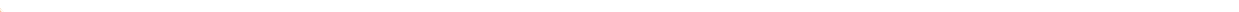


**West Midlands - Coventry & Warwickshire
Research Ethics Committee**

Annual Report

01 April 2016 - 31 March 2017



Part 1 – Committee Membership and Training

Name of REC:	West Midlands - Coventry & Warwickshire Research Ethics Committee
Type of REC:	RECs recognised to review CTIMPS in patients - type iii
Type of Flag:	Phase 1 Studies in Patients, Qualitative Research, Research Involving Adults Lacking Capacity, Research Involving Children, Social Care Research
Chair:	Dr Helen Brittain (Chair)
Vice-Chair:	Dr Ronald Jubb
Alternate Vice-Chair:	Professor Jane Appleton
REC Manager:	Ms Rachel Nelson
REC Assistant:	Ms Teagan Allen (until February 2017) Mr Adam Garretty (from February 2017)
Committee Address:	The Old Chapel Royal Standard Place Nottingham NG1 6FS
Telephone:	02071048105
Email:	NRESCommittee.WestMidlands-CoventryandWarwick@nhs.net

Chair's overview of the past year:

Chair's Comments 2016-7

Many thanks to Rachel and Teagan for their hard work and dedication. We wish them well in their new roles, and look forward to working with Tad and Adam. The Committee members also continue to contribute much time and hard work, which is even more demanding at a time away from the work place is difficult for some. We thanked members who have retired during this period and we are also pleased to welcome new members. We enjoyed our lunch together again and thank the HRA for providing this.

The new challenges will probably come with the uncertainty of changes for CTIMPS and also for the increased role of genetics and genomics in much health related research.

West Midlands - Coventry & Warwickshire Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Professor Jane Appleton	Nurse	Expert	01/04/2010	
Mr Roger Balcombe	Retired Chartered Engineer	Lay Plus	01/04/2010	
Dr Geraldine Brady	Senior Research Fellow	Lay	27/07/2011	14/11/2016
Dr Helen Brittain (Chair)	Clinical Psychologist Retired	Lay	01/04/2010	
Ms Yasumati Damodar	Pharmacist	Expert	22/09/2015	
Dr John S Fenlon	Statistical Consultant	Lay	01/05/2015	01/12/2016
Ms Chelsea Gilsean	Trust Risk Manager	Lay Plus	16/03/2016	18/11/2016
Mrs Louise Harmer	Undergraduate Medical Education Manager, Technology Enhanced Learning and Clinical Skills and Resuscitation Tutor	Expert	01/04/2010	
Dr Siew Wan Hee	Medical Statistician	Expert	07/02/2017	
Mrs Evette Hunkins-Hutchinson	Lecturer Health Care Management	Lay Plus	01/04/2010	16/05/2016
Dr Christopher Jones	Academic Clinical Fellow in Clinical Oncology	Expert	07/08/2014	10/11/2016
Dr Ronald Jubb	Retired Consultant Rheumatologist	Expert	24/09/2014	
Miss Rebecca Keyte	Visiting Lecturer in Psychology	Lay Plus	29/03/2017	
Dr Aisha Malik	Part-time Tutor Medical ethics; Part-time and distance learning Tutor for Oxford University Department for continuing education (OUDCE).	Expert	03/11/2016	
Dr Karen Schofield	Retired Consultant Haematologist	Expert	14/08/2014	
Mrs Laura Strumidlo	Senior Lecturer Adult Nursing/End of Life Care	Expert	01/12/2016	
Mr Jonathan Ward	Retired Self-employed IT consultant	Lay	27/02/2017	

West Midlands - Coventry & Warwickshire Research Ethics Committee: Deputy Members

None

West Midlands - Coventry & Warwickshire Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended
Mr Chris Foy	Statistician	Expert	28/09/2016
Reverend Keith Lackenby	Reverend	Lay Plus	23/11/2016
Professor Paula McGee	Professor of Nursing	Expert	23/11/2016

West Midlands - Coventry & Warwickshire Research Ethics Committee: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Professor Jane Appleton	Sometimes asked to act as a reviewer for CLRN funding and NIHR funding applications. Is a trustee of the charity The British Association for the Study and Prevention of Child Abuse and Neglect (BASPCAN). Is an external advisor to NICE.	31/03/2017
Mr Roger Balcombe	None declared	25/05/2016
Dr Helen Brittain (Chair)	Trustee Warwickshire Wild Life Trust Member of British Red Cross Psychological Team	05/01/2017
Ms Yasumati Damodar	None declared	31/03/2017
Ms Chelsea Gilsean	None declared	27/07/2016
Mrs Louise Harmer	Work with medical students and sometimes give advice about ethics for their proposals.	10/01/2017
Dr Ronald Jubb	None declared	24/02/2017
Dr Aisha Malik	Research fellow at the Health services management centre, University of Birmingham, started on the 5th of January 2017.	30/01/2017
Dr Karen Schofield	Member of a Keele University research ethics committee	27/01/2017
Mrs Laura Strumidlo	Chair of Research Ethics & Governance Committee HLS Faculty, Coventry University	27/01/2017
Mr Jonathan Ward	None declared	06/03/2017
Dr Siew Wan Hee	I am an active researcher in Warwick Medical School and it is likely that I will be a co-applicant on a number of research projects considered by HRA REC. I am also a member of a Data Monitoring Committee on Rational MCC (a trial for Merkel Cell Carcinoma sponsor by University of Birmingham). From 1 June 2017 I will move to a new role with the Warwick Hub, Research Design Service West Midlands.	01/03/2017
Miss Rebecca Keyte	PhD Student / Visiting Lecturer within the Psychology department at Birmingham City University.	31/03/2017

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

Month	Date	Number of Members Present at Meeting
April	27/04/2016	7
May	25/05/2016	8
June	22/06/2016	7
July	27/07/2016	10
August	24/08/2016	7
September	28/09/2016	8
October	26/10/2016	7
November	23/11/2016	8
January	25/01/2017	8
February	22/02/2017	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	20/04/2016	3
May	25/05/2016	3
June	22/06/2016	3
July	27/07/2016	3
August	24/08/2016	3
September	28/09/2016	3
October	26/10/2016	3
November	23/11/2016	3
January	25/01/2017	3
February	22/02/2017	3
March	22/03/2017	3

11 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	01/04/2016	2
April	15/04/2016	2
April	26/04/2016	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	04/08/2016	2

August	18/08/2016	2
September	02/09/2016	2
September	22/09/2016	2
September	29/09/2016	2
October	14/10/2016	2
October	28/10/2016	2
November	02/11/2016	2
November	11/11/2016	2
November	25/11/2016	2
December	09/12/2016	2
December	19/12/2016	2
December	29/12/2016	2
January	09/01/2017	2
January	20/01/2017	2
February	06/02/2017	2
February	23/02/2017	2
March	07/03/2017	2
March	27/03/2017	2

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

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

None

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

Name	Number of Meetings Attended
Professor Jane Appleton	6
Mr Roger Balcombe	9
Dr Helen Brittain (Chair)	9
Ms Yasumati Damodar	10
Dr John S Fenlon	6
Ms Chelsea Gilsean	2
Mrs Louise Harmer	8
Dr Christopher Jones	3
Dr Ronald Jubb	9
Dr Aisha Malik	3
Dr Karen Schofield	9
Mrs Laura Strumidlo	2

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

Name	Number of Meetings Attended
Professor Jane Appleton	5
Mr Roger Balcombe	1
Dr Helen Brittain (Chair)	9
Ms Yasumati Damodar	2
Dr John S Fenlon	3
Mrs Louise Harmer	2
Dr Christopher Jones	3
Dr Ronald Jubb	5
Dr Karen Schofield	3

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

Name	Number of Meetings Attended
Professor Jane Appleton	8
Dr Helen Brittain (Chair)	16
Ms Yasumati Damodar	4
Dr John S Fenlon	2
Mrs Louise Harmer	6
Dr Christopher Jones	3
Dr Ronald Jubb	13
Dr Karen Schofield	4

Training 01 April 2016 - 31 March 2017

Name of Member	Date	Event(s) attended
Professor Jane Appleton	23/09/2016	Local Training Day Leicester
Mr Roger Balcombe	01/02/2017	Medical Devices Training
Dr Helen Brittain (Chair)	23/09/2016	Local Training Day Leicester
Dr Helen Brittain (Chair)	01/12/2016	National Training Day for Committee Chairs
Dr Helen Brittain (Chair)	16/12/2016	Equality And Diversity
Ms Yasumati Damodar	06/04/2016	Quantitative Research Methods & Statistics
Ms Yasumati Damodar	23/09/2016	Local Training Day Leicester
Ms Yasumati Damodar	16/02/2017	National Member's Training Day
Ms Yasumati Damodar	03/03/2017	Buddy / Mentor to Jonathan Ward
Ms Yasumati Damodar	29/03/2017	Equality and Diversity
Dr John S Fenlon	23/09/2016	Local Training Day Leicester
Mrs Louise Harmer	12/05/2016	Mentor to new member Chelsea Gilsean
Mrs Louise Harmer	23/09/2016	Local Members Training Day
Dr Ronald Jubb	03/11/2016	Chair's Network Meeting
Dr Karen Schofield	14/10/2016	Genetic and Genomic Research

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	24.56
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	43	75.44
Total Applications Reviewed	57	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	19
Number of paediatric applications reviewed	14
Number of device applications reviewed	2
Number of prisoner applications reviewed	2
Number of applications involving adults unable consent reviewed	17
Number of applications reviewed that are funded by the US DHHS	0
Number of qualitative applications reviewed	9

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	3	5.26
Favourable Opinion with Additional Conditions	7	12.28
Unfavourable Opinion	4	7.02
Provisional Opinion	43	75.44
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	57	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	31	54.39
Further Information Favourable Opinion with Additional Conditions	11	19.30
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	3	5.26
Favourable Opinion with Additional Conditions	7	12.28
Unfavourable Opinion	4	7.02
Provisional Opinion	1	1.75
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	57	100

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

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

Number of applications made invalid by the REC Manager	2
Number of studies withdrawn prior to the meeting	0
Number of student applications reviewed	16
Number of paediatric applications reviewed	2
Number of device applications reviewed	0
Number of qualitative applications reviewed	4

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	4	13.33
Favourable Opinion with Additional Conditions	3	10.00
No Opinion transfer to full committee for review	2	6.67
Provisional Opinion	21	70.00
Unfavourable Opinion	0	0.00
Total	30	100

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

Average number of applications reviewed per full meeting	5.70
Number of completed applications for full ethical review	57
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	1
Number of completed applications over 40 days as a % of total	1.75%
Number of days taken to final decision – average (mean)	27
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)	5
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	17.24%
Number of SSAs (non-Phase 1) reviewed	0
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	106
Number of completed substantial amendments over 35 days	0
Number of completed substantial amendments over 35 days as a % of total substantial amendments	0.00%
Number of completed substantial amendments over 28 days	1
Number of completed substantial amendments over 28 days as a % of total substantial amendments	0.94%
Number of modified amendments reviewed	8
Number of completed modified amendments over 14 days	1
Number of completed modified amendments over 14 days as a % of total modified amendments	12.50%
Number of non substantial amendments received	143

Number of substantial amendments received for information	4
Number of substantial amendments received for new sites/PIs	49
Number of annual progress reports received	72
Number of safety reports received	29
Number of Serious Adverse Events received	1
Number of final reports received	10

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/WM/0124	Fixation versus arthroplasty for undisplaced intracapsular fractures	28
16/WM/0160	VOC's in body fluids of treated and untreated Coeliac disease	27
16/WM/0164	SMARTChip study	30
16/WM/0175	A Narrative Study of Adolescent Males who Self-Harm	28
16/WM/0204	Neuromuscular Electrical Stimulation and Acquired brain injury	25
16/WM/0215	Comparison of Humacyte's Human Acellular Vessel with ePTFE grafts V1.2	28
16/WM/0218	Exploring the lived experience of women with rosacea	32
16/WM/0268	What after the first proppess?	27
16/WM/0275	ORL-OSS-2545	24
16/WM/0279	Prevalence of MGUS in acute hospital admissions, version 1.0	26
16/WM/0285	Evolocumab (AMG 145) in HIV & Hyperlipidemia and/or Mixed Dyslipidemia	32
16/WM/0299	COMPRESS-RCT	38
16/WM/0304	Bayraktutan DMT EPC Study	30
16/WM/0307	The OSCAR study - Patient outcomes for scar management therapy	25
16/WM/0317	Efficacy / safety of oral S44819 after recent ischemic cerebral event	25
16/WM/0364	Dopamine release during epileptic seizures	29
16/WM/0366	Long term follow up of NI-0501 in HLH patients	24
16/WM/0367	The Brooklands Insight Scale	23
16/WM/0369	Comparison of X-396 to Crizotinib in ALK Positive NSCLC Patients	29
16/WM/0370	Antibody incompatible transplantation- a prospective study	26
16/WM/0435	The Behavioural Phenotype of Cornelia de Lange and Fragile X syndrome	26
16/WM/0478	LEO 90100 twice weekly maintenance regimen for psoriasis vulgaris	44
16/WM/0479	INCLUDE: Using Lived Experience to Improve Mental Health Diagnosis V.1	23
16/WM/0480	POLERISE	23
16/WM/0481	Feasibility study investigating use of an exercise app.	24
16/WM/0485	AWE Study	29
17/WM/0002	Resilience in people with intellectual and developmental disabilities	37
17/WM/0008	The Walker Study	28
17/WM/0029	The Relationship Between NIRS, SSEPs & EEG	23
17/WM/0032	Breath and urine organic compounds in GMP and Phe-free L-AA	36
17/WM/0041	ASCEND-ID	34

Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/WM/0169	Evaluation of novel biomarkers in classical galactosaemia	39
16/WM/0395	200807 Anaemia of CKD (dialysis): daprodustat vs erythropoietin	29
16/WM/0396	200808 Anaemia of CKD (non-dialysis): daprodustat vs darbepoetin alfa	29
16/WM/0401	Seclusion and women with learning disabilities in secure care	24
16/WM/0424	Mucosal biomarkers of bowel cancer risk: 10 year follow-up of BORICC	25
16/WM/0440	NGAL 1.1	26
16/WM/0448	Open label Study with Maribavir and Investigator-Assigned Tx for CMV	23
16/WM/0454	Mental health difficulties and risky alcohol use in young people.	26
17/WM/0022	ALPHABET - SUCCESS Phase 3	30
17/WM/0077	BP39365 Phase 1b Study of RO6874281 in Metastatic Renal Cell Carcinoma	29
17/WM/0081	Sri Lankan Tamil asylum seekers' garden based trauma intervention	36

Further Information Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
None	None	None

Favourable Opinion with Standard Conditions

REC Reference	Title	Number of Days on Clock
16/WM/0451	Reducing Implant Infection in Orthopaedics (RIliO) Pilot Study (v1.0)	21
16/WM/0456	PIPS	21
17/WM/0074	Efficacy of Vein Sheath in Peripheral Nerve Repair.	22

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/WM/0179	A study of the physiology of circulatory death	26
16/WM/0217	SIFTI-2	27
16/WM/0272	The Journey through Care: palliative care for children & young people.	22
16/WM/0294	TRIAC trial in MCT8 patients	23
16/WM/0379	INSIDE PVs study	28
16/WM/0402	Hyperpolarised lung MRI post surgery & mechanical ventilation	21
17/WM/0033	Facilitating Skin-to-Skin Contact In The Postnatal Period.	21

Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock
16/WM/0221	Sixteen Plus:Whole family approach to understanding declining capacity	27
16/WM/0284	masitinib vs irinotecan in advanced esophagogastric adenocarcinoma V1	24
16/WM/0488	Shared care digital platform for children & young people with ADHD v1	23
17/WM/0040	LUSTRO: A Clinical Assessment Study in Crigler Najjar syndrome	22

Provisional Opinion		
REC Reference	Title	Number of Days on Clock
16/WM/0205	Measurement of flow in sepsis	n/a

Provisional Opinion Pending Consultation with Referee		
REC Reference	Title	Number of Days on Clock
None	None	None

Further information response not complete		
REC Reference	Title	Number of Days on Clock
None	None	None

Withdrawn after the meeting		
REC Reference	Title	Number of Days on Clock
None	None	None

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/WM/0208	Anticoagulation in Atrial Fibrillation	8

16/WM/0253	Prostate MRI Patient Preparation Questionnaire	17
16/WM/0345	HASMID	12
16/WM/0347	Appointment Allocation Systems of GP Practices in Tayside	8
16/WM/0348	Otsuka non-interventional: Recent Onset SZ Survey	9
16/WM/0389	Tongue tie outcomes	9
16/WM/0393	Cognitive impairment in patients with chronic kidney disease.	12
16/WM/0429	Urgent and emergency care in mid and south Essex	9
16/WM/0493	360 Selfie	13
17/WM/0045	Reading speed after using ocular lubricants in dry eye disease	11
17/WM/0076	Qualitative study of barriers to vaccine uptake in pregnancy	16
17/WM/0078	A link between body fat, its distribution and lifestyle and sperm	10
17/WM/0079	SALIVA TO PREDICT DISEASE RISK (version 1)	10
17/WM/0080	The iTrend study Version1.0	10
17/WM/0119	Support for older male caregivers.	23

Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/WM/0302	The experiences of patients taking part in rheumatology trials	11
16/WM/0461	Phase IV EORTC study to validate new LC29 module	6
16/WM/0462	Quality of online information on breast cancer	6
16/WM/0491	Perineal ultrasound versus urodynamics	10
16/WM/0494	Combined frailty score (HAT score)	11

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/WM/0207	Childhood Hypertrophic Cardiomyopathy: A new risk stratification tool	7
16/WM/0209	Therapist Effects Over Time: A Multilevel Modelling Analysis - v1.0	7
16/WM/0433	Use of Thrombopoietin-Receptor Agonists in the management of ITP	7
17/WM/0042	Our experience of tonsillectomy for asymmetrical tonsils in children	14

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
16/WM/0211	Towards improvement in care delivery in Huntington's Disease (HD)	7
16/WM/0391	Impacts of skill, uncertainties and delays on prosthesis functionality	7
16/WM/0392	ADC-ICE Study Version1	9

Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock
None	None	None

Provisional Opinion		
REC Reference	Title	Number of Days on Clock
None	None	None

Further information response not complete		
REC Reference	Title	Number of Days on Clock
17/WM/0044	Nurses role in paediatric rehabilitation following brain injury	n/a

Withdrawn after the meeting		
REC Reference	Title	Number of Days on Clock
None	None	None

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/Q2802/26/AM09	Indicators of oocyte and embryo development - version 1	Substantial Amendment 10, 25 A	25/04/2016	23
07/H1210/141/AM03	Hormonal regulation of normal and abnormal pregnancy	Substantial Amendment	19/11/2015	15
09/H1211/38/AM16	(duplicate) FaMIsHED study	Substantial Amendment 9 July 2	28/07/2016	11
09/H1211/38/AM18	(duplicate) FaMIsHED study	10	08/02/2017	19
10/H1210/1/AM13	Understanding Behaviour in Neurodevelopmental Disorders_V1	Substantial Amendment 5	16/06/2016	22
10/H1210/1/AM14	Understanding Behaviour in Neurodevelopmental Disorders_V1	Substantial Amendment 6	06/10/2016	19
10/H1210/10/AM12	Distal Radius Acute Fracture Fixation Trial	Substantial Amendment SA_10	04/08/2016	11
11/WM/0367/AM04	IMMUNOTACE	Substantial Amendment 04	17/11/2016	19
11/WM/0381/AM27	De-ESCALaTE HPV_Final Version 1.0_28 Oct 2011	Substantial Amendment 23	05/12/2016	12
12/WM/0072/AM02	Tissue specific hypothyroidism and the heart version 1	Substantial Amendment 1	01/12/2016	13
12/WM/0149/AM13	3659 Liraglutide in children & adolescents with Type 2 diabetes	Substantial Amendment No.4 06	06/05/2016	11
12/WM/0187/AM06	ROCSS - Reinforcement of closure of stoma site	Amendment No. 6	08/12/2016	12
12/WM/0215/AM07	Apremilast(CC-10004) in the Treatment of Active Ankylosing Spondylitis	Substantial Amendment IB v17 2	10/03/2016	8
12/WM/0247/AM14	Liraglutide in PCOS	Substantial Amendment 07	11/08/2016	17
13/WM/0017/AM25	select-d	Substantial	21/09/2016	14

		Amendment 19		
13/WM/0049/AM02	Cemented versus uncemented hemiarthroplasty for hip fractures	Substantial Amendment 1	28/11/2016	10
13/WM/0090/AM01	Antibody Mediated Rejection in Renal Transplantation	Substantial Amendment 1	08/12/2015	8
13/WM/0090/AM03	Antibody Mediated Rejection in Renal Transplantation	Substantial Amendment Antibody	13/12/2016	23
13/WM/0347/AM08	Evaluate Clinical Characteristics and Disease Progression in MPS IIIB	26.08.16	26/08/2016	22
13/WM/0419/AM08	MAMMO-50 version 1.0 [date]	Substantial Amendment AM04 SUB	24/03/2016	11
13/WM/0419/AM09	MAMMO-50 version 1.0 [date]	Substantial Amendment AM05 SUB	06/07/2016	21
13/WM/0421/AM07	A Phase I/II Trial of TG01 and Gemcitabine Protocol V5.1	Substantial Amendment 08.07.20	06/07/2016	17
13/WM/0466/AM04	Molecular Genetic Analysis and Clinical Studies (MGAC)	3	01/12/2016	21
14/WM/0019/AM10	PRONIA	Substantial Amendment 5 03/03/	03/03/2016	24
14/WM/0019/AM11	PRONIA	Substantial Amendment 06, 10.0	10/05/2016	10
14/WM/0022/AM08	Phase 2 Study of UX007 in Subjects with LC-FAOD	Substantial Amendment 4 2016/0	03/02/2016	11
14/WM/0027/AM36	The effect of Ticagrelor on the CV outcomes of patient with diabetes	3	07/02/2017	14
14/WM/0057/AM06	BASIL-2. Version 1.0	Substantial Amendment 5 26th J	26/07/2016	13
14/WM/0101/AM07	CA209-026 Nivolumab in advanced NSCLC	Substantial Amendment 09	09/12/2015	22

14/WM/0101/AM08	CA209-026 Nivolumab in advanced NSCLC	Substantial Amendment CA209-02	27/10/2016	17
14/WM/0101/AM09	CA209-026 Nivolumab in advanced NSCLC	Substantial Amendment 9	16/01/2017	14
14/WM/0116/AM03	Continuity of care post-hospitalisation - Version 1	Substantial Amendment Version	29/04/2016	13
14/WM/0139/AM12	Telbivudine in children/ adolescents with compensated chronic HBV	Substantial Amendment	08/12/2016	10
14/WM/0156/AM09	Phase 2 Study of Enzalutamide with Trastuzumab in Breast Cancer	Substantial Amendment 6	06/09/2016	23
14/WM/1145/AM08	PRISM Study: Study of I10E in Patients with CIDP	Substantial Amendment SA07	22/04/2016	1
14/WM/1145/AM10	PRISM Study: Study of I10E in Patients with CIDP	Substantial Amendment 08	07/10/2016	14
14/WM/1163/AM02	Leeds Osteoarthritis Hip Cohort	Substantial Amendment 2	05/10/2016	20
14/WM/1211/AM09	IMPRESS-AF trial, version 1.0	Substantial Amendment 05	10/03/2016	22
14/WM/1211/AM10	IMPRESS-AF trial, version 1.0	Substantial Amendment	05/01/2017	29
14/WM/1215/AM01	Control study of the Solihull Approach Antenatal Group	Substantial Amendment 1.0 8.5.	08/05/2016	6
14/WM/1234/AM02	MESALO MEaSure ALOpecia	Substantial Amendment 2 - 23 M	23/03/2016	10
15/WM/0025/AM07	Decision-making for intensive care unit admissions	Substantial Amendment 5.0 19/1	19/10/2016	21
15/WM/0036/AM11	Gabapentin for Pelvic Pain (GaPP 2)	Substantial Amendment 08	28/04/2016	14
15/WM/0036/AM22	Gabapentin for Pelvic Pain (GaPP 2)	16	07/02/2017	19
15/WM/0080/AM02	Urban Health Centers Europe 2.0: Phase II	Substantial Amendment	10/02/2016	19

		Version		
15/WM/0115/AM01	Using behavioural insights to reduce non-urgent A&E attendance rates	Substantial Amendment 1	21/06/2016	17
15/WM/0119/AM02	Reducing reattendance at a GP surgery co-located with an A&E	Substantial Amendment 2	17/06/2016	17
15/WM/0150/AM15	A Better Start Evaluation	Substantial Amendment No6,	25/05/2016	19
15/WM/0207/AM05	A.R.R.O.W. Study	3.0	15/07/2016	12
15/WM/0222/AM04	DIASTOLIC	Substantial Amendment 3	08/06/2016	20
15/WM/0222/AM06	DIASTOLIC	Substantial Amendment 04	06/10/2016	15
15/WM/0244/AM03	TEAM GB	Substantial Amendment 01,	25/11/2016	16
15/WM/0261/AM04	ALIFE 2	Substantial Amendment 3	22/03/2016	17
15/WM/0261/AM06	ALIFE 2	Substantial Amendment 4	12/05/2016	13
15/WM/0261/AM12	ALIFE 2	Substantial Amendment	07/12/2016	14
15/WM/0285/AM04	Muscle Physiology& Function in Crohn's and Non-Alcoholic Liver Disease	Substantial Amendment 3 19 Jul	19/07/2016	13
15/WM/0331/AM01	HeartMate III post-market registry	Substantial Amendment 05/09/16	05/09/2016	23
15/WM/0331/AM02	HeartMate III post-market registry	Substantial Amendment 2,	21/12/2016	18
15/WM/0336/AM04	Screening for Obstructive Sleep Apnoea in chronic Tetraplegia (SOSAT)	Substantial Amendment No 1	28/12/2016	7
15/WM/0360/AM01	Screening pregnant women using late pregnancy ultrasound	Substantial Amendment 1	18/12/2016	20
15/WM/0399/AM01	Bladder sensation in health and disease	Substantial Amendment 1 13.05.	13/05/2016	22
15/WM/0399/AM02	Bladder sensation in health and disease	Substantial	19/07/2016	17

		Amendment 2		
15/WM/0424/AM01	The Stimulation Ventilation Study	Substantial Amendment no. 1 25	25/02/2016	16
15/WM/0443/AM02	PD COMM	Substantial Amendment 3	04/05/2016	21
16/WM/0001/AM03	WHiTE Four	Substantial Amendment 04 28 June 2016	28/06/2016	16
16/WM/0001/AM06	WHiTE Four	7	09/03/2017	19
16/WM/0004/AM01	Profiling anxiety in adolescents and adults with Williams Syndrome	Substantial Amendment 1	27/07/2016	9
16/WM/0006/AM04	WHIST - Wound Healing In Surgery for Trauma	Substantial Amendment 4, 18 Oc	18/10/2016	20
16/WM/0006/AM08	WHIST - Wound Healing In Surgery for Trauma	SA 8	23/02/2017	14
16/WM/0025/AM01	DIAMOND-Lewy: A pilot study of care provided by NHS services.	Substantial Amendment 1	01/06/2016	12
16/WM/0066/AM01	Remote Ischaemic Conditioning After Stroke 2 (ReCAST-2)	1	13/02/2017	15
16/WM/0076/AM02	Parenting of mothers with borderline personality disorder V1	Substantial Amendment 1	17/10/2016	14
16/WM/0154/AM02	Self-conscious emotions in partners of people with dementia	Substantial Amendment 1	18/10/2016	10
16/WM/0164/AM01	SMARTChip study	Substantial Amendment 1,	16/10/2016	11
16/WM/0164/AM02	SMARTChip study	Substantial Amendment 2,	14/11/2016	14
16/WM/0164/AM04	SMARTChip study	Substantial Amendment 4,	16/12/2016	15
16/WM/0164/AM05	SMARTChip study	Substantial Amendment 5,	06/01/2017	14
16/WM/0179/AM01	A study of the physiology of circulatory death	Substantial Amendment 1	09/09/2016	13
16/WM/0215/AM01	Comparison of Humacyte's Human Acellular Vessel with ePTFE grafts V1.2	Substantial Amendment 1 12.08.	12/08/2016	6

16/WM/0215/AM05	Comparison of Humacyte's Human Acellular Vessel with ePTFE grafts V1.2	Substantial Amendment 4	04/11/2016	13
16/WM/0217/AM01	SIFTI-2	Substantial Amendment 1	11/10/2016	14
16/WM/0268/AM01	What after the first proposs?	Substantial Amendment 1.2	11/12/2016	10
16/WM/0279/AM01	Prevalence of MGUS in acute hospital admissions, version 1.0	Substantial Amendment 1,	10/10/2016	10
16/WM/0285/AM02	Evolocumab (AMG 145) in HIV & Hyperlipidemia and/or Mixed Dyslipidemia	2	15/03/2017	13
16/WM/0317/AM01	Efficacy / safety of oral S44819 after recent ischemic cerebral event	Substantial Amendment 1	26/09/2016	9
16/WM/0317/AM02	Efficacy / safety of oral S44819 after recent ischemic cerebral event	Substantial Amendment 2	16/10/2016	18
16/WM/0317/AM03	Efficacy / safety of oral S44819 after recent ischemic cerebral event	Substantial Amendment	04/01/2017	19
16/WM/0345/AM02	HASMID	SA1	02/09/2016	9
16/WM/0391/AM01	Impacts of skill, uncertainties and delays on prosthesis functionality	Substantial Amendment 1	11/10/2016	19
16/WM/0402/AM01	Hyperpolarised lung MRI post surgery & mechanical ventilation	Substantial Amendment One, 25	25/11/2016	13
16/WM/0429/AM01	Urgent and emergency care in mid and south Essex	Substantial Amendment 1	08/11/2016	21
16/WM/0448/AM01	Open label Study with Maribavir and Investigator-Assigned Tx for CMV	SA1: Protocol Amendment 2 v.3.	01/12/2016	7
16/WM/0451/AM01	Reducing Implant Infection in Orthopaedics (RIIiO) Pilot Study (v1.0)	1	17/01/2017	18
16/WM/0478/AM01	LEO 90100 twice weekly maintenance regimen for psoriasis vulgaris	Substantial Amendment 1	14/12/2016	10
16/WM/0479/AM01	INCLUDE: Using Lived Experience to Improve Mental Health Diagnosis V.1	1	16/02/2017	13

Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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12/WM/0001/AM16	WOLLF - Wound Management of Open Lower Limb Fractures	Substantial Amendment 9	05/05/2016	11
12/WM/0067/AM01	MRI study of the effects of hypoxia on cerebral arterial vasculature	2	07/03/2017	15
12/WM/0079/AM08	Long term continuous infusion ch14.18/CHO plus s.c. aldesleukin (IL-2)	Substantial Amendment 08	10/08/2016	23
14/WM/1202/AM12	B0401016 - PF-04447943 Sickle Cell Disease Study	Substantial Amendment 9	26/04/2016	14
14/WM/1209/AM08	CENTAUR - CVC	Substantial Amendment	07/07/2016	18
14/WM/1233/AM07	ALX-HPP-501 V1.1	Substantial Amendment 4.2	06/05/2016	20
15/WM/0025/AM06	Decision-making for intensive care unit admissions	Substantial Amendment 4.0	18/04/2016	22
15/WM/0156/AM09	Study of the Progression of Choroideremia, V1, 23Mar2015	Substantial Amendment #04 11-A	11/08/2016	9
15/WM/0206/AM02	KFORT - Knee Fix or Replacement Trial	Substantial Amendment 2	21/07/2016	17
16/WM/0395/AM01	200807 Anaemia of CKD (dialysis): daprodustat vs erythropoietin	Substantial Amendment	12/10/2016	23
16/WM/0396/AM01	200808 Anaemia of CKD (non-dialysis): daprodustat vs darbepoetin alfa	Substantial Amendment 02	12/10/2016	23

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
12/WM/0001/AM16/1	WOLLF - Wound Management of Open Lower Limb Fractures	Modified Amendment 26.05.016	26/05/2016	13
	CENTAUR - CVC	Protocol	29/07/2016	3

14/WM/1209/AM08/1		Amendment- 02,		
14/WM/1233/AM07/1	ALX-HPP-501 V1.1	Modified Amendment 4.2	06/05/2016	1
15/WM/0156/AM09/1	Study of the Progression of Choroideremia, V1, 23Mar2015	Modified Amendment 4	14/09/2016	2
15/WM/0206/AM02/1	KFORT - Knee Fix or Replacement Trial	Modified Amendment for	21/07/2016	9
16/WM/0395/AM01/1	200807 Anaemia of CKD (dialysis): daprodustat vs erythropoietin	Modified Amendment 02	13/01/2017	12
16/WM/0396/AM01/1	200808 Anaemia of CKD (non-dialysis): daprodustat vs darbepoetin alfa	Modified Amendment 02	13/01/2017	13

Unfavourable opinion timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
12/WM/0079/AM08/1	Long term continuous infusion ch14.18/CHO plus s.c. aldesleukin (IL-2)	Substantial Amendment 08	10/08/2016	15

Table 11: Items exceeding timelines**Full applications for ethical review over 60 day timeline**

REC Reference	Title	Number of Days on Clock
None	None	None

Proportionate review applications for ethical review over 21 day timeline

REC Reference	Title	Number of Days on Clock
17/WM/0119	Support for older male caregivers.	23

SSAs (non Phase 1) over 25 day timeline

REC Reference	Title	Number of Days on Clock
None	None	None

SSAs (Phase 1) over 14 day timeline

REC Reference	Title	Number of Days on Clock
None	None	None

Substantial Amendments over 35 day timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
None	None	None	None	None

Modified Amendments over 14 day timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
2/WM/0079/AM08/1	Long term continuous infusion ch14.18/CHO plus s.c. aldesleukin (IL-2)	Substantial Amendment 08	10/08/2016	15