

**West Midlands - Edgbaston Research Ethics
Committee**

Annual Report

01 April 2017 - 31 March 2018



Part 1 – Committee Membership and Training

Name of REC:	West Midlands - Edgbaston Research Ethics Committee
Type of REC:	RECs recognised to review CTIMPS in patients - type iii
Type of Flag:	Phase 1 Studies in Patients Research Involving Children Medical Device Study
Chair:	Mr Paul Hamilton
Vice-Chair:	Professor John Marriott
Alternate Vice-Chair:	Dr Sarahjane Jones
REC Manager:	Miss Rebecca Morledge – February 2018 – present Mrs Joanne O’Neil – covering REC Manager from October 2017 – February 2018 Mrs Helen Poole – until October 2017
REC Assistant:	Ellena Stansbury – February 2018 – present Mrs Joanne O’Neil – until October 2017
Committee Address:	The Old Chapel Royal Standard Place Nottingham NG1 6FS
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Chair's overview of the past year:

The committee has worked well over the last twelve months, particularly taking into account the tight time constraints set by our current meeting hosts who require us, after a 1 pm start, to vacate the building by 5 pm without fail. The reduction in the number of studies to be reviewed at any one meeting has been most welcome.

Some members have acted as co-opted members of other committees and we all find this a valuable experience providing an opportunity to compare working practices and to develop collegiality. In addition, one member visits other committees as an applicant and has found sitting 'both sides of the table' very informative.

Our substantive REC Manager took maternity leave during the reporting period and we were supported by colleagues, who some members had met while co-opting, and rapport was, therefore, easily established.

The committee continues to work well and members approach the work conscientiously and with good humour. We continue to receive positive feedback from applicants through management processes.

West Midlands - Edgbaston Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Dr Oladipo Babalola	Relief Pharmacy Manager	Expert	05/06/2015	
Dr Hora Ejtehad	Senior Academic Lecturer	Lay	07/05/2015	
Mr Chris Foy	Medical Statistician	Expert	01/05/2010	
Mr Paul Hamilton	Parish Administrator	Lay Plus	01/01/2008	
Dr Adrian Hamlyn	Consultant Physician & Hepatologist	Expert	01/02/2007	14/12/2017
Dr Sarahjane Jones	Senior Research Fellow	Lay	05/02/2013	
Dr Nigel Langford	Consultant Clinical Pharmacologist & General Physician	Expert	01/01/2009	
Professor John Marriott	Pharmaceutical Chemist/Academic Pharmacist	Expert	01/01/2008	
Mrs Alison Parsons	Retired Senior Manager	Lay Plus	01/01/2013	
Mr Philip Russell	Retired Head Teacher	Lay Plus	05/11/2008	
Dr Michael Wolffe	Optometrist	Expert	01/04/2008	

West Midlands - Edgbaston Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended
Professor Paula McGee	Professor of Nursing	Expert	19/07/2017
Mrs Rita Patel	Contracts and Innovation Manager	Lay	16/08/2017 30/08/2017 – Sub-Committee
Dr Helen Brittain	Clinical Psychologist Retired	Lay	31/08/2018 – Sub-Committee

West Midlands - Edgbaston Research Ethics Committee: Members' Declarations of

Name	Declaration of Interest	Date
Dr Oladipo Babalola	None declared	04/02/2018
Dr Hora Ejtehad	Employee at Birmingham City University and member of local ethics committee at BCU.	16/01/2018
Mr Chris Foy	Works for NIHR research design service which provides advice and support for NHS and other researchers applying for grants	17/01/2018
Mr Paul Hamilton	I am an external member of Warwick University's research governance and ethics committee, a lay member of its biomedical and scientific research ethics sub-committee. Both roles are voluntary and unpaid.	16/01/2018
Dr Sarahjane Jones	Volunteers as Support Group Leader for the Charity Endometriosis UK. Works as Senior Research Fellow at Birmingham City University and is responsible for design, delivery and oversight of many NHS-relevant research projects. Also have honorary researcher contract with Birmingham Community Healthcare Trust and University Hospitals Coventry And Warwickshire Trust.	16/01/2018
Dr Nigel Langford	NICE HTA Appraisal Committee C, CQC Specialist Advisor, Member for the Medical Practitioners Tribunal Service, Medical Protection Society member.	17/01/2018
Mrs Alison Parsons	Acts as advisor to a Community Interest Company working with offenders - 'Mentoring West Midlands'	11/01/2018
Mr Philip Russell	Volunteer at Good Hope Hospital (Heart of England NHS Foundation Trust) in Patient Service (PALS team), one day per week.	17/01/2018
Dr Michael Wolffe	Trustee & Vice Chair of Partially Sighted Society. Trustee & Chair of Look - Federation of families of visually impaired children. Trustee & Chair of Institute of Optometry. Research ethical committee of Institute of Optometry. Chair of BSI committee responsible for Ophthalmic optics CH/172. Chair of BSI committee responsible for ophthalmic instruments CH/172/6. Leader of ISO Light Hazards task group	31/03/2018

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

Month	Date	Number of Members Present at Meeting
April	19/04/2017	8
June	21/06/2017	8
July	19/07/2017	7
August	16/08/2017	8
November	15/11/2017	9
December	13/12/2017	10
January	17/01/2018	9
February	21/02/2018	7
March	21/03/2018	7

9 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	19/04/2017	3
May	17/05/2017	3
June	21/06/2017	3
July	19/07/2017	3
August	16/08/2017	3
October	18/10/2017	3
November	15/11/2017	3
December	13/12/2017	3
January	17/01/2018	3
February	21/02/2018	3
March	21/03/2018	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	17/04/2017	2
May	01/05/2017	2
May	15/05/2017	2
May	22/05/2017	2
May	29/05/2017	2
June	12/06/2017	2
June	26/06/2017	2
July	17/07/2017	3
July	24/07/2017	2
August	07/08/2017	2
August	21/08/2017	2

August	30/08/2017	8 (review of expert comments)
August	31/08/2017	2
September	04/09/2017	2
September	18/09/2017	2
October	02/10/2017	2
October	16/10/2017	2
October	30/10/2017	2
November	13/11/2017	2
November	27/11/2017	2
December	11/12/2017	2
December	28/12/2017	2
January	08/01/2018	2
January	22/01/2018	2
February	05/02/2018	2
February	19/02/2018	2
March	05/03/2018	2
March	18/03/2018	2

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

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

None

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

Name	Number of Meetings Attended
Dr Oladipo Babalola	6
Dr Hora Ejtehadi	6
Mr Chris Foy	9
Mr Paul Hamilton	9
Dr Adrian Hamlyn	4
Dr Sarahjane Jones	7
Dr Nigel Langford	3
Professor John Marriott	7
Mrs Alison Parsons	5
Mr Philip Russell	8
Dr Michael Wolfe	7

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

Name	Number of Meetings Attended
Dr Oladipo Babalola	2
Mr Chris Foy	6
Mr Paul Hamilton	11
Dr Sarahjane Jones	3
Dr Nigel Langford	2
Professor John Marriott	3
Mrs Alison Parsons	2
Mr Philip Russell	1
Dr Michael Wolfe	3

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

Name	Number of Meetings Attended
Dr Oladipo Babalola	3
Dr Hora Ejtehadi	2
Mr Chris Foy	6
Mr Paul Hamilton	19
Dr Adrian Hamlyn	1
Dr Sarahjane Jones	3
Dr Nigel Langford	4
Professor John Marriott	15
Mrs Alison Parsons	3
Mr Philip Russell	3
Dr Michael Wolfe	2

Training 01 April 2017 - 31 March 2018

Name of Member	Date	Event(s) attended
Dr Oladipo Babalola	29/09/2017	Regional Training Day - Nottingham
Mr Chris Foy	29/09/2017	Regional Training Day - Nottingham
Mr Chris Foy	24/11/2017	HRA National Chairs' Day and Policy Event
Mr Paul Hamilton	29/09/2017	Regional Training Day - Nottingham
Mr Paul Hamilton	24/11/2017	HRA National Chairs' Day and Policy Event
Dr Sarahjane Jones	04/07/2017	Research Involving Adults Who Lack Capacity (including research in emergency situations)
Dr Nigel Langford	29/09/2017	Regional Training Day - Nottingham
Professor John Marriott	10/04/2017	Equality and Diversity Training - within College Misconduct and Fitness to Practice Training Day
Professor John Marriott	29/09/2017	Regional Training Day - Nottingham
Mrs Alison Parsons	29/09/2017	Regional Training Day - Nottingham
Mr Philip Russell	29/09/2017	Regional Training Day - Nottingham
Dr Michael Wolffe	29/09/2017	Regional Training Day - Nottingham
Dr Hora Ejtehad	29/09/2017	Members regional Training Day
Dr Hora Ejtehad	10/02/2018	Data Protection
Dr Hora Ejtehad	10/02/2018	Safe Guarding
Dr Hora Ejtehad	10/02/2018	E&D and Inclusion
Dr Hora Ejtehad	15/03/2018	Update on the new Data Protection Act and the relevant in house Data Protection Principles to Research
Dr Hora Ejtehad	24/03/2018	Attending in house Research Seminar Researching Taboo Subjects
Dr Hora Ejtehad	17/03/2018	Attending in house Research seminar Toxic handling; using emotionally charged data
Dr Hora Ejtehad	24/01/2018	Attending Faculty Annual Research Conference

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	46.67
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	24	53.33
Total Applications Reviewed	45	100

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

Number of applications made invalid by the REC Manager	0
Number of applications withdrawn prior to the meeting	2
Number of student applications reviewed	13
Number of paediatric applications reviewed	9
Number of device applications reviewed	6
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	0
Number of applications reviewed that are funded by the US DHHS	0
Number of qualitative applications reviewed	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	0	0.00
Favourable Opinion with Additional Conditions	4	8.89
Unfavourable Opinion	1	2.22
Provisional Opinion	37	82.22
Provisional Opinion Pending Consultation with Referee	3	6.67
Total	45	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	39	86.67
Further Information Favourable Opinion with Additional Conditions	0	0.00
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	4	8.89
Unfavourable Opinion	1	2.22
Provisional Opinion	0	0.00
Provisional Opinion Pending Consultation with Referee	0	0.00
Further Information response not complete	1	2.22
No decision entered on system	0	0.00
Number of studies withdrawn after the meeting	0	0.00
Total	45	100

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

Total Applications Reviewed	32
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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	0
Number of studies withdrawn prior to the meeting	2
Number of student applications reviewed	13
Number of paediatric applications reviewed	2
Number of device applications reviewed	0
Number of qualitative applications reviewed	7

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	5	15.63
Favourable Opinion with Additional Conditions	9	28.13
No Opinion transfer to full committee for review	1	3.13
Provisional Opinion	16	50.00
Unfavourable Opinion	1	3.13
Total	32	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	5.00
Number of completed applications for full ethical review	45
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 days taken to final decision – average (mean)	34
Number of completed proportionate review applications for ethical review	30
Number of completed proportionate review applications for ethical review over 21 days	7
Number of completed proportionate review applications over 21 days as a % of total	22.58%
Number of SSAs (non-Phase 1) reviewed	15
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	169
Number of completed substantial amendments over 35 days	3
Number of completed substantial amendments over 35 days as a % of total substantial amendments	1.78%
Number of modified amendments reviewed	3
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	144
Number of substantial amendments received for information	2
Number of substantial amendments received for new sites/PIs	65
Number of annual progress reports received	98
Number of safety reports received	73
Number of Serious Adverse Events received	0
Number of final reports received	26

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/WM/0117	Setmelanotide trial in patients with rare genetic disorders of obesity	29
17/WM/0123	Parents' Active Role & ENgagement in Their Stillbirth/perinatal death	34
17/WM/0146	Efficacy and Safety of E2609 in Subjects with Alzheimer's Disease	51
17/WM/0151	Finding Evidence to Treat Or Reassure in Appendicitis (FETOR)	29
17/WM/0155	A Modular, Multi-arm, Multi-part, Phase 1/2a study to evaluate RXC004	31
17/WM/0222	MP0274-CP101	26
17/WM/0238	OSA and T1D Version 1	34
17/WM/0239	AIR - Ankle Injury Rehabilitation	27
17/WM/0248	Preventing Cardiotoxicity in Breast Cancer Patients: PROACT	33
17/WM/0260	IMPULSE enhanced	23
17/WM/0265	Experiences of traumatic birth, couple and family relationships.	27
17/WM/0266	Anterior Thoracic Surface Topography	24
17/WM/0267	MK-3475 with chemo vs placebo with chemo in Esophageal carcinoma	41
17/WM/0269	Investigating the validity of D-KEFS for executive functions in TBI	29
17/WM/0270	PMCF Study to evaluate the Safety and efficacy of the MID-C system	28
17/WM/0290	S-AVANT observational study follow up	24
17/WM/0293	Exploring weight management in children living with asthma	32
17/WM/0299	T2NOW	32
17/WM/0300	Improving End of Life Care for People with Severe Mental Illness	28
17/WM/0301	RUBATO	36
17/WM/0407	AceticA	58
17/WM/0408	Does biofeedback practice help to regulate emotions?	34
17/WM/0411	Study of Urinary Predictors of Exacerbations in CF Adults (SUPERB-CF)	35
17/WM/0412	First-Episode Psychosis and Exercise Study	34
17/WM/0420	Brief Attachment-Based Imagery Intervention in Psychosis	36
17/WM/0421	RaiLRoAD Study	29
17/WM/0426	Time of Day Vaccination Study	36
17/WM/0444	The role of hydrosalpinx in recurrent miscarriage	29
17/WM/0445	AMBER: VAY736 in Autoimmune Hepatitis	27
18/WM/0007	hypophosphatemia following IV iron therapy in IDA due to IBD	36
18/WM/0013	RePROM Pilot/Feasibility Study in Chronic Kidney Disease	35
18/WM/0021	INTREPID: INvestigation of TRELEGY Effectiveness: Usual Practlce	35

18/WM/0022	AG-348 in Regularly Transfused Adult Subjects with PK Deficiency	48
18/WM/0037	M14-431 - Upadacitinib CD Ph 3 Biologics Inadequate Response	27
18/WM/0038	M14-433 - Upadacitinib CD Ph 3 Conventional Therapy IR	27
18/WM/0039	M14-430 - Upadacitinib CD Ph 3 Maintenance & Extension	28
18/WM/0042	Decision-making in paediatric epilepsy surgery	33
18/WM/0077	CVAY736X2207 efficacy, safety, and tolerability of VAY736	47
18/WM/0078	CrNAg MRK Pilot Study	57

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
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Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
17/WM/0234	Dispatcher REsusCitation Terminology study (The DIRECT study)	21
17/WM/0292	WWIC Speckle study	27
18/WM/0020	Ferric Iron in Heart Failure (FERRIC-HF) III Trial	59
18/WM/0080	MOB015B in the treatment of mild to moderate DSO	39

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
17/WM/0450	The in vivo effect of tiger nut/black seed oil on sickle cell patients	28

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

Further information response not complete		
REC Reference	Title	Number of Days on Clock
18/WM/0075	SUNFISH	n/a

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

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/WM/0152	Psychosis recovery	18
17/WM/0153	Abdominal Cutaneous Nerve Entrapment Syndrome (ACNES) Version 1	10
17/WM/0199	Exploring patient experiences of SMAs	25
17/WM/0201	OPERATE study 0001	22
17/WM/0246	Obs study of tafluprost/timolol in glaucoma or ocular hypertension	19
17/WM/0249	Exploring relationships between pain and exercise adherence	16
17/WM/0287	APOMYL	14
17/WM/0326	CEQ-2 validation study	26
17/WM/0422	Dogs & adjustment of people with post-stroke aphasia	16
17/WM/0457	Quantification of instability in osteoarthritic knees	19
18/WM/0062	The effects of FES in a variety of walking conditions in MS population	29

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
17/WM/0202	Peer support for Mothers with Antenatal Depression version 1.	12

17/WM/0387	What is therapeutic about task-oriented occupational therapy groups?	17
17/WM/0458	POSH project	18
18/WM/0031	Global Myoclonus Dystonia Registry & Dystonia Non-Motor Symptoms Study	24

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
17/WM/0149	Hospital admission, an opportunity for physical activity advice?	16
17/WM/0285	Preventing Return to Smoking Postpartum (PReS Study)	17
17/WM/0324	Attitudes towards early salpingectomy for ovarian cancer prevention	13
17/WM/0388	Driving Pressure during Lung Resection	22
17/WM/0417	CRP post oesophagectomy	16

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
17/WM/0150	Modifications to C-reactive protein in Diabetes Mellitus (V 1.0)	15
17/WM/0197	SPiRE Study	19
17/WM/0250	SLE Prospective Observational Cohort Study (SPOCS)	11
17/WM/0284	Using event descriptions to aid suspected first seizure diagnosis	15
17/WM/0325	Vitamin D and immune responses in haematopoietic stem cell transplant	20
17/WM/0419	Stratification of Irritable Bowel Syndrome	21
18/WM/0036	Embedding Diabetes Education (RCT)	14
18/WM/0059	PRiMeR	21
18/WM/0081	PALI-COPD	24

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
18/WM/0163	Use of immersive 360-degree videos in CBT for dental phobia	18

Provisional Opinion		
REC Reference	Title	Number of Days on Clock
17/WM/0389	The role of inhibition in language impairment	n/a

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
17/WM/0389	The role of inhibition in language impairment	17

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
00/7/061/AM09	Tuberous Sclerosis 2000 Study	SA16	10/05/2017	27
00/7/061/AM11	Tuberous Sclerosis 2000 Study	SA18	05/10/2017	31
01/7/026/AM27	TEAM (Tamoxifen and Exemestane Multicentre Trial)	13	11/10/2017	14
04/MRE07/35/AM126	Stampede (version 1.0) – PR08	SA 27.06.27	27/06/2017	24
04/MRE07/35/AM128	Stampede (version 1.0) – PR08	18.10.2017	18/10/2017	25
04/MRE07/35/AM130	Stampede (version 1.0) – PR08	18	13/02/2018	12
05/MRE07/25/AM23	The IMPACT Study, Version 8, February 2005	SA22	25/10/2017	27
05/MRE07/26/AM27	Dialysis Outcomes and Practice Patterns Study (DOPPS) v.2	SA7	07/04/2017	21
06/MRE07/31/AM23	NEO-EXCEL. Version 1.0, 12th April 2006	9	10/11/2017	14
10/H1208/41/AM04	Rehabilitation for Operated lung cancer, Version 1	SA4	25/04/2017	13
13/WM/0114/AM17	SHINE MCL3002	SA11	03/04/2017	31
13/WM/0114/AM18	SHINE MCL3002	SA12	15/09/2017	21
13/WM/0232/AM12	Decitabine for Acute Myeloid Leukaemia in Children	SA01.06.2017	01/06/2017	11
13/WM/0299/AM10	NOSH: Feasibility Study and RCT	SA03	11/07/2017	8
13/WM/0480/AM02	Effects of Oxyntomodulin on energy expenditure and food intake	SA2	04/10/2017	23
14/WM/0013/AM17	Developing a new drug to treat infants hospitalised with RSV infection	SA12	13/09/2017	30
14/WM/0049/AM10	NN7999-3895 Trial Evaluating Safety & Efficacy of N9-GP in Haem B PUPs	Substantial Protocol Amendment	01/03/2018	35
14/WM/0052/AM10	PARTNERS2: collaborative care for people with serious mental illness	AM09	20/06/2017	9
14/WM/0052/AM11	PARTNERS2: collaborative care for people with serious mental illness	SA10	22/06/2017	6
14/WM/0052/AM13	PARTNERS2: collaborative care for people with serious mental	SA11	28/09/2017	18

	illness			
14/WM/0052/AM15	PARTNERS2: collaborative care for people with serious mental illness	SA12	23/10/2017	25
14/WM/0052/AM16	PARTNERS2: collaborative care for people with serious mental illness	SA13	22/11/2017	8
14/WM/0052/AM21	PARTNERS2: collaborative care for people with serious mental illness	AM15	26/01/2018	14
14/WM/0112/AM16	NOVOCART 3D PLUS (N3D) Study	SA6	09/11/2017	21
14/WM/0124/AM06	UK FASHIoN	SA4	25/08/2017	16
14/WM/0170/AM12	Phase III study of Momelotinib in Patients with Myelofibrosis	SA8	14/08/2017	16
14/WM/1055/AM10	Masitinib/Placebo + FOLFIRI in Metastatic Colorectal Cancer V1.0	SA9	04/07/2017	17
14/WM/1062/AM10	Recovering Quality of Life (ReQoL)	SA7.0	26/06/2017	22
14/WM/1062/AM12	Recovering Quality of Life (ReQoL)	Substantial Amendment 8.0	06/12/2017	23
14/WM/1097/AM09	Impulse control behaviour in Parkinson's	SA5	23/10/2017	29
14/WM/1146/AM06	CHHIP (Cellular humoral and hormonal control of immunity in pregnancy)	SA4	26/06/2017	25
14/WM/1161/AM02	Cognitive Training for Brain Injury	SA2	03/08/2017	20
14/WM/1170/AM11	CompARE Trial, Version 1.0	SA11	11/05/2017	29
14/WM/1185/AM11	Sofosbuvir/Ribavirin in Adolescents and Children	SA8	05/06/2017	11
14/WM/1190/AM05	IDEAL LM study	SA2	05/01/2018	28
14/WM/1213/AM12	ROSCO V1.0, 15th October 2014	SA10	23/03/2017	20
14/WM/1213/AM13	ROSCO V1.0, 15th October 2014	11	22/12/2017	10
15/WM/0009/AM10	Daratumumab + VMP vs VMP only in newly diagnosed multiple myeloma	SA6	18/04/2017	21
15/WM/0015/AM09	A Dose Finding Study In Pediatric Subjects With Biliary Atresia.	SA5	02/06/2017	10
15/WM/0015/AM12	A Dose Finding Study In Pediatric Subjects With Biliary Atresia.	SA6	27/09/2017	19
15/WM/0017/AM03	Bile Acid Effects on Fetal Arrhythmia after UDCA Therapy Study (BEATS)	SA2	25/10/2017	21
15/WM/0101/AM06	dCELL® ACL Scaffold	7	30/11/2017	16
15/WM/0102/AM06	Randomised Trial To Evaluate 3 Daratumumab Dose Schedules in SMM	SA04	03/05/2017	21
15/WM/0102/AM07	Randomised Trial To Evaluate 3 Daratumumab Dose Schedules in SMM	SA05	27/07/2017	12
15/WM/0102/AM08	Randomised Trial To Evaluate 3 Daratumumab Dose	6	28/02/2018	20

	Schedules in SMM			
15/WM/0139/AM15	UCB5857 For Participants with Primary Sjogren's Syndrome	SA10	13/04/2017	21
15/WM/0211/AM07	Phase 1b Study in Subjects with Multiple Myeloma ACE-MY-001	SA4	13/06/2017	13
15/WM/0211/AM08	Phase 1b Study in Subjects with Multiple Myeloma ACE-MY-001	SA5	16/11/2017	21
15/WM/0263/AM04	GS-US-401-1787,Open label Study - Long-term Safety of ONO/GS-4059	SA4	20/06/2017	6
15/WM/0263/AM05	GS-US-401-1787,Open label Study - Long-term Safety of ONO/GS-4059	9	01/01/2018	22
15/WM/0268/AM10	ENRICH Ibrutinib for untreated mantle cell lymphoma	SA07 2017/12/07	07/12/2017	22
15/WM/0323/AM01	Evaluation of the Senspoint Lactate Meter	SA1	26/04/2017	20
15/WM/0327/AM08	Treatment Of Pulmonary Hypertension (TROPHY) 1 study, UK version 1	SA3	03/05/2017	20
15/WM/0363/AM08	COBALT: Study of Obeticholic Acid in Primary Biliary Cirrhosis	SA07	30/06/2017	18
15/WM/0363/AM09	COBALT: Study of Obeticholic Acid in Primary Biliary Cirrhosis	SA 08 2017/12/14	14/12/2017	22
15/WM/0377/AM10	Study evaluating MEDI4736 + AZD9150/AZD5069 in solid tumors & RMSCCHN	SA7	03/07/2017	18
15/WM/0444/AM12	Lifestyle Health and Wellbeing Survey	SA10	03/05/2017	13
15/WM/0444/AM18	Lifestyle Health and Wellbeing Survey	AM18	05/09/2017	18
15/WM/0444/AM24	Lifestyle Health and Wellbeing Survey	AM22	05/12/2017	14
15/WM/0444/AM27	Lifestyle Health and Wellbeing Survey	Amendment 25	18/01/2018	21
15/WM/0444/AM28	Lifestyle Health and Wellbeing Survey	Substantial Amendment 26	23/02/2018	12
15/WM/0447/AM02	Cerebral vasomotor regulation in atrial fibrillation (CVR-AF)	SA2	18/10/2017	21
15/WM/0453/AM02	AZD9496 Vs Fulvestrant in Primary Breast Cancer	06.07.17	06/07/2017	22
15/WM/0455/AM02	SAFE-TKR Study	SA2	17/08/2017	15
15/WM/0455/AM03	SAFE-TKR Study	3	15/12/2017	22
15/WM/0456/AM09	CGAI - The REGAIN Study (Treatment for Chronic Migraine)	SA7	03/05/2017	15
15/WM/0456/AM10	CGAI - The REGAIN Study (Treatment for Chronic Migraine)	8	20/11/2017	28
16/WM/0009/AM05	The 'Can Do Ramadan' Study	SA5	06/07/2017	15
16/WM/0009/AM06	The 'Can Do Ramadan' Study	Substantial Amendment 6	15/02/2018	13
16/WM/0010/AM05	A phase II trial of pembrolizumab in NSCLC PS2 patients	SA04	04/05/2017	20
16/WM/0010/AM06	A phase II trial of pembrolizumab in NSCLC PS2 patients	SA05	07/07/2017	10
16/WM/0010/AM07	A phase II trial of pembrolizumab in NSCLC PS2 patients	SA6	11/09/2017	20

16/WM/0014/AM04	HOLDS	SA3	12/04/2017	21
16/WM/0014/AM09	HOLDS	SA7	11/10/2017	32
16/WM/0014/AM11	HOLDS	Substantial Amendment 9	16/02/2018	28
16/WM/0036/AM05	GBS2	SA1	06/04/2017	12
16/WM/0036/AM09	GBS2	2	30/01/2018	21
16/WM/0055/AM05	The relationship between CTCA and EPC count.	SA2	16/01/2018	24
16/WM/0108/AM04	CABP	SA4	31/03/2017	18
16/WM/0162/AM01	Effect of peripheral defocus on axial growth in hyperopes	SA1	09/05/2017	13
16/WM/0170/AM08	ISIS 304801-CS7 - The APPROACH Open-Label Extension	SA6	01/06/2017	11
16/WM/0170/AM09	ISIS 304801-CS7 - The APPROACH Open-Label Extension	SA7	22/09/2017	11
16/WM/0170/AM10	ISIS 304801-CS7 - The APPROACH Open-Label Extension	SA8	24/11/2017	41
16/WM/0170/AM11	ISIS 304801-CS7 - The APPROACH Open-Label Extension	9	15/01/2018	12
16/WM/0265/AM01	The TREADON pilot and feasibility trial (Version I)	SA1	04/05/2017	19
16/WM/0314/AM01	Jobe study- Monitoring the brain function after cardiac arrest	SA1	04/10/2017	12
16/WM/0315/AM01	Jobe study- Monitoring the brain function after head injury	SA1	04/10/2017	27
16/WM/0353/AM07	Antimicrobial urinary catheter safety study	SA05	21/09/2017	11
16/WM/0353/AM08	Antimicrobial urinary catheter safety study	SA6	04/12/2017	16
16/WM/0356/AM08	Open-label ALN-AS1 in Patients with Acute Intermittent Porphyrria	SA4	06/09/2017	15
16/WM/0356/AM09	Open-label ALN-AS1 in Patients with Acute Intermittent Porphyrria	SA5	17/10/2017	27
16/WM/0356/AM10	Open-label ALN-AS1 in Patients with Acute Intermittent Porphyrria	SA6	27/11/2017	38
16/WM/0359/AM02	Blinatumomab in Aggressive B-Cell Non Hodgkin Lymphoma	SA2	28/06/2017	22
16/WM/0365/AM03	A study of a new medicine for the treatment of ulcerative colitis	SA1	05/04/2017	13
16/WM/0365/AM04	A study of a new medicine for the treatment of ulcerative colitis	SA2	04/05/2017	14
16/WM/0365/AM08	A study of a new medicine for the treatment of ulcerative colitis	SA3	05/09/2017	16
16/WM/0365/AM10	A study of a new medicine for the treatment of ulcerative colitis	5	03/01/2018	6
16/WM/0436/AM02	AGB002 - SAIT101 vs Rituximab in patients with low tumour burden FL	SA2	09/06/2017	14
16/WM/0437/AM03	Ariel 4	SA02	19/05/2017	24
16/WM/0464/AM08	Edoxaban treatment versus VKA in patients with AF undergoing PCI	SA4	25/09/2017	8
16/WM/0468/AM01	Neuroimaging predictors of RA fatigue	SA1	04/04/2017	13
16/WM/0471/AM03	Phase 2 - MBX-8025 in Participants with Primary Biliary	SA3	07/04/2017	27

	Cholangitis			
16/WM/0471/AM05	Phase 2 - MBX-8025 in Participants with Primary Biliary Cholangitis	SA04	02/08/2017	28
16/WM/0471/AM07	Phase 2 - MBX-8025 in Participants with Primary Biliary Cholangitis	Substantial Amendment 5	26/02/2018	27
16/WM/0472/AM11	CONFIRM	Substantial Amendment 10	14/02/2018	20
16/WM/0473/AM02	CA209-817 - Nivolumab and Ipilimumab in advanced malignancies	02	07/07/2017	21
16/WM/0501/AM02	WISTERIA: WEE1 inhibitor with Cisplatin and Radiotherapy	SA2	12/04/2017	22
16/WM/0501/AM03	WISTERIA: WEE1 inhibitor with Cisplatin and Radiotherapy	SA3	08/06/2017	17
16/WM/0501/AM05	WISTERIA: WEE1 inhibitor with Cisplatin and Radiotherapy	4	18/01/2018	19
16/WM/0511/AM02	071102 - BAX 111 rVWF in Paediatrics	SA 01 2017/12/13	13/12/2017	22
16/WM/0512/AM07	AEGIS Kids PK (ST10-01-103)	SA03	11/10/2017	33
16/WM/0513/AM04	Phase 2 study of INCB054828 for FGFR1-rearranged neoplasms	SA3	01/12/2017	19
17/WM/0011/AM01	Phase II Placebo-Controlled Study of Atacicept in IgA Nephropathy	SA1	29/03/2017	20
17/WM/0011/AM02	Phase II Placebo-Controlled Study of Atacicept in IgA Nephropathy	SA2	25/04/2017	21
17/WM/0011/AM03	Phase II Placebo-Controlled Study of Atacicept in IgA Nephropathy	SA3	25/04/2017	21
17/WM/0011/AM04	Phase II Placebo-Controlled Study of Atacicept in IgA Nephropathy	SA4	02/11/2017	25
17/WM/0011/AM07	Phase II Placebo-Controlled Study of Atacicept in IgA Nephropathy	Substantial Amendment 5	20/02/2018	21
17/WM/0017/AM01	MifeMiso	SA1	24/03/2017	12
17/WM/0021/AM02	Phase 2 - GS-9674 in patients with NASH	SA1	05/04/2017	13
17/WM/0027/AM01	Goals in Mind	SA1	11/04/2017	23
17/WM/0049/AM01	Magic - Magnetic resonance imaging in paediatric constipation	SA1	20/09/2017	11
17/WM/0049/AM02	Magic - Magnetic resonance imaging in paediatric constipation	2.0	05/12/2017	27
17/WM/0049/AM03	Magic - Magnetic resonance imaging in paediatric constipation	Substantial Amendment 3	15/02/2018	25
17/WM/0050/AM01	Tommy's Net	SA1	26/06/2017	24
17/WM/0063/AM01	ABT-foodASIT001	SA1	11/05/2017	26
17/WM/0063/AM02	ABT-foodASIT001	SA2	11/10/2017	28

17/WM/0104/AM01	Improving Primary Care After Stroke: Testing a new stroke service	SA01	18/07/2017	11
17/WM/0105/AM02	GSK525762 in combination with fulvestrant in the treatment of ER+BC	SA1 - Protocol Amendment 3	31/05/2017	7
17/WM/0105/AM03	GSK525762 in combination with fulvestrant in the treatment of ER+BC	SA02	20/07/2017	8
17/WM/0105/AM04	GSK525762 in combination with fulvestrant in the treatment of ER+BC	SA3	12/09/2017	8
17/WM/0105/AM05	GSK525762 in combination with fulvestrant in the treatment of ER+BC	Substantial Amendment 4	20/02/2018	15
17/WM/0106/AM02	MRI for early response prediction to anti-TNF therapy	Substantial Amendment 1	21/02/2018	14
17/WM/0110/AM01	PHITT	SA3	05/12/2017	14
17/WM/0117/AM01	Setmelanotide trial in patients with rare genetic disorders of obesity	SA1	29/06/2017	22
17/WM/0117/AM02	Setmelanotide trial in patients with rare genetic disorders of obesity	SA2	23/08/2017	16
17/WM/0123/AM01	Parents' Active Role & ENgagement in Their Stillbirth/perinatal death	1	11/11/2017	28
17/WM/0146/AM01	Efficacy and Safety of E2609 in Subjects with Alzheimer's Disease	Sub Amt 2	21/08/2017	21
17/WM/0146/AM02	Efficacy and Safety of E2609 in Subjects with Alzheimer's Disease	1	18/08/2017	21
17/WM/0146/AM06	Efficacy and Safety of E2609 in Subjects with Alzheimer's Disease	SA5	29/09/2017	17
17/WM/0146/AM08	Efficacy and Safety of E2609 in Subjects with Alzheimer's Disease	SA7	16/10/2017	28
17/WM/0146/AM11	Efficacy and Safety of E2609 in Subjects with Alzheimer's Disease	SA9	08/11/2017	18
17/WM/0146/AM12	Efficacy and Safety of E2609 in Subjects with Alzheimer's Disease	SA11	30/11/2017	35
17/WM/0153/AM01	Abdominal Cutaneous Nerve Entrapment Syndrome (ACNES) Version 1	SA1	25/01/2018	11
17/WM/0155/AM02	A Modular, Multi-arm, Multi-part, Phase 1/2a study to evaluate RXC004	Substantial Amendment 2	15/02/2018	21
17/WM/0222/AM01	MP0274-CP101	1	08/12/2017	27
17/WM/0238/AM01	OSA and T1D Version 1	1	06/12/2017	21

17/WM/0239/AM01	AIR - Ankle Injury Rehabilitation	SA1	28/07/2017	11
17/WM/0246/AM03	Obs study of tafluprost/timolol in glaucoma or ocular hypertension	SA1	03/10/2017	13
17/WM/0246/AM07	Obs study of tafluprost/timolol in glaucoma or ocular hypertension	1	05/03/2018	15
17/WM/0267/AM02	MK-3475 with chemo vs placebo with chemo in Esophageal carcinoma	SA1	17/11/2017	13
17/WM/0267/AM04	MK-3475 with chemo vs placebo with chemo in Esophageal carcinoma	3	02/03/2018	11
17/WM/0285/AM02	Preventing Return to Smoking Postpartum (PReS Study)	SA2	14/11/2017	19
17/WM/0292/AM01	WWIC Speckle study	1	02/01/2018	8
17/WM/0299/AM01	T2NOW	SA1	17/10/2017	27
17/WM/0299/AM02	T2NOW	SA 02 2017/12/14	14/12/2017	22
17/WM/0300/AM01	Improving End of Life Care for People with Severe Mental Illness	SA1	01/12/2017	29
17/WM/0301/AM01	RUBATO	SA1	09/10/2017	7
17/WM/0301/AM02	RUBATO	SA2	16/11/2017	13
17/WM/0301/AM03	RUBATO	3	10/01/2018	10
17/WM/0458/AM01	POSH project	Substantial Amendment 1	01/03/2018	19
18/WM/0007/AM01	hypophosphatemia following IV iron therapy in IDA due to IBD	Substantial Amendment 1	28/02/2018	20
18/WM/0021/AM01	INTREPID: INvestigation of TRELEGY Effectiveness: Usual Practlce	1	02/03/2018	18
97/7/001/AM12		SA10	23/11/2017	21

Unfavourable opinion				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
06/MRE07/40/AM13	Cognitive processes underlying disorders of memory	SA8	13/04/2017	28
16/WM/0353/AM04	Antimicrobial urinary catheter safety study	SA04	17/05/2017	21
16/WM/0472/AM02	CONFIRM	SA2	06/04/2017	12
16/WM/0513/AM03	Phase 2 study of INCB054828 for FGFR1-rearranged neoplasms	SA2	18/08/2017	41
17/WM/0146/AM10	Efficacy and Safety of E2609 in Subjects with Alzheimer's Disease	SA10	16/11/2017	22

17/WM/0146/AM15	Efficacy and Safety of E2609 in Subjects with Alzheimer's Disease	14	02/03/2018	32
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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
06/MRE07/40/AM13/1	Cognitive processes underlying disorders of memory	SA8 Mod1	18/07/2017	12
14/WM/0112/AM13/1	NOVOCART 3D PLUS (N3D) Study	Mod1 of SA5	23/03/2017	11
16/WM/0472/AM02/1	CONFIRM	Mod1SA2	21/04/2017	10

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
17/WM/0199	Exploring patient experiences of SMAs	25
17/WM/0201	OPERATE study 0001	22
17/WM/0326	CEQ-2 validation study	26
17/WM/0388	Driving Pressure during Lung Resection	22
18/WM/0031	Global Myoclonus Dystonia Registry & Dystonia Non-Motor Symptoms Study	24
18/WM/0062	The effects of FES in a variety of walking conditions in MS population	29
18/WM/0081	PALI-COPD	24

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
16/WM/0170/AM10	ISIS 304801-CS7 - The APPROACH Open-Label Extension	SA8	24/11/2017	41
16/WM/0356/AM10	Open-label ALN-AS1 in Patients with Acute Intermittent Porphyria	SA6	27/11/2017	38
16/WM/0513/AM03	Phase 2 study of INCB054828 for FGFR1-rearranged neoplasms	SA2	18/08/2017	41

Modified Amendments over 14 day timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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