

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

Annual Report

01 April 2017 - 31 March 2018



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, ALC, IRB, Phase 1 in patients
Chair:	Professor Sobhan Vinjamuri
Vice-Chair:	Mr Richard Hovey
Alternate Vice-Chair:	Mrs Lesley Thornton
REC Manager:	Ms Gemma Warren
REC Assistant:	Miss Ewa Grzegorska until 01/12/2017 Miss Nina Bakhshayesh from 01/12/2017
Committee Address:	3rd Floor, Barlow House 4 Minshull Street Manchester M1 3DZ
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Chair's overview of the past year:

The GM South Committee continues to function well as a unit with some expected turnover of members. There have been more meetings planned in our usual venue rather than the central venue. We have participated in shared ethical debates and also in some preparatory work for the EU regulatory framework.

There has been good quorate attendance at all meetings, and all members have kept themselves updated with key training requirements.

Due to the need to reduce paper copies, increasing number of members have opted for electronic access, which has associated challenges such as needing high speed internet access during committee meetings, but I am sure this will get better with time.

The option of telephonic participation by the researchers has been availed on a few occasions, but we remain convinced that the face-to-face physical attendance of the researchers at meetings of the ethics committee provides the best means of discussion, interaction and decision making.

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	Clinical Trials Project Manager	Lay	13/09/2016	
Mrs Carmen Byrne	Freelance Strategist	Lay Plus	01/02/2018	
Mrs Caroline Dutton	Nurse	Expert	01/07/2017	
Miss Kathryn Fellows	CRO Monitor	Expert	11/07/2013	
Mr Ian Harrison	Chief Scientific Officer	Expert	01/07/2016	
Mr Richard Hovey	Business Analyst	Lay Plus	31/01/2007	
Dr Derrick Martin	Retired Consultant Radiologist	Expert	10/06/2016	
Ms Victoria Moore	Healthcare Ethics and Law Graduate	Lay Plus	01/07/2017	
Mrs Jessica Naphine-Hodgkinson	Research Support Officer	Lay Plus	01/11/2017	
Dr Joel Sanderson	Medical Expert	Expert	01/07/2016	
Dr Jacques SinFat Tamin	Honorary Senior Lecturer in Occupational Medicine	Expert	02/06/2014	27/09/2017
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
Mr James Burns	Retired Housing Consultant	Lay Plus	10/08/2017
Mrs Christine Holly	Retired Librarian	Lay	08/03/2018
Dr Lorraine Lighton	Retired Consultant in Communicable Disease Control	Expert	11/05/2017
Mr Paul Mooney	Senior Clinical Pharmacist	Expert	13/04/2017
Dr Jane Orton	Consultant Clinical Oncologist	Expert	08/06/2017
Dr Christopher Skidmore	Retired University Lecturer	Lay	08/06/2017

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

Name	Declaration of Interest	Date
Dr Anne Armstrong	Member of NCRI Breast Clinical Studies Group/Metastatic Sub Group/Symptom Management SubGroup. Involved in Clinical research as part of NHS role (Consultant Medical oncologist)	12/07/2017
Mr Robert Bedford	Senior Clinical Trials Coordinator at Manchester University Hospitals NHS Foundation Trust	31/03/2018
Mrs Carmen Byrne	Just finished a term with as a Trustee for the British Mountaineering Council Access and Conservation Trust. Still listed as a Trustee until legal documents are updated. There may be some research conducted by the BMC team which I am not involved in. Worked with Inspiring Change Manchester in 2017 on a freelance basis, no current work underway.	28/02/2018
Mrs Caroline Dutton	As part of my role as a senior sister at University Hospital of Manchester, occasionally involved with research projects. Peer review for the "Emergency Medicine Journal" Peer review for the "International Emergency Nursing Journal"	20/07/2017
Miss Kathryn Fellows	Paid Employment by Contract Research Organisation	01/01/2018
Mr Ian Harrison	Director/Part Owner of Alchemy Pharmatech Ltd. (42% Shares)	13/07/2017
Mr Richard Hovey	None	13/06/2017
Dr Derrick Martin	None	09/04/2017
Ms Victoria Moore	None	10/07/2017
Mrs Jessica Naphthine-Hodgkinson	Research Support Officer in the School of Sciences, University of Manchester	24/11/2017
Dr Joel Sanderson	None	12/07/2017
Mrs Lesley Thornton	200 AstraZeneca shares. Trustee - Family & Counselling Centre. Advisory Board Member for Trafford Clinical Commissioning Group	12/10/2017
Dr Nader Touqan	None	01/06/2017
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	09/06/2017

Meetings for Full Ethical Review 01 April 2017 - 31 March 2018:

Month	Date	Number of Members Present at Meeting
April	13/04/2017	7
May	11/05/2017	8
June	08/06/2017	8
July	13/07/2017	8
August	10/08/2017	8
October	12/10/2017	7
November	09/11/2017	10
January	11/01/2018	9
February	08/02/2018	9
March	08/03/2018	7

10 full committee meetings were held during the reporting period.

Proportionate Review Sub-Committee Meetings held during 01 April 2017 - 31 March 2018:

Month	Date	Number of Members Present at Meeting
April	28/04/2017	3
May	26/05/2017	3
June	23/06/2017	3
July	24/07/2017	3
August	28/08/2017	3
September	25/09/2017	3
October	23/10/2017	3
November	27/11/2017	3
January	22/01/2018	3
February	26/02/2018	3
March	26/03/2018	3

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

Sub-Committee Meetings held during 01 April 2017 - 31 March 2018:

Month	Date	Number of Members Present at Meeting
April	07/04/2017	2
April	21/04/2017	2
May	05/05/2017	2
May	19/05/2017	2
June	02/06/2017	2
June	16/06/2017	2
June	30/06/2017	2
July	14/07/2017	2
July	28/07/2017	2
August	11/08/2017	2
August	25/08/2017	2

August	31/08/2017	6
September	08/09/2017	2
September	22/09/2017	2
October	06/10/2017	2
October	20/10/2017	2
November	03/11/2017	2
November	17/11/2017	2
December	01/12/2017	2
December	15/12/2017	2
December	29/12/2017	2
January	12/01/2018	2
January	17/01/2018	8
January	26/01/2018	2
February	09/02/2018	2
February	23/02/2018	2
March	09/03/2018	2
March	23/03/2018	2

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

Details of inquorate meeting held: 01 April 2017 - 31 March 2018

0

Attendance of Members at full committee meetings: 01 April 2017 - 31 March 2018

Name	Number of Meetings Attended
Dr Anne Armstrong	2
Mr Robert Bedford	7
Mrs Carmen Byrne	1
Mrs Caroline Dutton	3
Miss Kathryn Fellows	3
Mr Ian Harrison	7
Mr Richard Hovey	9
Dr Derrick Martin	8
Ms Victoria Moore	4
Mrs Jessica Naphine-Hodgkinson	2
Dr Joel Sanderson	10
Dr Jacques SinFat Tamin	1
Mrs Lesley Thornton	6
Dr Nader Touqan	5
Professor Sobhan Vinjamuri	8

Attendance of Members at proportionate review sub-committee meetings: 01 April 2017 - 31 March 2018

Name	Number of Meetings Attended
Mr Robert Bedford	3
Mr Ian Harrison	2
Mr Richard Hovey	7
Professor Derrick Martin	2
Dr Derrick Martin	2
Dr Joel Sanderson	4
Mrs Lesley Thornton	3
Professor Sobhan Vinjamuri	10

Attendance of Members at sub-committee meetings: 01 April 2017 - 31 March 2018

Name	Number of Meetings Attended
Mr Robert Bedford	1
Mrs Caroline Dutton	1
Mr Ian Harrison	1
Mr Richard Hovey	27
Dr Derrick Martin	2
Ms Victoria Moore	2
Dr Joel Sanderson	2
Mrs Lesley Thornton	1

Dr Nader Touqan	2
Professor Sobhan Vinjamuri	27

Training 01 April 2017 - 31 March 2018

Name of Member	Date	Event(s) attended
Mrs Caroline Dutton	21/09/2017	Committee Members Induction
Mr Richard Hovey	01/01/2018	EU Clinical Trials Presentation and review during REC Meeting
Ms Victoria Moore	21/09/2017	Committee Members Induction
Ms Victoria Moore	31/01/2018	Complex Cases
Dr Joel Sanderson	04/07/2017	Research Involving Adults Who Lack Capacity (including research in emergency settings)
Dr Joel Sanderson	20/07/2017	Medical Devices Course
Dr Joel Sanderson	06/03/2018	Training - Assessing the Consequences (benefits and harms) of Research:
Mrs Lesley Thornton	31/01/2018	Complex Cases

PART 2: REC WORKLOAD AND ACTIVITY DURING THE REPORTING PERIOD

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

Applications for full ethical review – Study Type	Number	%
Clinical Trial of Investigational Medicinal Product	20	36.36
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	1	1.82
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	0
Number of student applications reviewed	7
Number of paediatric applications reviewed	4
Number of device applications reviewed	10
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	6
Number of applications reviewed that are funded by the US DHHS	1
Number of qualitative applications reviewed	6

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	11	20.00
Unfavourable Opinion	0	0.00
Provisional Opinion	42	76.36
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	40	72.73
Further Information Favourable Opinion with Additional Conditions	1	1.82
Further Information Unfavourable Opinion	1	1.82
Favourable Opinion with Standard Conditions	2	3.64
Favourable Opinion with Additional Conditions	11	20.00
Unfavourable Opinion	0	0.00
Provisional Opinion	0	0.00
Provisional Opinion Pending Consultation with Referee	0	0.00
Further Information response not complete	0	0.00
No decision entered on system	0	0.00
Number of studies withdrawn after the meeting	0	0.00
Total	55	100

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

Total Applications Reviewed	21
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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	1
Number of student applications reviewed	7
Number of paediatric applications reviewed	5
Number of device applications reviewed	1
Number of qualitative applications reviewed	2

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	8	38.10
Favourable Opinion with Additional Conditions	7	33.33
No Opinion transfer to full committee for review	1	4.76
Provisional Opinion	5	23.81
Unfavourable Opinion	0	0.00
Total	21	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	55
Number of completed applications for full ethical review over 60 days	1
Number of completed applications over 60 days as a % of total	1.82%
Number of days taken to final decision – average (mean)	41
Number of completed proportionate review applications for ethical review	21
Number of completed proportionate review applications for ethical review over 21 days	5
Number of completed proportionate review applications over 21 days as a % of total	23.81%
Number of SSAs (non-Phase 1) reviewed	29
Number of completed applications for SSA review over 25 days	5
Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs	17.24%
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	144
Number of completed substantial amendments over 35 days	5
Number of completed substantial amendments over 35 days as a % of total substantial amendments	3.47%
Number of modified amendments reviewed	0
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	102
Number of substantial amendments received for information	1
Number of substantial amendments received for new sites/PIs	30
Number of annual progress reports received	94
Number of safety reports received	53
Number of Serious Adverse Events received	8
Number of final reports received	47

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
17/NW/0216	BI443651 methacholine challenge in asthmatic patients	39
17/NW/0227	Clinical outcomes study of the Zimmer Nexel total elbow	47
17/NW/0228	Phase 3 Carfilzomib Study in Patients With Relapsed/Refractory Myeloma	36
17/NW/0230	Natural history of Familial Chylomicronaemia Syndrome	39
17/NW/0236	SuPPORT 4 All Clinical Feasibility Trial	43
17/NW/0238	Peer Mentorship in Osteoarthritis	40
17/NW/0282	Healthy lifestyles in people with SMI v1	34
17/NW/0292	Phase 1b multi-indication study of anetumab ravtansine	26
17/NW/0300	A pilot study using MR to assess cervix motion during radiotherapy	34
17/NW/0315	ELSI-NAPS	39
17/NW/0350	Metastatic Breast Cancer: Towards a Chronic Condition?	40
17/NW/0351	TITAN RCC	39
17/NW/0372	Effectiveness /safety of S95002 implant vs GLP-1 RA in T2 diabetes	54
17/NW/0389	Manchester Intermittent and Daily diet Diabetes App Study (MIDDAS)	53
17/NW/0395	Evaluation of a new technology for treatment of bladder leakage v1.0	34
17/NW/0421	T4P1010 treatment in patients with Osteoarthritic Pain of Knee or Hip	56
17/NW/0430	R475-OA-1611 Patients with Pain Due to Osteoarthritis of the Knee/Hip	37
17/NW/0431	DemPower: Living Life & Doing Things Together Couple-Management Guide	45
17/NW/0439	CA209-914 Nivolumab in Patients with Renal Cell Carcinoma	30
17/NW/0460	PEARL	31
17/NW/0480	Dietary intervention for gastroparesis in systemic sclerosis	28
17/NW/0573	Phase III: UbLiTuximab In Multiple Sclerosis Treatment Effects (ULTIMATE I STUDY)	42
17/NW/0574	Phase III: UbLiTuximab In Multiple Sclerosis Treatment Effects (ULTIMATE II STUDY)	41
17/NW/0580	myAirCoach: Evaluation Campaign	39
17/NW/0584	Study of Serlopitant for the Treatment of Refractory Chronic Cough	42
17/NW/0593	MOW-01-2017	33
17/NW/0615	The Manchester Needs Tool for Injured Children MANTIC	58
17/NW/0634	COMICE	36
17/NW/0635	207702 Effect of GSK2798745 in participants with chronic cough	59
17/NW/0637	OUTREACH study: Urine analysis and antihypertensive treatment	44
18/NW/0006	GLPG2737-CL-105 Assessment of multiple oral doses of GLPG2451/GLPG2222	79
18/NW/0008	Immunogenicity and Safety of TDV Co-administered with an Hepatitis A V	59

18/NW/0016	Efficacy & Safety of JNJ-42165279 in Subjects with MDD & Anxiety	58
18/NW/0024	A study of the factors affecting AMHPs' decision-making	51
18/NW/0033	[11C]-(R)-PK11195 PET in metastatic prostate cancer	58
18/NW/0088	SPLASH/In-home use study in babies	60
18/NW/0092	Manchester Cancer Research Centre Biobank	50
18/NW/0107	cAVM-Phil Registry	58
18/NW/0109	dAVF-PHIL Registry	60
18/NW/0141	SAFE Research Study	39

Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
17/NW/0614	Factors relating to repeat admissions for COPD exacerbations. v1	37

Further Information Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
17/NW/0596	Indoor air quality and pregnancy	52

Favourable Opinion with Standard Conditions

REC Reference	Title	Number of Days on Clock
17/NW/0591	CCHIRAL version 1	29
18/NW/0009	Improving Access to Psychological Therapy on Acute Mental Health Wards	29

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
17/NW/0242	PARIS	25
17/NW/0262	DISKO: Effect of Denosumab on pain and BMLs in knee osteoarthritis	25
17/NW/0320	PRedSS: Prednisolone in Early Diffuse Systemic Sclerosis. Version 1.0	32
17/NW/0345	The assessment of risk and safety in mental health services.	32
17/NW/0352	UK REBOA Study	32
17/NW/0394	24/7 closed-loop in older subjects with type 1 diabetes	26
18/NW/0017	BREELIB	28
18/NW/0026	SentiPen	28

18/NW/0052	RUPA v1.0	29
18/NW/0066	Assessing the impact of Genetic Counselling on South Asian Families	29
18/NW/0094	Sodium-23 MR imaging in CNS tumours (SMIC)	29

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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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
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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
17/NW/0337	ZEUS - Zalviso in the EU after Surgery	22
17/NW/0452	CPAP use and exercise capacity in tracheo/bronchomalacia patients	20
17/NW/0619	Providing insight into patients' care needs using hospital datasets	17
18/NW/0217	Managing opioid reduction in chronic pain: A qualitative study	33

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
18/NW/0059	Progression risk of low-grade anal neoplasia.	22

Further Information Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock
18/NW/0162	An exploration of self management physiotherapy programmes (SMPP)	28

Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
17/NW/0397	Rare cell isolation from whole blood	9
17/NW/0513	Detection of EGFR mutation in circulating tumor DNA	1
17/NW/0516	SDQ AVS replication with the SHIFT study	8
17/NW/0567	Antiseptic skin washes to reduce S. aureus cannula infections	22
17/NW/0681	Follow up of H Pylori screening study	14
18/NW/0143	Family/friends' experiences of Early Intervention in Psychosis group	17
18/NW/0144	Clinical Consequences of Aspergillus Disease in Cystic Fibrosis	14
18/NW/0146	An evaluation of a 'hub and spoke' model of peer support.	5

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
17/NW/0269	Delivery of Patient Reported Health Status Questions in Stroke	14
17/NW/0390	Development of orientation skills for listening to speech in noise	12
17/NW/0393	A prospective multi-centre observational cohort study of ACJ Injuries	10
17/NW/0449	Gender differences in self-harm in young people	12
17/NW/0518	ALSFRS-R Online Validation	14
17/NW/0679	Velopharyngeal dimensions in patients with 22q11 deletion	18
18/NW/0223	Bezlotoxumab effect on the positivity of C.difficile toxin detection	20

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/AM26	Predictors of Etanercept response.	Substantial Amendment 16	10/07/2017	34
10/H1003/77/AM04	Understanding the conditions of the RAS-MAPK pathway: version 1	Substantial Amendment 7	01/11/2017	32
11/NW/0075/AM06	Lung ART (Lung Adjuvant Radiotherapy Trial)	Substantial Amendment 2	29/11/2017	25
11/NW/0699/AM04	Determining effect of Apical vs Septal pacing using cardiac MR	SA03	08/07/2017	25
12/NW/0790/AM16	BASICS	SA9	11/08/2017	23
13/NW/0003/AM17	3-001:Study of ART-123 in Subjects with Severe Sepsis and Coagulopathy	Substantial Amendment 3-001 Informed Consent Video	01/05/2017	16
13/NW/0003/AM18	3-001:Study of ART-123 in Subjects with Severe Sepsis and Coagulopathy	IB v9.0 dated 24/04/17; ICF v5	19/06/2017	23
13/NW/0189/AM05	GOAL Trial	Substantial Amendment 2	08/03/2018	32
13/NW/0411/AM05	D081AC00001 Two Part, Phase 1 study in patients with solid tumours	SA4 - IB12	18/05/2017	27
13/NW/0714/AM08	ECASS-4: EXTEND	Protocol Amendment 2	18/04/2017	29
14/NW/0010/AM15	LEE011 + BYL719 with Letrozole in patients with ER+ breast cancer	Protocol Amendment 06 & 07	01/06/2017	19
14/NW/0010/AM16	LEE011 + BYL719 with Letrozole in patients with ER+ breast cancer	CLEE011X2107	12/07/2017	11
14/NW/0010/AM17	LEE011 + BYL719 with Letrozole in patients with ER+ breast cancer	CLEE011X2107 LEE011 IB Ed11	25/09/2017	34
14/NW/0010/AM18	LEE011 + BYL719 with Letrozole in patients with ER+ breast cancer	Protocol Amendment 08	20/09/2017	14
14/NW/0073/AM01	European Journey II BCS Safety and Efficacy study; Protcl ^o :R11009-7	Amendment 2	10/04/2017	21
14/NW/0289/AM02	Refractoriness in Neurological Conditions	Amendment 2	19/11/2017	31
14/NW/1084/AM07	CA209-205	SA7 - EC6	27/03/2017	21

14/NW/1258/AM13	Phase 3 efficacy&safety study of ODM-201 in high risk non-met CRPC	Substantial Amendment - Update to IB Amendment 1	10/04/2017	28
14/NW/1258/AM15	Phase 3 efficacy&safety study of ODM-201 in high risk non-met CRPC	Substantial Amendment – Updated IB	30/06/2017	17
14/NW/1258/AM16	Phase 3 efficacy&safety study of ODM-201 in high risk non-met CRPC	Substantial Amendment IB update 1 for IB V3.1	22/12/2017	20
14/NW/1294/AM07	4-stage LCI699 study with optional extension in Cushing's Disease	Substantial Amendment 4	02/08/2017	30
15/NW/0004/AM12	MO29112 Biomarker Driven Maintenance Treatment of Metastatic CRC	SA09	14/06/2017	20
15/NW/0004/AM13	MO29112 Biomarker Driven Maintenance Treatment of Metastatic CRC	Amendment 10	02/11/2017	14
15/NW/0004/AM14	MO29112 Biomarker Driven Maintenance Treatment of Metastatic CRC	Substantial Amendment 11	10/01/2018	19
15/NW/0004/AM15	MO29112 Biomarker Driven Maintenance Treatment of Metastatic CRC	Substantial Amendment 12	02/03/2018	21
15/NW/0005/AM06	MRK Poly Vs Metal	Substantial Amendment 4	26/09/2017	23
15/NW/0076/AM02	LungTech Stereotactic Body Radiotherapy Trial	Substantial Amendment 2	10/03/2017	33
15/NW/0076/AM03	LungTech Stereotactic Body Radiotherapy Trial	Substantial Amendment 3	29/05/2017	22
15/NW/0076/AM04	LungTech Stereotactic Body Radiotherapy Trial	Substantial Amendment 4	26/06/2017	9
15/NW/0382/AM11	Pembrolizumab (MK-3475) vs Paclitaxel in 2L Subjects with Advanced Gastric Adenocarcinoma	SA08	10/05/2017	22
15/NW/0382/AM13	Pembrolizumab (MK-3475) vs Paclitaxel in 2L Subjects with Advanced Gastric Adenocarcinoma	SA09	14/09/2017	27
15/NW/0382/AM14	Pembrolizumab (MK-3475) vs Paclitaxel in 2L Subjects with Advanced Gastric Adenocarcinoma	SA11 - Protocol Amendment 10	21/09/2017	20
15/NW/0382/AM15	Pembrolizumab (MK-3475) vs Paclitaxel in 2L Subjects with Advanced Gastric Adenocarcinoma	SA12 - IB V15	26/10/2017	25

15/NW/0382/AM16	Pembrolizumab (MK-3475) vs Paclitaxel in 2L Subjects with Advanced Gastric Adenocarcinoma	SA13 - Protocol amendment v12	20/02/2018	26
15/NW/0393/AM08	Breath Analysis in ICU for Diagnosis of Ventilator Associated Pneumonia	SA6	09/05/2017	26
15/NW/0478/AM07	Breast Cancer - Anti-Progestin Prevention Study 1	SA6	24/03/2017	17
15/NW/0478/AM08	Breast Cancer - Anti-Progestin Prevention Study 1	Substantial Amendment 7	11/05/2017	21
15/NW/0478/AM09	Breast Cancer - Anti-Progestin Prevention Study 1	Substantial Amendment 8	01/06/2017	13
15/NW/0478/AM12	Breast Cancer - Anti-Progestin Prevention Study 1	Substantial Amendment 10	13/02/2018	34
15/NW/0505/AM12	Switch to MK-1439A from Ritonavir-boosted Protease Inhibitor regimen in HIV-1 infected subjects	SA11	14/06/2017	13
15/NW/0505/AM13	Switch to MK-1439A from Ritonavir-boosted Protease Inhibitor regimen in HIV-1 infected subjects	SA12	30/08/2017	22
15/NW/0548/AM01	Vascular Function in Obesity	SA1	17/05/2017	25
15/NW/0618/AM09	CA209-358 Nivolumab in virus positive and virus negative tumors	SA7	07/09/2017	21
15/NW/0618/AM10	CA209-358 Nivolumab in virus positive and virus negative tumors	Notice of Substantial Amendment 8	08/03/2018	28
15/NW/0775/AM03	Cross-sectional study antipsychotic-induced cardiometabolic toxicity	Amendment 3	13/11/2017	12
15/NW/0776/AM07	Characterisation of myocardial inflammation in cardiomyopathies	Fourth Major Amendment	21/06/2017	19
15/NW/0776/AM08	Characterisation of myocardial inflammation in cardiomyopathies	Fifth Major Amendment	29/08/2017	16
15/NW/0827/AM05	0301 – Phase 3 study of ASP2215 vs salvage chemotherapy in AML patient	Substantial Amendment 4	23/05/2017	22
15/NW/0827/AM06	0301 – Phase 3 study of ASP2215 vs salvage chemotherapy in AML patient	Substantial Amendment 5	03/10/2017	20
15/NW/0827/AM07	0301 – Phase 3 study of ASP2215 vs salvage chemotherapy in AML patient	Substantial Amendment 6	14/11/2017	13
15/NW/0831/AM10	Trigger_V1_03Aug2015	SA _ Updated IB	08/09/2017	21
15/NW/0832/AM08	Trimaran_V1_03Aug2015	SA - Updated IB	08/09/2017	21
16/NW/0004/AM02	Lidocaine levels In DLTBs Study (LID Study)	Substantial Amendment 2	01/03/2017	27

16/NW/0018/AM01	The role of troponin I measurement in non cardiac aortic surgery	Amendment 1	25/07/2017	27
16/NW/0084/AM06	Pembrolizumab vs chemotherapy in Subjects with Oesophageal Cancer	SA02	21/06/2017	14
16/NW/0084/AM08	Pembrolizumab vs chemotherapy in Subjects with Oesophageal Cancer	SA03	16/11/2017	35
16/NW/0085/AM01	ActION-PD	Amendment 1	10/08/2017	27
16/NW/0085/AM02	ActION-PD	Substantial Amendment 2	27/02/2018	28
16/NW/0086/AM06	Study of Avelumab in pts with previously treated Hodgkin's Lymphoma	Protocol Amendment 3 - IB v7	31/07/2017	27
16/NW/0086/AM07	Study of Avelumab in pts with previously treated Hodgkin's Lymphoma	Amendment 4	18/12/2017	39
16/NW/0089/AM03	Linacotide for abdominal distension V1	MCP-103-403-PO4 25/04/17 Version 4	08/06/2017	22
16/NW/0126/AM01	Deaf life-stories project	Amendment 1	08/11/2017	15
16/NW/0153/AM02	Comparison of 2D US to tUS for conduit mapping	Substantial Amendment 1	11/12/2017	28
16/NW/0162/AM03	Phase 2 trial of Axitinib and TRC105 versus Axitinib alone	SA3	23/03/2017	18
16/NW/0162/AM05	Phase 2 trial of Axitinib and TRC105 versus Axitinib alone	Substantial Amendment 7	20/02/2018	27
16/NW/0197/AM03	ASD2 Study	Substantial Amendment 2	11/03/2017	6
16/NW/0239/AM01	A prospective trial of DXM gel for early stage chronic low back pain	Amendment 1	26/09/2017	23
16/NW/0242/AM02	Phase I pharmacokinetics, safety and tolerability study of DITEST	Substantial Amendment 1	21/09/2017	7
16/NW/0242/AM03	Phase I pharmacokinetics, safety and tolerability study of DITEST	Substantial Amendment 3	05/01/2018	24
16/NW/0262/AM06	Safety & Efficacy of VX-371 in CF patients Homozygous for F508del-CFTR	Substantial Amendment 5	10/07/2017	14
16/NW/0264/AM05	A pilot RCT on the Management of Term Prelabour Rupture of Membranes	Substantial Amendment 1	01/08/2017	24
16/NW/0414/AM01	Magnetic Resonance Imaging of Patients with Knee Replacements	Amendment 1	08/08/2017	24
16/NW/0414/AM03	Magnetic Resonance Imaging of Patients with Knee	Substantial	05/11/2017	13

	Replacements	Amendment 2		
16/NW/0417/AM02	CA008-002 Phase I/II study of mesothelin directed ADC in solid tumours	EC02	21/06/2017	25
16/NW/0417/AM04	CA008-002 Phase I/II study of mesothelin directed ADC in solid tumours	Substantial Amendment 3	29/01/2018	9
16/NW/0499/AM03	Developing and validating a therapeutic alliance measure	Substantial Amendment 1	05/07/2017	25
16/NW/0506/AM05	CAIN457F3301 (ACHILLES) Secukinumab in patients with PsA and axSpA	Substantial Amendment 4	26/07/2017	20
16/NW/0510/AM02	A feasibility study of Baby Triple P for mothers with MH difficulties	Substantial Amendment 2	25/05/2017	9
16/NW/0510/AM03	A feasibility study of Baby Triple P for mothers with MH difficulties	Substantial Amendment 3	05/10/2017	42
16/NW/0510/AM05	A feasibility study of Baby Triple P for mothers with MH difficulties	Substantial Amendment 4	22/02/2018	27
16/NW/0541/AM01	Care Home Acute Norovirus Gastroenteritis Study	1.9 (dated 10/05/2017)	10/05/2017	15
16/NW/0541/AM02	Care Home Acute Norovirus Gastroenteritis Study	2.0	23/11/2017	19
16/NW/0548/AM02	TSPO PET Imaging in GBM	Substantial Amendment 1	08/01/2018	9
16/NW/0564/AM01	A study of BET Inhibitor BMS-986158 in advanced solid tumours	Substantial Amendment 1	03/04/2017	20
16/NW/0567/AM05	Otsuka non-interventional: Quality of life of ADPKD patients	Substantial Amendment 2	17/05/2017	6
16/NW/0705/AM02	Pilot PET study of regional cerebral protein synthesis in Alzheimer's	Substantial Amendment 2	07/12/2017	21
16/NW/0727/AM01	Multi Centre RCT for postnatal depression in BSA women - ROSHNI-2	2.0	15/02/2018	21
16/NW/0772/AM01	PAMDC version 1	Substantial Amendment – Version 2.0 10/03/2017	12/06/2017	21
16/NW/0772/AM02	PAMDC version 1	Substantial Amendment Version 3.0	18/01/2018	4
16/NW/0781/AM05	An AMP challenge study of escalating repeat doses of FF, FP and BUD	Substantial Amendment 01	07/08/2017	8

16/NW/0781/AM06	An AMP challenge study of escalating repeat doses of FF, FP and BUD	Substantial Amendment 02	13/10/2017	25
16/NW/0805/AM03	Ph I dose escalation of INC280+food in cMET advanced solid tumors	Substantial Amendment 02	24/03/2017	13
16/NW/0812/AM03	Safety, tolerability, PK & PD effects of REGN3500 in Asthma Patients	Substantial Amendment 2	21/04/2017	27
16/NW/0837/AM02	The effectiveness of functional appliance in Class II malocclusion	1.0	05/02/2018	13
16/NW/0838/AM01	Delivery of interventions in children with speech sound disorder	Amendment 1	10/05/2017	28
17/NW/0003/AM01	REmLap	Amendment 1	21/04/2017	28
17/NW/0005/AM01	Investigating beliefs and goal appraisals in severe mental illness	Substantial Amendment 1	07/08/2017	20
17/NW/0015/AM01	FLiP-GD2	SA1	31/08/2017	25
17/NW/0030/AM01	Circadian Disruption on ICU - CADI	Substantial Amendment 1.1	27/04/2017	29
17/NW/0055/AM01	Endocrine disrupting chemicals in adipose tissue of diabetics	Amendment 1	04/05/2017	5
17/NW/0089/AM01	CARMS v1	SA1	07/06/2017	12
17/NW/0089/AM02	CARMS v1	SA2	21/09/2017	25
17/NW/0111/AM01	UMANC	Substantial Amendment 1	01/09/2017	20
17/NW/0111/AM02	UMANC	Substantial Amendment 2	10/10/2017	27
17/NW/0162/AM01	HER2CLIMB	Substantial Amendment 1	15/06/2017	19
17/NW/0162/AM04	HER2CLIMB	Substantial Amendment 2	21/12/2017	46
17/NW/0163/AM04	A Study in Adult Patients with Allergic Asthma	Substantial Amendment 01	16/05/2017	23
17/NW/0163/AM06	A Study in Adult Patients with Allergic Asthma	Substantial Amendment 3	09/01/2018	20
17/NW/0163/AM07	A Study in Adult Patients with Allergic Asthma	Substantial Amendment 4	26/02/2018	25
17/NW/0163/AM08	A Study in Adult Patients with Allergic Asthma	Substantial Amendment 5	26/02/2018	29
17/NW/0228/AM03	Phase 3 Carfilzomib Study in Patients With Relapsed/Refractory Myeloma	Amendment 3	27/07/2017	21

17/NW/0228/AM04	Phase 3 Carfilzomib Study in Patients With Relapsed/Refractory Myeloma	Amendment 4	01/03/2018	22
17/NW/0230/AM01	Natural history of Familial Chylomicronaemia Syndrome	Amendment 1	03/09/2017	27
17/NW/0230/AM03	Natural history of Familial Chylomicronaemia Syndrome	Amendment 2	30/10/2017	11
17/NW/0242/AM01	PARIS	SA01	07/08/2017	26
17/NW/0262/AM01	DISKO: Effect of Denosumab on pain and BMLs in knee osteoarthritis	Substantial Amendment 1	21/07/2017	20
17/NW/0262/AM03	DISKO: Effect of Denosumab on pain and BMLs in knee osteoarthritis	Substantial Amendment 3	13/11/2017	31
17/NW/0292/AM01	Phase 1b multi-indication study of anetumab ravtansine	Substantial Amendment 1	10/07/2017	8
17/NW/0292/AM03	Phase 1b multi-indication study of anetumab ravtansine	Substantial Amendment 3	11/08/2017	24
17/NW/0300/AM01	A pilot study using MR to assess cervix motion during radiotherapy	Substantial Amendment 1.0	06/12/2017	35
17/NW/0315/AM01	ELSI-NAPS	Amendment 1	18/12/2017	27
17/NW/0320/AM01	PRedSS: Prednisolone in Early Diffuse Systemic Sclerosis. Version 1.0	Substantial Amendment 1	06/07/2017	26
17/NW/0320/AM02	PRedSS: Prednisolone in Early Diffuse Systemic Sclerosis. Version 1.0	Substantial Amendment 3	02/10/2017	17
17/NW/0351/AM01	TITAN RCC	Substantial Amendment 1	08/09/2017	28
17/NW/0389/AM01	Manchester Intermittent and Daily diet Diabetes App Study (MIDDAS)	1.0	28/12/2017	39
17/NW/0390/AM01	Development of orientation skills for listening to speech in noise	Amendment 1	13/10/2017	24
17/NW/0390/AM02	Development of orientation skills for listening to speech in noise	Amendment 2	27/11/2017	35
17/NW/0390/AM03	Development of orientation skills for listening to speech in noise	Substantial Amendment 3	05/03/2018	31
17/NW/0394/AM01	24/7 closed-loop in older subjects with type 1 diabetes	Amendment 1	08/02/2018	20
17/NW/0421/AM01	T4P1010 treatment in patients with Osteoarthritic Pain of Knee or Hip	Substantial Amendment 1	02/10/2017	18
17/NW/0430/AM01	R475-OA-1611 Patients with Pain Due to Osteoarthritis of the Knee/Hip	Protocol Amendment 1 VHP	22/09/2017	41
17/NW/0430/AM03	R475-OA-1611 Patients with Pain Due to Osteoarthritis of the	Substantial	20/10/2017	15

	Knee/Hip	Amendment 2		
17/NW/0449/AM01	Gender differences in self-harm in young people	Amendment 1	24/09/2017	20
17/NW/0460/AM01	PEARL	Amendment 1	22/09/2017	22
17/NW/0460/AM02	PEARL	Substantial Amendment 2	06/11/2017	27
17/NW/0480/AM01	Dietary intervention for gastroparesis in systemic sclerosis	Substantial Amendment 1	14/12/2017	6
17/NW/0573/AM01	Phase III: UbLiTuximab In Multiple Sclerosis Treatment Effects (ULTIMATE I STUDY)	Substantial Amendment 1	12/02/2018	17
17/NW/0574/AM01	Phase III: UbLiTuximab In Multiple Sclerosis Treatment Effects (ULTIMATE II STUDY)	Substantial Amendment 1	12/02/2018	17
17/NW/0584/AM03	Study of Serlopitant for the Treatment of Refractory Chronic Cough	Substantial Amendment 2	08/03/2018	20
18/NW/0009/AM04	Improving Access to Psychological Therapy on Acute Mental Health Wards	Substantial Amendment 1.0	14/03/2018	5
ERP/96/136/AM17	The National Confidential Inquiry into Suicide and Safety in Mental Health	Amendment 17	09/05/2017	17
ERP/96/136/AM18	The National Confidential Inquiry into Suicide and Safety in Mental Health	Substantial Amendment 18	12/06/2017	18
ERP/96/136/AM19	The National Confidential Inquiry into Suicide and Safety in Mental Health	Substantial Amendment 19	29/06/2017	11
ERP/96/136/AM23	The National Confidential Inquiry into Suicide and Safety in Mental Health	Substantial Amendment 20	13/09/2017	25

Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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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
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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
18/NW/0006	GLPG2737-CL-105 Assessment of multiple oral doses of GLPG2451/GLPG2222	79

Proportionate review applications for ethical review over 21 day timeline

REC Reference	Title	Number of Days on Clock
17/NW/0337	ZEUS - Zalviso in the EU after Surgery	22
17/NW/0567	Antiseptic skin washes to reduce S. aureus cannula infections	22
18/NW/0059	Progression risk of low-grade anal neoplasia.	22
18/NW/0162	An exploration of self management physiotherapy programmes (SMPP)	28
18/NW/0217	Managing opioid reduction in chronic pain: A qualitative study	33

SSAs (non Phase 1) over 25 day timeline

REC Reference	Title	Number of Days on Clock
17/NW/0731	A Phase 3 Randomized, Double-Blind, Multi-Dose, Placebo and Naproxen-Controlled Study to Evaluate the Efficacy and Safety of Fasinumab in Patients with Pain Due to Osteoarthritis of the Knee or Hip.	28
17/NW/0732	A Phase 3 Randomized, Double-Blind, Multi-Dose, Placebo and Naproxen-Controlled Study to Evaluate the Efficacy and Safety of Fasinumab in Patients with Pain Due to Osteoarthritis of the Knee or Hip.	28
17/NW/0733	A Phase 3 Randomized, Double-Blind, Multi-Dose, Placebo and Naproxen-Controlled Study to Evaluate the Efficacy and Safety of Fasinumab in Patients with Pain Due to Osteoarthritis of the Knee or Hip.	31
17/NW/0734	A Phase 3 Randomized, Double-Blind, Multi-Dose, Placebo and Naproxen-Controlled Study to Evaluate the Efficacy and Safety of Fasinumab in Patients with Pain Due to Osteoarthritis of the Knee or Hip.	31
17/NW/0735	A Phase 3 Randomized, Double-Blind, Multi-Dose, Placebo and Naproxen-Controlled Study to Evaluate the Efficacy and Safety of Fasinumab in Patients with Pain Due to Osteoarthritis of the Knee or Hip.	30

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
16/NW/0086/AM07	Study of Avelumab in pts with previously treated Hodgkin's Lymphoma	Amendment 4	18/12/2017	39
16/NW/0510/AM03	A feasibility study of Baby Triple P for mothers with MH difficulties	Substantial Amendment 3	05/10/2017	42
17/NW/0162/AM04	HER2CLIMB	Substantial Amendment 2	21/12/2017	46
17/NW/0389/AM01	Manchester Intermittent and Daily diet Diabetes App Study (MIDDAS)	1.0	28/12/2017	39
17/NW/0430/AM01	R475-OA-1611 Patients with Pain Due to Osteoarthritis of the Knee/Hip	Protocol Amendment 1 VHP	22/09/2017	41

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