

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

Annual Report

01 April 2015 - 31 March 2016



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
Chair:	Dr Helen Brittain
Vice-Chair:	Dr Ronald Jubb
Alternate Vice-Chair:	Professor Jane Appleton
REC Manager:	Ms Rachel Nelson
REC Assistant:	Ms Teagan Allen
Committee Address:	The Old Chapel Royal Standard Place Nottingham NG1 6FS
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Chair's overview of the past year:

The Committee was very pleased to welcome Rachel and Teagan and wish to acknowledge their hard work and very efficient management in meeting time deadlines so well, as well as communicating with all of us.

The Committee members also continue to contribute much time and hard work. Some members 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 introduction of HARP and a new way of working has proved a challenge for all but I hope it will prove a better way of working, and save a lot of paper.

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	
Dr Helen Brittain (Chair)	Clinical Psychologist Retired	Lay	01/04/2010	
Mrs Barbara Canning	Senior University Lecturer	Lay	01/04/2010	25/01/2016
Ms Yasumati Damodar	Pharmacist	Expert	22/09/2015	
Dr John S Fenlon	Statistical Consultant	Lay	01/05/2015	
Ms Chelsea Gilsenan	Maternity Risk Management Officer	Lay Plus	16/03/2016	
Mrs Louise Harmer	Undergraduate Medical Education Manager, Technology Enhanced Learning and Clinical Skills and Resuscitation Tutor	Expert	01/04/2010	
Mrs Evette Hunkins-Hutchinson	Lecturer Health Care Management	Lay Plus	01/04/2010	
Dr Christopher Jones	Academic Clinical Fellow in Clinical Oncology	Expert	07/08/2014	
Dr Ronald Jubb	Retired Consultant Rheumatologist	Expert	24/09/2014	
Dr Karen Schofield	Retired Consultant Haematologist	Expert	14/08/2014	
Dr Gurnam Singh	Principal Lecturer in Social Work	Lay Plus	01/04/2010	27/04/2015

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

Name	Profession	Status	Meeting date attended
None	None	None	None

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

Name	Profession	Status	Meeting date attended
Mr John Baker	Radiation Protection Advisor and Senior Lecturer (retired)	Lay	23/09/2015 27/01/2016
Mr Chris Foy	Statistician	Expert	23/09/2015
Professor Paula McGee	Professor of Nursing	Expert	27/01/2016

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

Name	Declaration of Interest	Date
Professor Jane Appleton	Trustee of the charity The British Association for the study and prevention of child abuse and neglect. Sometimes asked to act as a reviewer for CLRN funding and NIHR funding applications	01/12/2015
Dr Helen Brittain	Trustee Warwickshire Wild Life Trust Member of British Red Cross Psychological Team	21/02/2016
Ms Yasumati Damodar	None Declared	25/10/2015
Mrs Louise Harmer	Involved with undergraduate medical students and may be involved for advice about the ethics process from time to time. PhD student - Currently on a break.	03/12/2015
Dr Christopher Jones	Honorary Research Fellow at the University of Birmingham Lead Clinical Fellow on the DSD-Life study On-going research interests in endocrinology Academic Clinical Fellow in Clinical Oncology at the University of Leeds and Leeds Cancer Centre Lead Clinical Fellow on the LCC-CARIS-01 Study Research interests in basic cancer cell biology and translational precision oncology approaches.	11/02/2016
Dr Ronald Jubb	None Declared	18/02/2016
Dr Karen Schofield	Member of a Keele University research ethics committee	01/12/2015
Mr Roger Balcome	None Declared	25/03/2016
Dr John Fenlon	None Declared	07/01/2016
Ms Chelsea Gilsean	Promotion to Trust Risk Manager at NHS Trust OHCW following recruitment to NREC 24.04.2016	28/03/2016

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

Month	Date	Number of Members Present at Meeting
April	22/04/2015	8
June	24/06/2015	10
July	22/07/2015	9
August	26/08/2015	8
September	23/09/2015	9
October	28/10/2015	8
November	25/11/2015	9
January	27/01/2016	9
February	24/02/2016	8

9 full committee meetings were held during the reporting period.

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

Month	Date	Number of Members Present at Meeting
April	20/04/2015	3
May	27/05/2015	3
June	24/06/2015	3
July	22/07/2015	3
August	26/08/2015	3
September	23/09/2015	3
October	28/10/2015	3
November	25/11/2015	3
January	08/01/2016	3
January	27/01/2016	3
February	24/02/2016	3
March	21/03/2016	3

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

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

Month	Date	Number of Members Present at Meeting
April	02/04/2015	2
April	17/04/2015	3
May	01/05/2015	2
May	15/05/2015	2
May	29/05/2015	2
June	12/06/2015	3
June	26/06/2015	2
July	10/07/2015	2
July	24/07/2015	2
August	07/08/2015	2

September	04/09/2015	2
September	18/09/2015	3
October	02/10/2015	2
October	16/10/2015	2
October	30/10/2015	2
November	13/11/2015	2
November	27/11/2015	2
December	11/12/2015	2
December	23/12/2015	2
January	08/01/2016	2
January	22/01/2016	2
February	05/02/2016	2
February	19/02/2016	2
March	04/03/2016	2
March	18/03/2016	2

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

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

Date	Reason	Action taken
None	None	None

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

Name	Number of Meetings Attended
Professor Jane Appleton	6
Mr Roger Balcombe	8
Dr Geraldine Brady	2
Dr Helen Brittain (Chair)	8
Mrs Barbara Canning	4
Ms Yasumati Damodar	3
Dr John S Fenlon	7
Mrs Louise Harmer	9
Mrs Evette Hunkins-Hutchinson	6
Dr Christopher Jones	5
Dr Ronald Jubb	6
Dr Karen Schofield	8

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

Name	Number of Meetings Attended
Professor Jane Appleton	3
Mr Roger Balcombe	1
Dr Helen Brittain	11
Mrs Barbara Canning	2
Dr John S Fenlon	1
Mrs Louise Harmer	3
Mrs Evette Hunkins-Hutchinson	2
Dr Christopher Jones	4
Dr Ronald Jubb	5
Dr Karen Schofield	2
Dr Gurnam Singh	1

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

Name	Number of Meetings Attended
Professor Jane Appleton	6
Dr Geraldine Brady	1
Dr Helen Brittain	20
Mrs Barbara Canning	1
Ms Yasumati Damodar	1
Dr John S Fenlon	3
Mrs Louise Harmer	3

Mrs Evette Hunkins-Hutchinson	2
Dr Christopher Jones	6
Dr Ronald Jubb	5
Dr Karen Schofield	3

Training 01 April 2015 - 31 March 2016

Name of Member	Date	Event(s) attended
Mr Roger Balcombe	01/05/2015	Equality and Diversity Training
Dr Geraldine Brady	27/04/2015	Equality and Diversity online training
Dr Helen Brittain	07/05/2015	NREAP Meeting
Dr Helen Brittain	09/12/2015	National Training Day for REC Chairs
Mrs Barbara Canning	23/04/2015	HRA guidance on Research Involving Medical Devices
Ms Yasumati Damodar	01/11/2015	Induction for New RES Committee Members e-learning
Ms Yasumati Damodar	10/03/2016	Member's Induction
Dr John S Fenlon	15/05/2015	NREAP Meeting
Dr John S Fenlon	25/09/2015	Members Regional Training Day
Dr John S Fenlon	20/11/2015	NREAP/Chair's training
Dr John S Fenlon	09/12/2015	National Training Day for Chairs
Dr John S Fenlon	14/01/2016	Training for new Chairs
Dr John S Fenlon	03/03/2016	Qualitative Research
Dr John S Fenlon	11/03/2016	Genetics and Genomics Research
Mrs Louise Harmer	16/07/2015	Equality and Diversity Update
Mrs Louise Harmer	24/08/2015	Reviewed guidance on completion of participant information sheets and consent forms
Mrs Louise Harmer	01/09/2015	Advised module lead at Warwick Medical School re proportionate review, full review and the R&D process for medical students completing research modules
Mrs Louise Harmer	08/09/2015	Reviewed guidance re proportionate review
Mrs Louise Harmer	16/11/2015	Read article re Human tissue and biological samples for use in research: operational and ethical guidelines MRC ethics series.
Mrs Evette Hunkins-Hutchinson	27/04/2015	Read Consent and Participant Information update
Mrs Evette Hunkins-Hutchinson	01/05/2015	Equality and Diversity Training
Dr Christopher Jones	24/07/2015	Personal Data in Research
Dr Ronald Jubb	07/05/2015	NREAP Meeting
Dr Ronald Jubb	15/07/2015	Equality and Diversity
Dr Karen Schofield	02/04/2015	E&D e-learning
Dr Karen Schofield	25/09/2015	Members Regional Training Day

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	3	6.12
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	46	93.88
Total Applications Reviewed	49	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	20
Number of paediatric applications reviewed	6
Number of device applications reviewed	4
Number of prisoner applications reviewed	0
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	5

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	5	10.20
Favourable Opinion with Additional Conditions	7	14.29
Unfavourable Opinion	2	4.08
Provisional Opinion	35	71.43
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	49	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	20	40.82
Further Information Favourable Opinion with Additional Conditions	14	28.57
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	5	10.20
Favourable Opinion with Additional Conditions	7	14.29
Unfavourable Opinion	2	4.08
Provisional Opinion	1	2.04
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	49	100

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

Total Applications Reviewed	35
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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	3
Number of studies withdrawn prior to the meeting	2
Number of student applications reviewed	19
Number of paediatric applications reviewed	2
Number of device applications reviewed	0
Number of qualitative applications reviewed	11

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	6	17.14
Favourable Opinion with Additional Conditions	5	14.29
No Opinion transfer to full committee for review	3	8.57
Provisional Opinion	21	60.00
Unfavourable Opinion	0	0.00
Total	35	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	5.44
Number of completed applications for full ethical review	49
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	2.04%
Number of days taken to final decision – average (mean)	30
Number of completed proportionate review applications for ethical review	32
Number of completed proportionate review applications for ethical review over 14 days	0
Number of completed proportionate review applications over 14 days as a % of total	0.00%
Number of SSAs (non-Phase 1) reviewed	9
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	127
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	6
Number of completed substantial amendments over 28 days as a % of total substantial amendments	4.72%
Number of modified amendments reviewed	2
Number of completed modified amendments over 14 days	0
Number of completed modified amendments over 14 days as a % of total modified amendments	0.00%
Number of minor amendments received	153
Number of substantial amendments received for information	2
Number of substantial amendments received for new sites/PIs	37
Number of annual progress reports received	94

Number of safety reports received	45
Number of Serious Adverse Events received	0
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
15/WM/0112	Ethicus 2	25
15/WM/0175	HO2T or NO2T Trial	31
15/WM/0207	A.R.R.O.W. Study	24
15/WM/0240	Frailty and Nutrition Study (FANS) in Lincoln - Version 2.4	30
15/WM/0244	TEAM GB	37
15/WM/0282	Coffee project - Version 1.0	29
15/WM/0285	Muscle Physiology& Function in Crohn's and Non-Alcoholic Liver Disease	40
15/WM/0286	Intermittent cycle training: titrating time and intensity	34
15/WM/0287	Short vs standard intramedullary nail for trochanteric hip fractures	31
15/WM/0288	Supporting the emotional needs of renal patients v.1.	30
15/WM/0337	Exploratory case-controlled longitudinal biomarker study on Alzheimer	36
15/WM/0389	Midwifery practice during the second stage of labour v1 01.10.15	28
15/WM/0424	The Stimulation Ventilation Study	36
16/WM/0004	Profiling anxiety in adolescents and adults with Williams Syndrome	30
16/WM/0025	DIAMOND-Lewy: A pilot study of care provided by NHS services.	25
16/WM/0026	Mechanisms of bacterial infection in patients with influenza - Pilot	30
16/WM/0066	Remote Ischaemic Conditioning After Stroke 2 (ReCAST-2)	27
16/WM/0076	Parenting of mothers with borderline personality disorder V1	27
16/WM/0097	An investigation of the experience of change in Personality Disorder	32
16/WM/0102	4D Flow MR Angiography of Abdominal Aortic Aneurysms	27

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
15/WM/0150	A Better Start Evaluation	33
15/WM/0151	Factors Associated with Non-Completion of Compassion-Focused Therapy	27
15/WM/0181	Male carer interview study	22
15/WM/0236	Experiences of mass media portrayals of mental health and recovery	44
15/WM/0243	Understanding Reciprocal Roles in Adults with Intellectual Disability	35
15/WM/0261	ALIFE 2	35
15/WM/0291	Effects of altering handle height of posterior walkers v1	40
15/WM/0331	HeartMate III post-market registry	40

15/WM/0333	ImpACT-24B(Implant Augmenting Cerebral blood flow) Rev 1.0	40
15/WM/0392	SARON	34
15/WM/0393	Investigating the Immune Response in Haematological Malignancies	37
15/WM/0399	Bladder sensation in health and disease	29
15/WM/0418	Expectations of individuals seeking therapy for depression	34
16/WM/0034	EXTOD Education	32

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
15/WM/0206	KFORT - Knee Fix or Replacement Trial	27
15/WM/0210	Efficacy of language games as therapy for post stroke aphasia	21
15/WM/0222	DIASTOLIC	21
15/WM/0336	Screening for Obstructive Sleep Apnoea in chronic Tetraplegia (SOSAT)	26
15/WM/0398	STABILITY	28

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/WM/0149	PEDAL (Pedal Exercise During Admission to hospital) -feasibility study	19
15/WM/0421	ORL-PGI-2261	26
15/WM/0442	Investigating Processing of Discharge Summaries in General Practice	25
15/WM/0443	PD COMM	26
16/WM/0001	WHiTE Four	23
16/WM/0006	WHIST - Wound Healing In Surgery for Trauma	23
16/WM/0089	Undernutrition in the ED	26

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
15/WM/0113	Exercise intervention in dementia patients_version0.1	21

16/WM/0099	Do Parents Know What Children are Watching? Screen Time.	26
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Provisional Opinion

REC Reference	Title	Number of Days on Clock
15/WM/0213	Social salience and depression (version V1)	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
15/WM/0154	New memory tests for early cognitive decline	12
15/WM/0156	Study of the Progression of Choroideremia, V1, 23Mar2015	12
15/WM/0160	Impact of bystander disease post PPCI to the culprit vessel post STEMI	12
15/WM/0234	Living with RDEB	13
15/WM/0272	The physical health needs of mental health service users	11
15/WM/0274	An Exploration of Night Eating Syndrome and Mood	13
15/WM/0276	Use of a patient-derived cell-line (A1ATD) in research on cancer genes	11

15/WM/0360	Screening pregnant women using late pregnancy ultrasound	9
15/WM/0404	Feasibility Study for recording of CAEPs in children with OME	11
15/WM/0406	Dapagliflozin and endothelial function in type 2 diabetes	8
15/WM/0448	Camera based balance assessment	9
15/WM/0451	AMD outcomes important for patients- Delphi study	11
16/WM/0016	Investigating Spinally-Mediated Hyperalgesia in Small Fibre Neuropathy	8
16/WM/0035	Exploring views on alcohol intervention delivery in primary healthcare	8
16/WM/0068	MapMySmoke Feasibility Study	7
16/WM/0070	Physical activity in people with hip or knee osteoarthritis	13
16/WM/0154	Self-conscious emotions in partners of people with dementia	13
16/WM/0158	Attitudes towards female genital mutilation (FGM)	12

Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/WM/0270	Caregiver Burden in Cystic Fibrosis	12
16/WM/0156	ICP position related changes	10

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
15/WM/0315	Lipodystrophy and Body Image: A Qualitative Analysis Version 1	8
15/WM/0316	Inflectra (infliximab) Post-Marketing Observational Study	8
15/WM/0449	Biomarker assessment in prostate cancer V1.0	7
16/WM/0017	Sociotechnical evaluation of a Smartphone App in HIV care	7
16/WM/0110	Critical thinking: psychosis as a contested area.	6
16/WM/0111	Evaluation of gene therapy vectors for cancer therapeutics	6

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
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15/WM/0203	Impact of Self-Management Education on Outcomes for Patients with COPD	11
15/WM/0204	Hybrid Imaging Study	6
15/WM/0232	Exploring patients' perceptions of root canal treatment	12
16/WM/0013	Peer Assisted Learning and Support in weight management (PALS) v.1.	7
16/WM/0112	Medical Adherence in Paediatric Cystic Fibrosis	6

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
15/WM/0361	The health visitors role in reducing inappropriate A&E attendance	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
05/Q2801/47/AM02	A pre-clinical study of human islets for the treatment of Diabetes	SA#07	22/04/2015	20
05/Q2801/70/AM06	Use of human amniotic epithelial cells as an adjunct to Islet trans	SA#05	23/04/2015	22
09/H1210/69/AM12	PARAMEDIC	SA#11	23/04/2015	12
09/H1210/75/AM03	Inflammatory cells, mediators & erythrocytes: variability in COPD	Substantial Amendment 19.10.20	19/10/2015	18
09/H1211/38/AM13	FaMIsHED study	Substantial amendment 7	08/07/2015	17
09/H1211/38/AM15	FaMIsHED study	Substantial Amendment 8	08/11/2015	11
09/H1211/87/AM04	Measuring effects of cancer therapy upon female fertility, version 1	SA#03	15/04/2015	17
10/H1210/1/AM09	Understanding Behaviour in Neurodevelopmental Disorders_V1	Substantial Amendment 3	23/09/2015	15
10/H1210/1/AM10	Understanding Behaviour in Neurodevelopmental Disorders_V1	Amendment 4	18/01/2016	19
10/H1210/10/AM11	Distal Radius Acute Fracture Fixation Trial	SA9	22/07/2015	17
10/H1211/20/AM29	LEADER, liraglutide cardiovascular outcome study in type 2 diabetes	Substantial Amendment 15.07.20	15/07/2015	21
11/WM/0220/AM38	TEAMM: Tackling early morbidity and mortality in myeloma	Substantial Amendment 33	14/10/2015	15
11/WM/0367/AM02	IMMUNOTACE	SA#02	29/04/2015	21
11/WM/0367/AM03	IMMUNOTACE	Substantial Amendment 3	08/10/2015	8
11/WM/0381/AM19	De-ESCALaTE HPV_Final Version 1.0_28 Oct 2011	16	27/03/2015	9
11/WM/0381/AM20	De-ESCALaTE HPV_Final Version 1.0_28 Oct 2011	Substantial amendment 17	06/05/2015	9
11/WM/0381/AM22	De-ESCALaTE HPV_Final Version 1.0_28 Oct 2011	19	09/07/2015	17

12/WM/0001/AM15	WOLFF - Wound Management of Open Lower Limb Fractures	Substantial Amendment 08	11/02/2016	21
12/WM/0149/AM11	3659 Liraglutide in children & adolescents with Type 2 diabetes	Substantial Protocol Amendment	30/03/2015	9
12/WM/0187/AM05	ROCSS - Reinforcement of closure of stoma site	Substantial Amendment 5	26/06/2015	21
12/WM/0215/AM05	Apremilast(CC-10004) in the Treatment of Active Ankylosing Spondylitis	SA#05	14/04/2015	17
12/WM/0247/AM13	Liraglutide in PCOS	SA6	17/07/2015	20
12/WM/0335/AM08	BCoS-Care	SA#03	11/06/2015	18
12/WM/0335/AM09	BCoS-Care	Substantial Amendment 4	14/12/2015	24
12/WM/0335/AM10	BCoS-Care	Substantial Amendment 5	17/02/2016	14
12/WM/0340/AM14	UK Fixation of Distal Tibia Fractures(UK FixDT) V1.0	SA#10	07/04/2015	13
13/WM/0017/AM18	select-d	SA#13	15/04/2015	11
13/WM/0017/AM22	select-d	Substantial Amendment 16	23/10/2015	31
13/WM/0023/AM05	BEACON-Neuroblastoma Trial: Bevacizumab, Temozolomide \pm Irinotecan	Substantial Amendment SA05	15/07/2015	23
13/WM/0023/AM07	BEACON-Neuroblastoma Trial: Bevacizumab, Temozolomide \pm Irinotecan	Substantial Amendment SA06	16/02/2016	8
13/WM/0075/AM05	Mitochondrial Study (MATCH Study)	SA#05	17/04/2015	11
13/WM/0143/AM09	Study of Moxetumomab Pasudotox in pALL or LL of B-Cell Origin	Substantial Amendment 5	25/06/2015	5
13/WM/0316/AM08	Perioperative Analgesia for Knee Arthroplasty	SA3	13/06/2015	21
13/WM/0319/AM02	Developing a core information set for consent to oral cancer surgery	SA#02	21/04/2015	11
13/WM/0373/AM09	BMN701 Phase 3 in rhGAA Exposed Subjects with Late Onset Pompe Disease	SA#07	05/06/2015	8
13/WM/0373/AM11	BMN701 Phase 3 in rhGAA Exposed Subjects with Late Onset Pompe Disease	Substantial Amendment	01/09/2015	23
13/WM/0373/AM12	BMN701 Phase 3 in rhGAA Exposed Subjects with Late Onset Pompe Disease	Substantial Amendment 9	14/10/2015	23
13/WM/0399/AM15	Brains in Transition (BrIT)	Substantial	08/01/2016	16

		Amendment 6		
13/WM/0419/AM07	MAMMO-50 version 1.0 [date]	Substantial Amendment 3	02/10/2015	24
13/WM/0421/AM05	A Phase I/II Trial of TG01 and Gemcitabine Protocol V5.1	SA#04	14/04/2015	17
13/WM/0468/AM09	Hypertension in Dementia - Feasibility Study	7	12/05/2015	25
14/WM/0019/AM07	PRONIA	SA#04	11/05/2015	28
14/WM/0027/AM14	The effect of Ticagrelor on the CV outcomes of patient with diabetes	SA for IB	22/05/2015	16
14/WM/0027/AM15	The effect of Ticagrelor on the CV outcomes of patient with diabetes	Substantial Amendment 09.06.20	09/06/2015	13
14/WM/0027/AM22	The effect of Ticagrelor on the CV outcomes of patient with diabetes	Substantial Amendment 16.10.20	16/10/2015	21
14/WM/0027/AM26	The effect of Ticagrelor on the CV outcomes of patient with diabetes	Substantial Amendment 19.11.20	19/11/2015	34
14/WM/0027/AM28	The effect of Ticagrelor on the CV outcomes of patient with diabetes	Substantial Amendment 16.12.20	16/12/2015	27
14/WM/0057/AM04	BASIL-2. Version 1.0	Substantial Amendment 4	13/01/2016	13
14/WM/0093/AM07	FOAM Trial, Version 1.0	SA5	15/07/2015	17
14/WM/0093/AM09	FOAM Trial, Version 1.0	Substantial Amendment AM07 5.0	24/11/2015	23
14/WM/0096/AM01	Prevalence Asymptomatic Carriage Clostridium difficile	Substantial Amendment SA01	26/10/2015	16
14/WM/0101/AM05	CA209-026 Nivolumab in advanced NSCLC	SA#05	17/04/2015	14
14/WM/0101/AM06	CA209-026 Nivolumab in advanced NSCLC	Substantial Amendment 15/09/20	15/09/2015	24
14/WM/0116/AM02	Continuity of care post-hospitalisation - Version 1	Substantial Amendment 3	18/12/2015	26
14/WM/0121/AM08	Palliative Care: Clinicians' EstimateS (P:CES)	Substantial Amendment 3	09/03/2016	11

14/WM/0139/AM03	Telbivudine in children/ adolescents with compensated chronic HBV	SA#03	20/05/2015	23
14/WM/0156/AM05	Phase 2 Study of Enzalutamide with Trastuzumab in Breast Cancer	Substantial Amendment 4	24/06/2015	6
14/WM/0156/AM07	Phase 2 Study of Enzalutamide with Trastuzumab in Breast Cancer	Substantial Amendment 4 2016/0	10/03/2016	11
14/WM/0160/AM02	The PEGASUS Trial - Comparing PGT with no-PGT	SA#02	15/04/2015	16
14/WM/0160/AM03	The PEGASUS Trial - Comparing PGT with no-PGT	Substantial Amendment 19.10.20	19/10/2015	18
14/WM/0182/AM02	CFZ533 in patients with primary Sjögren's syndrome	4.0	14/05/2015	29
14/WM/0182/AM03	CFZ533 in patients with primary Sjögren's syndrome	Substantial Amendment 15.10.20	15/10/2015	22
14/WM/1003/AM02	Are beliefs about emotions related to outcomes in fibromyalgia?	Substantial Amendment 1	24/09/2015	11
14/WM/1011/AM02	Growing into adulthood with HIV	Substantial Amendment 1	29/06/2015	14
14/WM/1050/AM09	Acute Lung Injury Trial	Substantial Amendment 07	17/12/2015	24
14/WM/1050/AM11	Acute Lung Injury Trial	Substantial Amendment 18.01.20	18/01/2016	23
14/WM/1057/AM01	Cap Blood Project	Substantial Amendment 3,	10/02/2015	9
14/WM/1065/AM02	Phase I Study to Evaluate Tafluprost Eye Drops in Paediatric Patients.	Substantial amendment 10.07.20	10/07/2015	20
14/WM/1065/AM03	Phase I Study to Evaluate Tafluprost Eye Drops in Paediatric Patients.	Substantial Amendment 03.11.20	03/11/2015	8
14/WM/1065/AM04	Phase I Study to Evaluate Tafluprost Eye Drops in Paediatric Patients.	Substantial Amendment 13.01.20	13/01/2016	13
14/WM/1069/AM01	Multidetector Cardiac CT to guide CRT implantation	SA#01	26/05/2015	13

14/WM/1069/AM02	Multidetector Cardiac CT to guide CRT implantation	Substantial Amendment 2 12.10.	12/10/2015	15
14/WM/1069/AM03	Multidetector Cardiac CT to guide CRT implantation	Substantial Amendment 3	10/12/2015	18
14/WM/1072/AM01	LUCID	Substantial amendment 1	08/05/2015	12
14/WM/1098/AM02	World Hip Trauma Evaluation study 3: Hemiarthroplasty Evaluation by Multicentre Investigation-WHiTE 3 : HEMI.	Substantial Amendment 2	22/06/2015	14
14/WM/1098/AM04	World Hip Trauma Evaluation study 3: Hemiarthroplasty Evaluation by Multicentre Investigation-WHiTE 3 : HEMI.	3.0	21/01/2016	15
14/WM/1103/AM08	1227 - Phase 2b double-blind study of hospitalised adults with RSV	Substantial Amendment 16/09/20	16/09/2015	23
14/WM/1103/AM10	1227 - Phase 2b double-blind study of hospitalised adults with RSV	Substantial Amendment 4	17/11/2015	11
14/WM/1106/AM09	A Phase 3 study comparing the bowel cleansing of NER1006 vs MOVIPREP	Substantial Amendment 05.05.20	05/05/2015	15
14/WM/1106/AM11	A Phase 3 study comparing the bowel cleansing of NER1006 vs MOVIPREP	Substantial Amendment: Protocol	06/07/2015	24
14/WM/1108/AM07	A Phase 3 study comparing the bowel cleansing of NER1006 vs (SP+MS)	Substantial Amendment - Protocol	06/07/2015	23
14/WM/1145/AM04	PRISM Study: Study of I10E in Patients with CIDP	Substantial Amendment 3	24/06/2015	6
14/WM/1145/AM05	PRISM Study: Study of I10E in Patients with CIDP	Substantial Amendment 4	09/12/2015	27
14/WM/1145/AM06	PRISM Study: Study of I10E in Patients with CIDP	Substantial Amendment SA5	31/12/2015	26
14/WM/1145/AM07	PRISM Study: Study of I10E in Patients with CIDP	Substantial Amendment 19.02.20	19/02/2016	14
14/WM/1202/AM06	B0401016 - PF-04447943 Sickle Cell Disease Study	SA#06	08/04/2015	12
14/WM/1202/AM11	B0401016 - PF-04447943 Sickle Cell Disease Study	Substantial	12/11/2015	26

		Amendment 8		
14/WM/1209/AM05	CENTAUR - CVC	Substantial Amendment 05/11/20	05/11/2015	28
14/WM/1210/AM02	HIV Once Daily ARV Single Tablet bPI Regimen	SA#02	19/03/2015	11
14/WM/1210/AM03	HIV Once Daily ARV Single Tablet bPI Regimen	Substantial Amendment 3	23/06/2015	18
14/WM/1211/AM01	IMPRESS-AF trial, version 1.0	Substantial Amendment AM02	10/03/2015	21
14/WM/1211/AM05	IMPRESS-AF trial, version 1.0	Substantial amendment 2	02/06/2015	10
14/WM/1211/AM07	IMPRESS-AF trial, version 1.0	Substantial Amendment 4	15/12/2015	26
14/WM/1214/AM06	Smartphone & Tablet Application for recording Medicines and Pain	Substantial Amendment 4	25/09/2015	14
14/WM/1234/AM01	MESALO MEaSure ALOpecia	SA#01	13/05/2015	29
14/WM/1235/AM01	PRISM 2 - Study of I10E in Patients with CIDP	Substantial Amendment 1	26/06/2015	10
14/WM/1235/AM02	PRISM 2 - Study of I10E in Patients with CIDP	Substantial Amendment SA#2	24/02/2016	9
14/WM/1236/AM01	P3-AMI Antiplatelet Trial	SA#01	24/05/2015	16
14/WM/1245/AM02	CAVIAR - RCT of lifestyle intervention post kidney transplantation	SA#01	07/04/2015	14
15/WM/0025/AM01	Decision-making for intensive care unit admissions	Substantial amendment 1	06/05/2015	12
15/WM/0025/AM02	Decision-making for intensive care unit admissions	Substantial Amendment 2	22/06/2015	13
15/WM/0025/AM05	Decision-making for intensive care unit admissions	Substantial Amendment 3	20/11/2015	31
15/WM/0036/AM07	Gabapentin for Pelvic Pain (GaPP 2)	Substantial Amendment 5	05/02/2016	14
15/WM/0039/AM01	Prevention and management of serious events in HIV positive patients	Substantial Amendment 02/06/20	02/06/2015	22
15/WM/0117/AM01	Prevention of chronic respiratory morbidity	1	03/08/2015	24
15/WM/0119/AM01	Reducing reattendance at a GP surgery co-located with an	SA#01	07/04/2015	13

	A&E			
15/WM/0150/AM01	A Better Start Evaluation	Substantial Amendment 1	05/06/2015	11
15/WM/0150/AM04	A Better Start Evaluation	Substantial Amendment No.2	08/09/2015	22
15/WM/0150/AM08	A Better Start Evaluation	Substantial Amendment Number 4	21/10/2015	25
15/WM/0150/AM10	A Better Start Evaluation	Substantial Amendment Number 5	04/12/2015	4
15/WM/0156/AM01	Study of the Progression of Choroideremia, V1, 23Mar2015	SA1	13/07/2015	14
15/WM/0156/AM02	Study of the Progression of Choroideremia, V1, 23Mar2015	Substantial Amendment #2	07/08/2015	30
15/WM/0156/AM03	Study of the Progression of Choroideremia, V1, 23Mar2015	Substantial Amendment #3	05/11/2015	22
15/WM/0206/AM01	KFORT - Knee Fix or Replacement Trial	Substantial Amendment 1	19/01/2016	20
15/WM/0207/AM02	A.R.R.O.W. Study	Substantial Amendment SA2	25/01/2016	16
15/WM/0210/AM01	Efficacy of language games as therapy for post stroke aphasia	Substantial amendment 1	21/07/2015	17
15/WM/0222/AM01	DIASTOLIC	Substantial Amendment 1	23/10/2015	28
15/WM/0222/AM02	DIASTOLIC	Substantial Amendment 2	17/12/2015	21
15/WM/0240/AM01	Frailty and Nutrition Study (FANS) in Lincoln - Version 2.4	1.0	21/01/2016	20
15/WM/0261/AM01	ALIFE 2	1.0	07/12/2015	12
15/WM/0285/AM02	Muscle Physiology& Function in Crohn's and Non-Alcoholic Liver Disease	Substantial Amendment 2.	28/10/2015	14
15/WM/0406/AM01	Dapagliflozin and endothelial function in type 2 diabetes	Substantial Amendment 13.11.20	13/11/2015	18
16/WM/0006/AM01	WHIST - Wound Healing In Surgery for Trauma	Substantial Amendment 1.0	02/03/2016	17
16/WM/0017/AM02	Sociotechnical evaluation of a Smartphone App in HIV care	Substantial	01/02/2016	19

		Amendment 1		
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Unfavourable opinion				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
14/WM/0121/AM06	Palliative Care: Clinicians' EstimateS (P:CES)	Substantial Amendment 2	28/01/2016	19
15/WM/0036/AM01	Gabapentin for Pelvic Pain (GaPP 2)	1	10/07/2015	16
15/WM/0315/AM03	Lipodystrophy and Body Image: A Qualitative Analysis Version 1	Substantial Amendment 1	09/12/2015	11

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
13/WM/0143/AM06/1	Study of Moxetumomab Pasudotox in pALL or LL of B-Cell Origin	Modified Amendment SA#07	10/04/2015	10
15/WM/0036/AM01/1	Gabapentin for Pelvic Pain (GaPP 2)	Modified amendment	03/08/2015	13

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

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 14 day timeline

REC Reference	Title	Number of Days on Clock
None	None	None

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
None	None	None	None	None