with Letrozole in patients with ER+ breast cancer	Protocol Amendment 5 & increase in number of patients	25/10/2016	25

14/NW/0010/AM13	LEE011 + BYL719 with Letrozole in patients with ER+ breast cancer	Temporary Halt	05/01/2017	7
14/NW/0010/AM14	LEE011 + BYL719 with Letrozole in patients with ER+ breast cancer	PIS/ICF Updates	30/01/2017	15
14/NW/0011/AM01	Investigating biomarkers in cognitively normal elderly participants.	Substantial Amendment 1	26/10/2016	20
14/NW/0153/AM01	Visceral hypersensitivity: a role in non-cardiac chest pain?	Amendment 1	14/07/2016	7
14/NW/0289/AM01	Refractoriness in Neurological Conditions	Substantial Amendment 1	08/09/2019	20
14/NW/1027/AM05	SORAMIC	Substantial Amendment 4	31/03/2016	16
14/NW/1068/AM07	GO28888 Neoadjuvant Letrozole and GDC-0032 in ER+/HER2- Breast Cancer	Substantial Amendment 6	01/08/2016	18
14/NW/1258/AM07	Phase 3 efficacy & safety study of ODM-201 in high risk non-met CRPC	Investigator Brochure_BAY 1841	10/06/2016	25
14/NW/1258/AM10	Phase 3 efficacy & safety study of ODM-201 in high risk non-met CRPC	Protocol Amendment 2	04/11/2016	32
14/NW/1258/AM11	Phase 3 efficacy & safety study of ODM-201 in high risk non-met CRPC	Substantial Amendment Updated Main PIS	10/03/2017	28
14/NW/1294/AM04	4-stage LCI699 study with optional extension in Cushing's Disease	Substantial Amendment 3	19/05/2016	18
14/NW/1393/AM03	PANasta	Substantial Amendment 3	27/05/2016	21
14/NW/1393/AM06	PANasta	Substantial Amendment 4	24/02/2017	26
15/NW/0001/AM03	The PEP-WARF Study	Substantial Amendment 1	15/12/2016	20
15/NW/0004/AM06	MO29112 Biomarker Driven Maintenance Treatment of Metastatic CRC	Substantial Amendment 6	12/05/2016	11
15/NW/0004/AM07	MO29112 Biomarker Driven Maintenance Treatment of Metastatic CRC	Substantial Amendment 06	09/06/2016	26
15/NW/0004/AM10	MO29112 Biomarker Driven Maintenance Treatment of Metastatic CRC	Substantial Amendment 7	20/10/2016	11
15/NW/0005/AM04	MRK Poly Vs Metal	Substantial Amendment 2	26/05/2016	16

15/NW/0005/AM05	MRK Poly Vs Metal	Substantial Amendment 3	24/01/2017	24
15/NW/0007/AM01	Determining important mechanisms that contribute to IBD	Version 3 04/01/2017	04/01/2017	7
15/NW/0076/AM01	LungTech Stereotactic Body Radiotherapy Trial	Substantial Amendment 1	26/10/2016	31
15/NW/0111/AM08	Biomarkers associated with known phenotypes across asthma severities.	3	10/05/2016	21
15/NW/0184/AM05	National investigation into suicide in children and young people	Substantial Amendment 3	24/06/2016	25
15/NW/0187/AM07	ORAL ZPL3893787 ON PRURITUS IN ADULTS WITH ATOPIC DERMATITIS	Investigator's Brochure	25/04/2016	26
15/NW/0196/AM01	Validation of Risk Assessment tools in CF-CAMHS	SA1	05/04/2016	26
15/NW/0255/AM04	Rempex 506	Updated Patients Emergency Card & Recruitment Posters	21/07/2016	20
15/NW/0359/AM04	U-SLEEP: Experimental Study	Substantial Amendment 4	20/04/2016	24
15/NW/0382/AM06	Pembrolizumab (MK-3475) vs Paclitaxel in 2L Subjects with Advanced Gastric Adenocarcinoma	Substantial Amendment 6	01/07/2016	14
15/NW/0382/AM08	Pembrolizumab (MK-3475) vs Paclitaxel in 2L Subjects with Advanced Gastric Adenocarcinoma	SA07	01/12/2016	11
15/NW/0393/AM05	Breath Analysis in ICU for Diagnosis of Ventilator Associated Pneumonia	Number 4		39
15/NW/0393/AM06	Breath Analysis in ICU for Diagnosis of Ventilator Associated Pneumonia	Substantial Amendment 5	19/09/2016	18
15/NW/0478/AM06	Breast Cancer - Anti-Progestin Prevention Study 1	UHSM0315 V1.5	05/08/2016	27
15/NW/0481/AM03	Safety and Efficacy of Ceftolozane/Tazobactam - ASPECT	Substantial Amendment 3	03/08/2016	16
15/NW/0505/AM07	Switch to MK-1439A from Ritonavir-boosted Protease Inhibitor regimen in HIV-1 infected subjects	SA06	27/06/2016	21
15/NW/0505/AM08	Switch to MK-1439A from Ritonavir-boosted Protease Inhibitor regimen in HIV-1 infected subjects	SA07	11/08/2016	28
15/NW/0505/AM09	Switch to MK-1439A from Ritonavir-boosted Protease Inhibitor regimen in HIV-1 infected subjects	Substantial Amendment 08	10/01/2017	4
15/NW/0546/AM04	Hip Injection Trial (HIT)	Substantial	05/08/2016	10

		Amendment 4		
15/NW/0546/AM05	Hip Injection Trial (HIT)	Substantial Amendment 5	12/09/2016	21
15/NW/0546/AM06	Hip Injection Trial (HIT)	Substantial Amendment 6	06/01/2017	6
15/NW/0582/AM01	The role of biochemical markers in the pathogenesis of kidney failure	1	19/04/2016	23
15/NW/0602/AM02	Optimum Use of Tympanometry in Adults with Down Syndrome	Substantial Amendment 1	17/11/2016	15
15/NW/0618/AM05	CA209-358 Nivolumab in virus positive and virus negative tumors	Substantial Amendment 4	13/05/2016	21
15/NW/0618/AM06	CA209-358 Nivolumab in virus positive and virus negative tumors	SA05	07/10/2016	24
15/NW/0618/AM08	CA209-358 Nivolumab in virus positive and virus negative tumors	Substantial Amendment 6	02/03/2017	26
15/NW/0756/AM03	The decision making process of ECT administration	Substantial Amendment 5	23/03/2016	28
15/NW/0769/AM02	Feasibility Study of the ReCell Device in Diabetic Foot Ulcers	Substantial Amendment 2	26/05/2016	17
15/NW/0776/AM04	Characterisation of myocardial inflammation in cardiomyopathies	First Major Amendment	08/04/2016	28
15/NW/0776/AM05	Characterisation of myocardial inflammation in cardiomyopathies	Second Major Amendment	16/11/2016	8
15/NW/0776/AM06	Characterisation of myocardial inflammation in cardiomyopathies	Third Major Amendment	15/02/2017	30
15/NW/0827/AM03	0301 – Phase 3 study of ASP2215 vs salvage chemotherapy in AML patient	Substantial Amendment 3	14/11/2016	28
15/NW/0831/AM05	Trigger_V1_03Aug2015	Substantial Amendment 2	01/06/2016	13
15/NW/0832/AM03	Trimaran_V1_03Aug2015	Substantial Amendment 2	01/06/2016	13
16/NW/0004/AM01	Lidocaine levels In DLTBs Study (LID Study)	Substantial Amendment 1	06/12/2016	15
16/NW/0005/AM02	Neuromodulation Therapy for Faecal Incontinence	Substantial Amendment 1	15/09/2016	14
16/NW/0011/AM01	Oral BI 1026706 and placebo in patients with COPD.	Substantial Amendment 1	13/04/2016	27

16/NW/0084/AM05	Pembrolizumab vs chemotherapy in Subjects with Oesophageal Cancer	SA01	17/03/2017	24
16/NW/0086/AM02	Study of Avelumab in pts with previously treated Hodgkin's Lymphoma	EC Amendment 1	06/06/2016	9
16/NW/0086/AM03	Study of Avelumab in pts with previously treated Hodgkin's Lymphoma	Amendment 2	17/08/2016	22
16/NW/0086/AM05	Study of Avelumab in pts with previously treated Hodgkin's Lymphoma	Substantial Amendment 3	14/10/2016	11
16/NW/0089/AM01	Linaclotide for abdominal distension V1	Substantial Amendment 1	03/08/2016	23
16/NW/0139/AM01	Real world effects of three-curve rocker sole shoe	Substantial Amendment 1	06/06/2016	7
16/NW/0139/AM02	Real world effects of three-curve rocker sole shoe	Amendment 2	22/11/2016	18
16/NW/0162/AM01	Phase 2 trial of Axitinib and TRC105 versus Axitinib alone	Substantial Amendment 1	06/09/2016	10
16/NW/0162/AM02	Phase 2 trial of Axitinib and TRC105 versus Axitinib alone	Substantial Amendment 2	12/01/2017	7
16/NW/0197/AM02	ASD2 Study	Substantial Amendment 1	04/10/2016	25
16/NW/0211/AM01	Self-Management App for young people with chronic rheumatic disease	Substantial Amendment 1	28/03/2016	28
16/NW/0262/AM01	Safety & Efficacy of VX-371 in CF patients Homozygous for F508del-CFTR	Substantial Amendment 1	04/07/2016	16
16/NW/0262/AM02	Safety & Efficacy of VX-371 in CF patients Homozygous for F508del-CFTR	Substantial Amendment 2	05/08/2016	22
16/NW/0262/AM03	Safety & Efficacy of VX-371 in CF patients Homozygous for F508del-CFTR	Substantial Amendment 3	07/11/2016	31
16/NW/0262/AM04	Safety & Efficacy of VX-371 in CF patients Homozygous for F508del-CFTR	Substantial Amendment 4	22/12/2016	25
16/NW/0387/AM02	Rehabilitation for Outdoor Activities and Mobility in Care Homes	Substantial Amendment 1	01/12/2016	11
16/NW/0398/AM01	Psychological Processes involved in voice-hearing	Substantial Amendment 1	09/09/2016	7
16/NW/0417/AM01	CA008-002 Phase I/II study of mesothelin directed ADC in solid tumours	EC01	20/03/2017	20
16/NW/0506/AM02	CAIN457F3301 (ACHILLES) Secukinumab in patients with PsA and axSpA	Substantial Amendment 1	11/11/2016	25

16/NW/0506/AM03	CAIN457F3301 (ACHILLES) Secukinumab in patients with PsA and axSpA	Substantial Amendment 2	23/01/2017	17
16/NW/0510/AM01	A feasibility study of Baby Triple P for mothers with MH difficulties	Substantial Amendment 1	06/02/2017	27
16/NW/0517/AM01	Myeloma XII (ACCoRd trial) Version 1.0	HM16/047/docs/010816	01/08/2016	19
16/NW/0517/AM02	Myeloma XII (ACCoRd trial) Version 1.0	HM16/047/docs/300916	06/10/2016	5
16/NW/0553/AM01	A study to evaluate the effect of inhaled CHF 6001 in adults with COPD	CCD-06001AA-10	29/09/2016	25
16/NW/0553/AM02	A study to evaluate the effect of inhaled CHF 6001 in adults with COPD	Substantial Amendment 2	14/12/2016	19
16/NW/0553/AM04	A study to evaluate the effect of inhaled CHF 6001 in adults with COPD	Substantial Amendment 3	13/02/2017	13
16/NW/0567/AM01	Otsuka non-interventional: Quality of life of ADPKD patients	Substantial Amendment 1	19/10/2016	16
16/NW/0705/AM01	Pilot PET study of regional cerebral protein synthesis in Alzheimer's	Substantial Amendment 1	10/02/2017	21
16/NW/0805/AM01	Phase I dose escalation of INC280+food in cMET advanced solid tumors	Substantial Amendment 01	17/01/2017	21
16/NW/0835/AM01	Positive antenatal parenting using a bespoke mobile music APP.	Substantial Amendment 1	20/01/2017	28
ERP/96/136/AM16	National Confidential Enquiry	Amendment 16	26/01/2017	14

Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
10/H1003/7/AM11	The Use of Silicone Gel in the Treatment of Stretch Marks	Amendment 7	25/08/2016	35
15/NW/0481/AM02	Safety and Efficacy of Ceftolozane/Tazobactam - ASPECT	2	15/03/2016	35

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

Favourable opinion timeline				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
10/H1003/7/AM11/1	The Use of Silicone Gel in the Treatment of Stretch Marks	Amendment 8 24/10/2016 (modified)	24/10/2016	10
15/NW/0481/AM02/1	Safety and Efficacy of Ceftolozane/Tazobactam - ASPECT	Modified Substantial Amendment	15/06/2016	7

Unfavourable opinion timeline				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock

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 21 day timeline

REC Reference	Title	Number of Days on Clock
16/NW/0407	Store-operated calcium entry in the human sweat gland version 1	29

SSAs (non Phase 1) over 25 day timeline

REC Reference	Title	Number of Days on Clock
17/NW/0110	A multicenter, open label, Phase 1 dose escalation study to evaluate the pharmacokinetics, safety, and tolerability of INC280 tablet formulation with food in patients with cMET dysregulated advance solid tumors	26

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
15/NW/0393/AM05	Breath Analysis in ICU for Diagnosis of Ventilator Associated Pneumonia	Amendment 4	03/05/2016	39

Modified Amendments over 14 day timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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