

East Midlands - Derby Research Ethics Committee

Annual Report

01 April 2016 - 31 March 2017



Part 1 – Committee Membership and Training

Name of REC:	East Midlands - Derby Research Ethics Committee
Type of REC:	RECs recognised to review CTIMPS in patients - type iii
Type of Flag:	Establishing Research Databases, Establishing Research Tissue Banks, Research Involving Children
Chair:	Mr Peter Korczak (Chair)
Vice-Chair:	Dr John S Fenlon
Alternate Vice-Chair:	Mrs Janet Mallett
REC Manager:	Miss Victoria Strutt
REC Assistant:	Miss Daniella Sarno
Committee Address:	The Old Chapel Royal Standard Place Nottingham NG1 6FS
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Chair's overview of the past year:

I am grateful to all those members who have worked so hard to cover the increasing workload of Proportionate Reviews and subcommittees. Our vice-chair, John Fenlon and alternate vice-chair Janet Mallett continue to help with the workload, they remain invaluable

Officers continue to attend the Chairs meetings, these meetings with other REC officers continue to be of help to the chair and officers; they provide a better understanding to the streamlining of the review process.

Our committee continues to work well and our members are very committed and put in a lot of work in preparation for meetings, sub-committee meetings and the proportionate review caseload. Two expert members and two lay plus members resigned from the REC in the reporting period. The REC office arranged interviews for new members to replace those who have resigned.

We only spend a short time with the researchers, but they do seem to appreciate the efforts we have made to carefully assess their applications and invariably accept the recommendations we make. In this way we are able to facilitate good quality research.

Finally we have been able to achieve a commendation for accreditation, thanks to the hard work of our REC manager Vic Strutt and REC Assistant Daniella Sarno.

East Midlands - Derby Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Miss Siobhan Ashton-Cleary	Specialist Diabetes Dietitian	Expert	07/10/2015	01/09/2016
Mrs Amanda Brammer	Student - Derby University	Lay Plus	07/12/2015	
Dr John S Fenlon	Statistical Consultant	Lay	01/05/2015	
Mr David Grenz	Retired Police Officer	Lay Plus	01/08/2011	03/08/2016
Dr Brian Hands	Retired General Practitioner	Expert	01/11/2007	
Dr David Henson	Principal Clinical Biochemist	Lay	10/06/2008	
Mr Phil Hopkinson	Retired Mental Health Act Manager	Lay	01/03/2012	
Mr Peter Korczak (Chair)	Consultant Maxillofacial Surgeon	Expert	31/03/2004	
Mrs Janet Mallett	Retired Nurse	Lay	01/09/2011	
Ms Ngozi Okwudili-Ince	R&D Manager	Lay	01/06/2014	
Dr Penny Smith	Self Employed Writer	Lay Plus	16/01/2013	19/04/2016
Dr Margaret Stone	Senior Research Fellow (Retired)	Lay	07/08/2014	
Mr Michael Wakeman	Consultant Pharmacist	Expert	01/02/2012	
Mrs Anne Walker	Voluntary worker in Health Care	Lay Plus	01/09/2011	
Miss Sarah Wane	Physiotherapist	Expert	18/11/2015	17/04/2016
Mrs Georgia Young	CT/MRI Senior Radiographer	Expert	29/03/2016	

East Midlands - Derby Research Ethics Committee: Deputy Members

None

East Midlands - Derby Research Ethics Committee: Co-opted Members

None

East Midlands - Derby Research Ethics Committee: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Mrs Amanda Brammer	None declared	02/02/2017
Dr John S Fenlon	None declared	05/01/2017
Dr Brian Hands	None declared	01/12/2016
Dr David Henson	None declared	07/12/2016
Mr Phil Hopkinson	None declared	01/12/2016
Mr Peter Korczak (Chair)	None declared	05/01/2017
Mrs Janet Mallett	None declared	01/12/2016
Ms Ngozi Okwudili-Ince	None declared	07/12/2016
Dr Margaret Stone	Currently working on a voluntary basis with Thane Madni Education	07/12/2016
Mr Michael Wakeman	Total Health and Wellbeing Ltd	02/02/2017
Mrs Anne Walker	None declared	07/12/2016
Mrs Georgia Young	None declared	07/12/2016

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

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

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	04/04/2016	3
May	05/05/2016	3
June	02/06/2016	3
July	07/07/2016	3
August	04/08/2016	3
September	01/09/2016	3
November	03/11/2016	4
December	01/12/2016	3
January	05/01/2017	3
February	02/02/2017	3
March	02/03/2017	4

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	05/04/2016	2
April	21/04/2016	2
May	05/05/2016	2
May	19/05/2016	2
June	02/06/2016	2
June	16/06/2016	2
July	07/07/2016	2
July	21/07/2016	2
August	04/08/2016	2
August	18/08/2016	2

September	01/09/2016	2
September	01/09/2016	2
September	26/09/2016	2
October	11/10/2016	2
October	13/10/2016	2
October	20/10/2016	2
November	03/11/2016	2
November	18/11/2016	2
December	01/12/2016	2
December	21/12/2016	2
January	05/01/2017	2
January	19/01/2017	2
February	02/02/2017	2
February	16/02/2017	2
March	02/03/2017	2
March	16/03/2017	2

26 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
Miss Siobhan Ashton-Cleary	3
Mrs Amanda Brammer	6
Dr John S Fenlon	9
Mr David Grenz	2
Dr Brian Hands	8
Dr David Henson	10
Mr Phil Hopkinson	9
Mr Peter Korczak	7
Mrs Janet Mallett	10
Ms Ngozi Okwudili-Ince	4
Dr Margaret Stone	10
Mr Michael Wakeman	7
Mrs Anne Walker	7
Mrs Georgia Young	6

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

Name	Number of Meetings Attended
Mrs Amanda Brammer	4
Dr John S Fenlon	2
Dr Brian Hands	1
Dr David Henson	5
Mr Peter Korczak	6
Mrs Janet Mallett	6
Dr Margaret Stone	4
Mr Michael Wakeman	4
Mrs Anne Walker	3

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

Name	Number of Meetings Attended
Dr John S Fenlon	26
Mr Peter Korczak	22
Mrs Janet Mallett	4

Training 01 April 2016 - 31 March 2017

Name of Member	Date	Event(s) attended
Mrs Amanda Brammer	16/05/2016	E&D Training
Mrs Amanda Brammer	15/06/2016	Induction
Mrs Amanda Brammer	23/09/2016	Local Training Day - Regional
Dr John S Fenlon	01/12/2016	National Training Day for Committee Chairs
Dr Brian Hands	12/07/2016	Research Involving Adults Who Lack Capacity (including research in emergency situations)
Dr Brian Hands	23/09/2016	Local Training Day - Regional
Mr Phil Hopkinson	24/09/2016	Why bad science persists; Incentive malus' in science and technology section of The Economist
Mr Phil Hopkinson	05/11/2016	Read 'Psychiatric Ethics'
Mr Phil Hopkinson	08/02/2017	Read 'Principles of Biomedical Ethics' (2002)
Mr Peter Korczak (Chair)	23/09/2016	Local Training Day - Regional
Mr Peter Korczak (Chair)	01/12/2016	National Training Day for Committee Chairs
Mrs Janet Mallett	15/09/2016	E & D Elearning
Mrs Janet Mallett	23/09/2016	Local Training Day - Regional
Ms Ngozi Okwudili-Ince	26/10/2016	Qualitative Research and Ethical Review
Ms Ngozi Okwudili-Ince	16/02/2017	National Members Training Day
Dr Margaret Stone	23/09/2016	Local Training Day - Regional
Mr Michael Wakeman	16/02/2017	National Members Training Day
Mrs Anne Walker	20/10/2016	Quantitative Research Methods and Statistics: A Health Research Authority Workshop
Mrs Anne Walker	22/03/2017	National Members Training Day
Mrs Georgia Young	15/09/2016	Committee Members Induction
Mrs Georgia Young	23/09/2016	Local Training Day - Regional

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	15	33.33
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	1	2.22
Research Database (including renewals)	4	8.89
Others	25	55.56
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	0
Number of student applications reviewed	7
Number of paediatric applications reviewed	8
Number of device applications reviewed	1
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	4

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

Decisions taken at meetings following review of applications	Number	%
Favourable Opinion with Standard Conditions	2	4.44
Favourable Opinion with Additional Conditions	1	2.22
Unfavourable Opinion	0	0.00
Provisional Opinion	42	93.33
Provisional Opinion Pending Consultation with Referee	0	0.00
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	38	84.44
Further Information Favourable Opinion with Additional Conditions	4	8.89
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	2	4.44
Favourable Opinion with Additional Conditions	1	2.22
Unfavourable Opinion	0	0.00
Provisional Opinion	0	0.00
Provisional Opinion Pending Consultation with Referee	0	0.00
Further Information response not complete	0	0.00
No decision entered on system	0	0.00
Number of studies withdrawn after the meeting	0	0.00
Total	45	100

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

Total Applications Reviewed	33
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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	5
Number of studies withdrawn prior to the meeting	0
Number of student applications reviewed	11
Number of paediatric applications reviewed	3
Number of device applications reviewed	2
Number of qualitative applications reviewed	0

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	18.18
Favourable Opinion with Additional Conditions	7	21.21
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	20	60.61
Unfavourable Opinion	0	0.00
Total	33	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	4.50
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 completed applications for full ethical review over 40 days	19
Number of completed applications over 40 days as a % of total	42.22%
Number of days taken to final decision – average (mean)	40
Number of completed proportionate review applications for ethical review	33
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)	8
Number of completed proportionate review applications for ethical review over 21 days	0
Number of completed proportionate review applications over 14 days as a % of total	24.24%
Number of SSAs (non-Phase 1) reviewed	17
Number of completed applications for SSA review over 25 days	1
Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs	5.88%
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	7
Number of completed substantial amendments over 28 days as a % of total substantial amendments	5.51%
Number of modified amendments reviewed	0
Number of completed modified amendments over 14 days	0
Number of completed modified amendments over 14 days as a % of total modified amendments	0.00%
Number of non substantial amendments received	133

Number of substantial amendments received for information	4
Number of substantial amendments received for new sites/PIs	44
Number of annual progress reports received	108
Number of safety reports received	49
Number of Serious Adverse Events received	65
Number of final reports received	15

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/EM/0178	RATE-AF	47
16/EM/0180	Study to select the daily dose of Estetrol for vasomotor symptoms	33
16/EM/0181	TAMARIN	31
16/EM/0184	Santhera CRS	30
16/EM/0185	Medical Records Investigation; Smoke Free Homes	31
16/EM/0213	CHARIOT: Cognitive Health in Ageing Register	51
16/EM/0229	Nigrosomal Iron Imaging in Parkinson's Disease (N3iPD)	59
16/EM/0234	Safety Extension Study to Bora (MELTEMI)	30
16/EM/0237	Supporting Underserved Patients with their Medicines	55
16/EM/0238	How do partners of ICD recipients respond to ICD Electrical Storms?	40
16/EM/0279	PIONEER 5 - Type 2 Diabetes with Moderate Renal Impairment	50
16/EM/0286	Investigation into predictors of diagnosis in PAH patients	30
16/EM/0290	A pilot study to assess tolerability of low temperature haemodialysis	60
16/EM/0291	CAM-Pain Study	51
16/EM/0292	Scleroderma Heart Study	40
16/EM/0324	Safety&Efficacy of suvorexant for treatment of insomnia in AD subjects	31
16/EM/0326	Sleep and wellbeing study	56
16/EM/0327	Pilot study of cardiac abnormalities in ANCA associated vasculitis	37
16/EM/0332	MAXIMISE	60
16/EM/0334	RESPECT Study	56
16/EM/0335	Safety and Efficacy of PRX167700 in Patients with Knee Osteoarthritis	54
16/EM/0362	Complex trauma in relation to mental health	-28
16/EM/0371	The role of self-management education on self-efficacy for hearing aid	39
16/EM/0376	AQX-1125-301:Ph3 study of AQX-1125 for IC/BPS	40
16/EM/0380	Study 15	52
16/EM/0381	Jazz 15-007	52
16/EM/0442	Assessing current clinical concepts in dental practice. v1.0	38
16/EM/0455	The effect of Darbepoetin alfa on forearm blood flow (OPERA-CKD)	33
16/EM/0483	Thermal imaging in old and frail in the community	28
16/EM/0485	Hearing the voice of Looked After Children: A qualitative study.	24
17/EM/0004	Optimising Pacemaker Therapy for Contractility	55
17/EM/0005	Study of Omecamtiv Mecarbil in Patients with Chronic Heart Failure	48

17/EM/0007	Preoperative Substance Use: Prevalence, Detection & Outcomes	47
17/EM/0008	Phase IIa study of Bimekizumab (UCB4940) in Ulcerative Colitis	46
17/EM/0053	Cell of Origin and MYC Rearrangements and Outcomes in Patients	31
17/EM/0055	Spirolactone with Patiromer in the Treatment of Resistant HTN in CKD	31
17/EM/0086	Can supplemental leucine offset disuse-induced muscle atrophy?	32
17/EM/0091	Managing Medicines	31

Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/EM/0282	The STAR articulation therapy app evaluation study	60
16/EM/0488	The BABY STEPS study	37
17/EM/0030	ROH Research Tissue Bank	41
17/EM/0094	Use of an automated pupilometer after a stroke	39

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/EM/0440	Linked de-identified research database for congenital anomaly outcomes	27
16/EM/0480	Epidemiology and causes of death in coeliac disease	21

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
17/EM/0002	NKTR-102 in Metastatic Breast Cancer	26

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
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Provisional Opinion

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

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

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

REC Reference	Title	Number of Days on Clock
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Table 9.2: Breakdown of current status of all PRS applications reviewed within the reporting period

Further Information Favourable Opinion with Standard Conditions

REC Reference	Title	Number of Days on Clock
16/EM/0138	Psychosocial outcomes in women at familial breast cancer risk 2	14
16/EM/0150	The impact of multimorbidity across the cancer care continuum.	17
16/EM/0187	HEAD-US SCORING SYSTEM-Real life experience study	11
16/EM/0245	Development of an EORTC QoL Module for Pancreatic NET: Phases 1-3 v1.0	13
16/EM/0247	CLEARLY - Janssen PACC ALZ0001 Study	11
16/EM/0249	Vascular function in cyclists	14
16/EM/0300	RLS Act-DM1 v1.4	14
16/EM/0302	Inflammasome regulation in Cryopyrin Associated Periodic Syndromes	14
16/EM/0303	A comparison of thermoplastic and 3D printed masks for EBRT	14
16/EM/0340	Atrial Morphology and Ethnicity	14
16/EM/0341	OPAL	14
16/EM/0342	Congenital Porto-Systemic Shunts and the Development of Liver Tumours	10
16/EM/0343	RECOVERY DVTPE Tt & Secondary Prevention/Acute Venous Thromboembolism	10
16/EM/0496	ELLIPTA Vs combined Inhalers in COPD patients	11
16/EM/0502	Making Waves: Ripple 2 Evaluation	19

17/EM/0048	Non-invasive vagus nerve stimulation for gait and cognition	19
17/EM/0049	Understanding Pain Study	20
17/EM/0050	Feasibility study of salivary pepsin measurement during AE-COPD	18
17/EM/0093	Digital Media and Engagement in Early Intervention Psychosis	21

Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/EM/0466	DIB-NET Study	14

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/EM/0387	Investigating the Burden of Illness associated with FCS	13
16/EM/0388	The identification of residual BPPV by telephone treatment	10
16/EM/0390	Expression of P504s and P53 in Serrated Polyps of the Colon	9
17/EM/0019	Microcirculatory normal ranges using CytoCam-IDF imaging - v1.0	8
17/EM/0095	Developing rapid screening for CPOs at Barts Trust	10
17/EM/0096	Patient-Centred Outcome Measures for Major Surgery (P-COMMaS)	14

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/EM/0148	Deep Brain Activity in Cluster Headache and Mood Disorder	16
16/EM/0151	Long non-coding RNA melanoma markers	8
16/EM/0188	Co-existing skin cancers and chronic lymphocytic leukaemia	11
16/EM/0191	AQUARiUS	14
16/EM/0389	The Role of Frailty in Patients with Multiple Myeloma	7
17/EM/0017	LVRC Microbiome Study	16
17/EM/0047	foot fungal infection in primary care population	15

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
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Provisional Opinion

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

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

REC Reference	Title	Number of Days on Clock
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Table 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
01/4/025/AM18	Effectiveness of Treatment for Clinically Localised Prostate Cancer	26	19/05/2016	27
01/4/025/AM19	Effectiveness of Treatment for Clinically Localised Prostate Cancer	SA 27	28/06/2016	24
03/4/093/AM05	The CAP (Comparison Arm to ProtecT) study	SA 9	22/12/2016	20
04/MRE04/79/AM35	EURAMOS 1 treatment strategies in resectable osteosarcoma (v 0.1)	SA 06.02.2017	06/02/2017	33
06/MRE04/18/AM18	Extension to efficacy and safety of laquinimod in patients with RR-MS	10	25/02/2016	20
06/MRE04/18/AM19	Extension to efficacy and safety of laquinimod in patients with RR-MS	local protocol amendment 5	03/06/2016	18
06/MRE04/18/AM20	Extension to efficacy and safety of laquinimod in patients with RR-MS	20	10/10/2016	20
06/MRE04/19/AM23	PI dasatinib childhood leukaemia study CA180-018	23	14/09/2016	22
06/MRE04/65/AM17	Bladder Cancer Prognosis Programme (incorporating SELENIB Trial)	17	18/08/2016	34
09/H0401/70/AM06	Implantable Cardioverter Defibrillators: Improving Risk Stratification	SA5	15/06/2015	27
09/H0401/70/AM07	Implantable Cardioverter Defibrillators: Improving Risk Stratification	30.06.2016	30/06/2016	20
09/H0401/88/AM02	Fibrotic quantification of renal transplant biopsies	19.07.2016	19/07/2016	27
09/H0405/28/AM14	CRUK / CCLG AT9283 in Paediatric Patients	11.03.2016	11/03/2016	17
09/H0405/44/AM32	Neratinib after Trastuzumab in early stage breast cancer.	SA07.10.16	07/10/2016	26
09/H0405/51/AM22	CA180226: PII childhood leukaemia dasatinib study (version 1 9/Jul/08)	18	11/11/2016	19
09/H0405/9/AM22	DMD-Heart Protection Trial	18	17/12/2015	13
10/H0401/16/AM16	Questionnaire for assessing everyday processing in children, version 2	5	30/06/2016	27
10/H0405/16/AM05	Surgery and Central Aortic Blood Pressure	SA3	10/08/2016	14
10/H0405/16/AM07	Surgery and Central Aortic Blood Pressure	SA 4	24/11/2016	14
10/H0405/29/AM10	FIAT	Amendment 7	11/03/2016	20

10/H0405/70/AM40	ExACT Extended anticoagulation treatment for VTE: a randomised trial	SA 33	31/08/2016	23
10/H0405/90/AM30	The seAFood Polyp Prevention Trial	19	22/08/2016	21
11/EM/0393/AM13	RADICAL, v1.0	SA8	29/07/2016	5
11/EM/0398/AM22	MK-0431A in Pediatric Patients with Type 2 Diabetes Mellitus	14	16/06/2016	20
12/EM/0048/AM02	ROH Research Tissue Bank	2	30/06/2016	30
12/EM/0208/AM09	The GENVASC Study:Genetics and the Vascular Health Check Programme	6	24/10/2016	18
12/EM/0426/AM08	Donate for Research Initiative (DRI)	26.04.2016	26/04/2016	9
12/EM/0448/AM10	MESO-02	SA 6	09/01/2017	12
13/EM/0029/AM07	Mito Exome Sequencing Study. Version 1.	SA3	29/09/2016	18
13/EM/0154/AM16	Scaphoid Waist Internal Fixation for Fractures (SWIFFT) Trial (v1)	SA 4	14/09/2016	27
13/EM/0264/AM02	UK LAM Cohort Version 1.0	2	13/10/2016	24
13/EM/0287/AM04	Respiratory Research Database	4	25/11/2016	35
13/EM/0395/AM15	Treatment of Advanced Glaucoma Study (TAGS)	SA 14	18/04/2016	9
13/EM/0395/AM17	Treatment of Advanced Glaucoma Study (TAGS)	SA 15	11/11/2016	28
13/EM/0398/AM07	EPIVIN trial (v 1.0)	7	01/06/2016	15
13/EM/0398/AM08	EPIVIN trial (v 1.0)	AM08	14/06/2016	21
13/EM/0398/AM09	EPIVIN trial (v 1.0)	SA 09	03/08/2016	23
13/EM/0398/AM10	EPIVIN trial (v 1.0)	SA 10	27/10/2016	27
13/EM/0479/AM04	ASPIRE	1	11/05/2016	7
14/EM/0031/AM07	Infra-red thermal imaging of the surgical wound: ver 1	01.06.2016	01/06/2016	28
14/EM/0031/AM08	Infra-red thermal imaging of the surgical wound: ver 1	11 July 2016	11/07/2016	28
14/EM/0174/AM06	Anti-FGF23 antibody, KRN23, in pediatric patients with XLH	IB Amendment, V11.0 19Nov2015	19/11/2015	8
14/EM/0174/AM07	Anti-FGF23 antibody, KRN23, in pediatric patients with XLH	SA 6	08/11/2016	22
14/EM/0203/AM08	109MS306, Paediatric Relapsing MS (10 - <18 years), BG00012	SA #8	22/04/2016	11
14/EM/0203/AM09	109MS306, Paediatric Relapsing MS (10 - <18 years), BG00012	SA 9	08/03/2017	12
14/EM/1011/AM01	Automated pupil measurement in glaucoma and other optic nerve diseases	1.0	10/05/2016	22
14/EM/1035/AM08	Prospective Study of Second Line Therapy for Acute GVHD(IRAS version1)	Substantial Amendment 1	03/08/2016	15
14/EM/1049/AM04	COCO Tx	SA4	03/11/2016	16

14/EM/1105/AM04	Inter-SPACE COPD self-management project	Amendment 2	01/04/2016	9
14/EM/1105/AM05	Inter-SPACE COPD self-management project	3	13/06/2016	28
14/EM/1105/AM07	Inter-SPACE COPD self-management project	SA#4	09/01/2017	14
14/EM/1105/AM08	Inter-SPACE COPD self-management project	5	01/03/2017	11
14/EM/1107/AM01	Fluorescent Imaging and Methylene Blue: Ureter Study	1	10/05/2016	20
14/EM/1111/AM02	Understanding the effects of acne	SA 2	20/09/2016	15
14/EM/1113/AM07	MOCAM	SA5	07/04/2016	27
14/EM/1124/AM03	Understanding Symptom Experiences Fully (The USEFUL study) version 1	2	15/11/2016	24
14/EM/1128/AM01	Birmingham Dental School Tooth Bank	Substantial amendment 1	04/04/2016	22
14/EM/1131/AM05	High intensity exercise training in older colorectal cancer patients	Amendment 2	18/03/2016	26
14/EM/1139/AM05	AP26113 in patients with Non-Small Cell Lung Cancer	14.03.2016	14/03/2016	17
14/EM/1139/AM06	AP26113 in patients with Non-Small Cell Lung Cancer	21/12/2016	21/12/2016	15
14/EM/1272/AM05	BUTEO: A clinical trial of BTT1023 in patients with PSC	Amendment 3	16/03/2016	27
14/EM/1290/AM07	UK Inflammatory Bowel Disease Inception Cohort Study	SA 4	14/10/2016	14
15/EM/0002/AM06	An Investigation of Arousal and Escape Behaviour in Fragile X Syndrome	SA2	12/05/2016	10
15/EM/0004/AM05	A 34-week Follow-up to: MK-0431A in Pediatric Patients with Type 2 Diabetes Mellitus	04	16/06/2016	20
15/EM/0066/AM04	Paediatric Study with Blinatumomab in Acute Lymphoblastic Leukaemia	Amendment 3	08/04/2016	19
15/EM/0066/AM05	Paediatric Study with Blinatumomab in Acute Lymphoblastic Leukaemia	4	09/05/2016	23
15/EM/0066/AM07	Paediatric Study with Blinatumomab in Acute Lymphoblastic Leukaemia	6	22/02/2017	14
15/EM/0066/AM08	Paediatric Study with Blinatumomab in Acute Lymphoblastic Leukaemia	SA 7	24/02/2017	24
15/EM/0069/AM09	CLL14 - study of GDC-0199 in CLL	SA 7	26/10/2016	15
15/EM/0196/AM05	Robot Assisted Physiotherapy Exercises With REX.	2	06/05/2016	23
15/EM/0197/AM05	A feasibility study of treatments for Dupuytren's Contracture	02	22/06/2016	15
15/EM/0222/AM01	Kidney Injury after Major Surgery (KIMS)	1	13/06/2016	18
15/EM/0240/AM01	OMMIT-1	Amendment 1	22/02/2016	8
15/EM/0244/AM03	OMMIT 2	3	09/12/2016	21
15/EM/0280/AM03	Left Ventricular Myocardial Fibrosis in early CKD	Second	31/03/2016	22

		amendment		
15/EM/0284/AM09	PRISM-2 Study	5	27/06/2016	11
15/EM/0323/AM01	LCH-IV	SA01	23/03/2016	16
15/EM/0358/AM03	Feasibility Study of a Mobile App for Preconception Care of Women v 1	21.06.2016	21/06/2016	17
15/EM/0391/AM02	PINK	2	15/06/2016	28
15/EM/0480/AM02	Sitagliptin vs. Dapagliflozin As Add-on to Metformin in Subjects with Mild Renal Impairment	02	03/06/2016	18
15/EM/0487/AM09	M13-594 - Study in Subjects with Genotype 3 Chronic HCV infection	SA (second)	09/08/2016	21
15/EM/0488/AM01	Factors Influencing Patient Choice in Type of Breast Reconstruction	04.07.16	04/08/2016	20
15/EM/0502/AM02	Rockers shoes and knee osteoarthritis	05.12.2016	05/12/2016	18
15/EM/0539/AM01	Advanced Care Planning & Decision Making for EOLC in PICU. Version 1.1	Amendment 1.0.1	31/05/2016	2
15/EM/0542/AM04	RSPR-008	Amendment 1		17
15/EM/0542/AM06	RSPR-008	SA#02	15/07/2016	27
15/EM/0543/AM03	Phase 3 Blinatumomab in Paediatric Subjects With B-precursor ALL	Amendment 1	19/04/2016	8
15/EM/0543/AM04	Phase 3 Blinatumomab in Paediatric Subjects With B-precursor ALL	SA 2	08/06/2016	13
16/EM/0006/AM04	LPS14409 - TAKE CONTROL	SA1	01/08/2016	26
16/EM/0006/AM05	LPS14409 - TAKE CONTROL	2	15/08/2016	35
16/EM/0006/AM07	LPS14409 - TAKE CONTROL	SA03	02/09/2016	8
16/EM/0007/AM03	GALILEO	Protocol V3	17/08/2016	15
16/EM/0007/AM05	GALILEO	SA 4	30/12/2016	22
16/EM/0008/AM02	ALXN1101 in Newborns with molybdenum cofactor deficiency	2.0	23/06/2016	15
16/EM/0008/AM03	ALXN1101 in Newborns with molybdenum cofactor deficiency	3.0	21/11/2016	21
16/EM/0009/AM01	Post-traumatic cognitive processes in secondary school pupils	Amendment 1	05/04/2016	7
16/EM/0009/AM02	Post-traumatic cognitive processes in secondary school pupils	SA2	06/10/2016	26
16/EM/0040/AM01	SEESAW	01	13/04/2016	21
16/EM/0040/AM04	SEESAW	SA2	06/10/2016	26
16/EM/0043/AM02	CEASE-AF	Revision G	23/08/2016	29
16/EM/0062/AM02	Clinical Study 3MESPE Crowns	SA 1	19/04/2016	7
16/EM/0081/AM02	Clinical Efficacy & Safety of AP CD/LD in Fluctuating PD	2	05/12/2016	8
16/EM/0082/AM02	OPEN-LABEL EXTENSION and FOLLOW-UP of STUDY IN 11	2	05/12/2016	8

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16/EM/0104/AM01	CIDP: Development of a PRO Strategy	SA 1	14/10/2016	23
16/EM/0108/AM01	Risk Stratification tools to identify patients with advanced COPD	1	01/06/2016	15
16/EM/0180/AM01	Study to select the daily dose of Estetrol for vasomotor symptoms	1	19/08/2016	33
16/EM/0180/AM02	Study to select the daily dose of Estetrol for vasomotor symptoms	SA 1 re submission	06/10/2016	26
16/EM/0180/AM03	Study to select the daily dose of Estetrol for vasomotor symptoms	SA 2	03/02/2017	21
16/EM/0213/AM01	CHARIOT: Cognitive Health in Ageing Register	SA 1	24/01/2017	27
16/EM/0213/AM02	CHARIOT: Cognitive Health in Ageing Register	2	17/02/2017	19
16/EM/0234/AM04	Safety Extension Study to Bora (MELTEMI)	SA 3	13/02/2017	23
16/EM/0247/AM01	CLEARLY - Janssen PACC ALZ0001 Study	SA 1	09/01/2017	16
16/EM/0249/AM01	Vascular function in cyclists	SA 1	13/10/2016	14
16/EM/0279/AM04	PIONEER 5 - Type 2 Diabetes with Moderate Renal Impairment	SA 01	19/01/2017	27
16/EM/0286/AM01	Investigation into predictors of diagnosis in PAH patients	SA 1	31/10/2016	8
16/EM/0290/AM01	A pilot study to assess tolerability of low temperature haemodialysis	SA 1	15/11/2016	17
16/EM/0291/AM01	CAM-Pain Study	SA 1	17/02/2017	16
16/EM/0324/AM04	Safety&Efficacy of suvorexant for treatment of insomnia in AD subjects	SA03	08/12/2016	9
16/EM/0326/AM01	Sleep and wellbeing study	SA 1	29/11/2016	10
16/EM/0327/AM01	Pilot study of cardiac abnormalities in ANCA associated vasculitis	SA1	23/09/2016	22
16/EM/0335/AM01	Safety and Efficacy of PRX167700 in Patients with Knee Osteoarthritis	SA 1	24/11/2016	18
16/EM/0343/AM01	RECOVERY DVTPE Tt & Secondary Prevention/Acute Venous Thromboembolism	SA 1	15/12/2016	14
16/EM/0376/AM01	AQX-1125-301:Ph3 study of AQX-1125 for IC/BPS	SA 2	19/10/2016	14
16/EM/0387/AM01	Investigating the Burden of Illness associated with FCS	SA1	21/09/2016	21
16/EM/0455/AM01	The effect of Darbepoetin alfa on forearm blood flow (OPERA-CKD)	1	01/03/2017	19
16/EM/0488/AM02	The BABY STEPS study	1	31/01/2017	14
17/EM/0002/AM04	NKTR-102 in Metastatic Breast Cancer	2	24/02/2017	18

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

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
None				

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

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

REC Reference	Title	Number of Days on Clock
None		

Proportionate review applications for ethical review over 21 day timeline

REC Reference	Title	Number of Days on Clock
None		

SSAs (non Phase 1) over 25 day timeline

REC Reference	Title	Number of Days on Clock
None		

SSAs (Phase 1) over 14 day timeline

REC Reference	Title	Number of Days on Clock
None		

Substantial Amendments over 35 day timeline

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

Modified Amendments over 14 day timeline

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