

East Midlands - Derby Research Ethics Committee

Annual Report

01 April 2015 - 31 March 2016



Part 1 – Committee Membership and Training

Name of REC:	East Midlands - Derby Research Ethics Committee
Type of REC:	Recognised to review CTIMPs in Patients – Type III
Type of Flag:	Research Involving Children Research Database Studies Research Tissue Bank Studies
Chair:	Mr Peter Korczak (Chair)
Vice-Chair:	Dr John S Fenlon
Alternate Vice-Chair:	Mrs Janet Mallett
REC Manager:	Miss Victoria Strutt
REC Assistant:	N/A
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 have been invaluable helping me with this workload.

The regular NREAP meetings have helped the chair and vice-chairs better understand and contribute to the streamlining of the review process. The committee has also enjoyed being part of the shared ethical debate exercise, although it would be better if it was truly anonymous.

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.

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.

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	
Mrs Amanda Brammer	Student - Derby University	Lay Plus	06/05/2015	
Dr John S Fenlon	Statistical Consultant	Lay	01/05/2015	
Mr David Grenz	Retired Police Officer	Lay Plus	01/08/2011	
Dr Brian Hands	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	
Mrs Bernadette Roberts	Retired Finance Manager	Lay	21/04/2015	03/12/2015
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

Name	Profession	Status	Meeting date attended
None			

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

Name	Profession	Status	Meeting date attended
None			

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

Name	Declaration of Interest	Date
Miss Siobhan Ashton-Cleary	Works at Diabetes Dietician at Royal Derby Hospital	04/03/2016
Dr John S Fenlon	None declared	18/01/2016
Mr David Grenz	None declared	18/01/2016
Dr Brian Hands	None declared, but has now retired as a GP (Nov 2015)	18/01/2016
Dr David Henson	None declared	12/02/2016
Mr Phil Hopkinson	None declared	18/01/2016
Mr Peter Korczak (Chair)	None declared	18/01/2016
Mrs Janet Mallett	None declared	18/01/2016
Ms Ngozi Okwudili-Ince	No longer involved in NHSA or University R&D Management.	01/04/2015
Dr Margaret Stone	Currently working on a voluntary basis with Thane Madni Education	18/01/2016
Mrs Anne Walker	Volunteer for Health Watch Derbyshire	18/01/2016
Mr Michael Wakeman	Total Health and Wellbeing LTD	02/02/2016
Mrs Georgia Young	None declared	29/03/2016

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

Month	Date	Number of Members Present at Meeting
May	07/05/2015	11
June	04/06/2015	11
July	02/07/2015	9
August	06/08/2015	9
September	03/09/2015	10
November	05/11/2015	11
December	03/12/2015	12
January	07/01/2016	11
February	04/02/2016	12
March	03/03/2016	9

10 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
May	07/05/2015	3
June	04/06/2015	3
August	06/08/2015	3
September	03/09/2015	3
October	01/10/2015	3
November	05/11/2015	3
December	03/12/2015	3
January	07/01/2016	3
February	04/02/2016	3
March	03/03/2016	3

10 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	16/04/2015	2
May	07/05/2015	2
May	07/05/2015	2
May	21/05/2015	2
June	04/06/2015	2
June	18/06/2015	2
July	02/07/2015	2
July	16/07/2015	2
August	06/08/2015	2
August	20/08/2015	2

September	03/09/2015	2
September	17/09/2015	2
October	01/10/2015	2
October	15/10/2015	2
November	05/11/2015	2
November	19/11/2015	2
December	03/12/2015	2
December	17/12/2015	2
January	07/01/2016	2
January	21/01/2016	2
February	04/02/2016	2
February	18/02/2016	2
March	03/03/2016	2
March	17/03/2016	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		

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

Name	Number of Meetings Attended
Miss Siobhan Ashton-Cleary	3
Mrs Amanda Brammer	3
Dr John S Fenlon	7
Mr David Grenz	9
Dr Brian Hands	10
Dr David Henson	9
Mr Phil Hopkinson	6
Mr Peter Korczak	10
Mrs Janet Mallett	10
Ms Ngozi Okwudili-Ince	7
Mrs Bernadette Roberts	7
Dr Margaret Stone	10
Mr Michael Wakeman	5
Mrs Anne Walker	8
Miss Sarah Wane	1

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

Name	Number of Meetings Attended
Mr David Grenz	3
Dr David Henson	2
Mr Peter Korczak (Chair)	5
Mrs Janet Mallett	7
Ms Ngozi Okwudili-Ince	1
Mrs Bernadette Roberts	1
Dr Margaret Stone	5
Mr Michael Wakeman	5
Mrs Anne Walker	1

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

Name	Number of Meetings Attended
Dr John S Fenlon	20
Dr Brian Hands	2
Mr Peter Korczak	22
Mrs Janet Mallett	4
Mr Michael Wakeman	1

Training 01 April 2015 - 31 March 2016

Name of Member	Date	Event(s) attended
Mrs Amanda Brammer	15/06/2015	Training - Committee Members 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 Geonomics Research
Mr David Grenz	25/09/2015	Members Regional Training Day
Dr David Henson	25/09/2015	Members Regional Training Day
Mr Phil Hopkinson	25/07/2015	Read article 'Spilling the Beans' article in Clinical trials section of The Economist
Mr Phil Hopkinson	01/11/2015	Bad Blood: the Tuskegee Syphilis Experiment' (1993) Free Press
Mr Phil Hopkinson	26/03/2016	For my next trick..... article in clinical trials section of The Economist
Mr Peter Korczak (Chair)	25/09/2015	Members Regional Training Day
Mrs Janet Mallett	15/05/2015	NREAP Meeting
Mrs Janet Mallett	25/09/2015	Members Regional Training Day
Ms Ngozi Okwudili-Ince	21/01/2016	Research involving adults who lack capacity
Ms Ngozi Okwudili-Ince	16/03/2016	National Members Training Day
Mrs Bernadette Roberts	20/05/2015	CTIMPS Training
Mrs Bernadette Roberts	15/06/2015	Committee members induction
Mrs Bernadette Roberts	30/06/2015	HTA
Mrs Bernadette Roberts	25/09/2015	Members Regional Training Day
Dr Margaret Stone	30/11/2015	Improving Healthcare through Clinical Research
Mr Michael Wakeman	27/11/2015	CTIMP Training Day
Mrs Anne Walker	11/03/2016	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)	3	5.26
Research Database (including renewals)	6	10.53
Others	34	59.65
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	15
Number of paediatric applications reviewed	10
Number of device applications reviewed	2
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	6

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

Decisions taken at meetings following review of applications	Number	%
Favourable Opinion with Standard Conditions	5	8.77
Favourable Opinion with Additional Conditions	6	10.53
Unfavourable Opinion	4	7.02
Provisional Opinion	42	73.68
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	41	71.93
Further Information Favourable Opinion with Additional Conditions	0	0.00
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	5	8.77
Favourable Opinion with Additional Conditions	6	10.53
Unfavourable Opinion	4	7.02
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	1	1.75
Total	57	100

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

Total Applications Reviewed	31
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Table 6: Breakdown of PRS applications and other activity during reporting period:

Number of applications made invalid by the REC Manager	6
Number of studies withdrawn prior to the meeting	0
Number of student applications reviewed	11
Number of paediatric applications reviewed	3
Number of device applications reviewed	1
Number of qualitative applications reviewed	3

Table 7: Decisions given at proportionate review sub-committee meetings held within the reporting period

Decisions taken at proportionate review sub-committee meetings	Number	%
Favourable Opinion with Standard Conditions	5	16.13
Favourable Opinion with Additional Conditions	1	3.23
No Opinion transfer to full committee for review	1	3.23
Provisional Opinion	21	67.74
Unfavourable Opinion	3	9.68
Total	31	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	56
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	7
Number of completed applications over 40 days as a % of total	12.28%
Number of days taken to final decision – average (mean)	32
Number of completed proportionate review applications for ethical review	30
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	4
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	150
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	10
Number of completed substantial amendments over 28 days as a % of total substantial amendments	6.67%
Number of modified amendments reviewed	1
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	114
Number of substantial amendments received for information	0
Number of substantial amendments received for new sites/Pis	19
Number of annual progress reports received	126

Number of safety reports received	49
Number of Serious Adverse Events received	61
Number of final reports received	27

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/EM/0150	Optimum Patient Care Research Database	19
15/EM/0158	Daslne: database of children with ASD living in the North East	26
15/EM/0196	Robot Assisted Physiotherapy Exercises With REX.	21
15/EM/0197	A feasibility study of treatments for Dupuytren's Contracture	22
15/EM/0231	Preemptive paracetamol for postoperative pain	20
15/EM/0236	'Our care through our eyes' study	19
15/EM/0244	OMMIT 2	22
15/EM/0252	Registry of Autoimmune Rheumatic Diseases	18
15/EM/0279	Improving compliance to radiotherapy in prostate cancer management.	26
15/EM/0280	Left Ventricular Myocardial Fibrosis in early CKD	42
15/EM/0281	Venous Leg Ulcers and Falls	29
15/EM/0284	PRISM-2 Study	36
15/EM/0295	Retinal Oxygenation Mapping in AMD	37
15/EM/0323	LCH-IV	38
15/EM/0339	An integrated intervention to prevent obesity in infants.	33
15/EM/0349	In ED resuscitation patients, can Renal RI predict development of AKI?	35
15/EM/0354	The diagnostic value of the median-ulnar 2LIO comparison study.	26
15/EM/0375	Experiences and sense-making of problematic mephedrone use	40
15/EM/0397	An investigation of patient experiences with PIP joint replacements	40
15/EM/0480	Sitagliptin vs. Dapagliflozin As Add-on to Metformin in Subjects with Mild Renal Impairment	35
15/EM/0482	Retinal imaging after TBI	31
15/EM/0487	M13-594 - Study in Subjects with Genotype 3 Chronic HCV infection	34
15/EM/0488	Factors Influencing Patient Choice in Type of Breast Reconstruction	36
15/EM/0523	Studies into nurturing and development of pregnancies	38
15/EM/0542	RSPR-008	30
15/EM/0543	Phase 3 Blinatumomab in Paediatric Subjects With B-precursor ALL	40
16/EM/0006	LPS14409 - TAKE CONTROL	43
16/EM/0007	GALILEO	34
16/EM/0008	ALXN1101 in Newborns with molybdenum cofactor deficiency	52
16/EM/0009	Post-traumatic cognitive processes in secondary school pupils	52
16/EM/0026	Collection of spine and joint tissues for research into human disease	26
16/EM/0034	Study of volatiles from pleural fluid	58

16/EM/0040	SEESAW	53
16/EM/0043	CEASE-AF	31
16/EM/0055	ACTION: A qualitative study	40
16/EM/0075	Preoperative HIIT in older cancer patients. Version 1.0	31
16/EM/0077	Placental site and other rare trophoblastic tumour database	33
16/EM/0081	Clinical Efficacy & Safety of AP CD/LD in Fluctuating PD	33
16/EM/0082	Open-label extension and follow up of study in 11 004	33
16/EM/0089	MACE study	34
16/EM/0095	The development of a blood test for early osteoarthritis	29

Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
None		

Further Information Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
None		

Favourable Opinion with Standard Conditions

REC Reference	Title	Number of Days on Clock
15/EM/0240	OMMIT-1	23
15/EM/0340	Role of Surgical Centralisation on Renal Cancer Survival	25
15/EM/0394	LD Service Users and Challenging Behaviour	29
15/EM/0541	(duplicate) Bladder Cancer Chemotherapy Analysis	25
16/EM/0013	Survival in Children and Young People with Life-limiting Conditions	43

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/EM/0186	Scottish Mental Health Research Register Database	28
15/EM/0251	High-flow nasal oxygen in high risk cardiac surgical patients	14
15/EM/0391	PINK	29
15/EM/0483	Drug Eluting balloon Venoplasty in Arterio-venous fistula stenosis: v1	28

15/EM/0539	Advanced Care Planning & Decision Making for EOLC in PICU. Version 1.1	25
16/EM/0038	STRIDE - 2 follow up study	26

Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock
15/EM/0292	A study of oral EMA401 in the treatment of painful diabetic neuropathy	39
15/EM/0293	A postherpetic neuralgia study about safety and efficacy of EMA401	39
15/EM/0396	West Midlands Regional Children's Tumour Registry	29
15/EM/0493	IPS Mental Health & Employment Support Evaluation	28

Provisional Opinion		
REC Reference	Title	Number of Days on Clock
None		

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

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

Withdrawn after the meeting		
REC Reference	Title	Number of Days on Clock
15/EM/0195	The effects of a 10-day meditation intervention in a prison population	21

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/EM/0221	Ambulatory blood pressure monitoring in patients on rivaroxaban	10
15/EM/0222	Kidney Injury after Major Surgery (KIMS)	14
15/EM/0223	Patient Use of Social Media - version 1	12
15/EM/0261	Smartphone-Based Monitoring of Cardiac Arrhythmia 1.0	14
15/EM/0263	Experiences of Psychological Support in Inpatient Settings	12
15/EM/0358	Feasibility Study of a Mobile App for Preconception Care of Women v 1	10
15/EM/0360	mHealth to assist with the self-management of asthma	13
15/EM/0361	A Positive Psychology Group for Stroke Survivors and Carers.	9
15/EM/0366	Trace Element Abundance and Renal Disease	7
15/EM/0412	Treating beyond symptoms patient views	12
15/EM/0458	functional ability & sensory processing mild - mod dementia	13
15/EM/0462	Levels of inhaled medicines in asthma and COPD patients, v1	10
15/EM/0502	Rockers shoes and knee osteoarthritis	9
15/EM/0504	A narrative exploration of unexplained chest pain	9
15/EM/0505	DNA damage and repair v1012015	13
15/EM/0556	MIC MAGEC	14
15/EM/0559	Lifestyle	12
16/EM/0061	Assessing serum chemokines in head and neck cancer patients	14
16/EM/0062	Clinical Study 3MESPE Crowns	10
16/EM/0104	CIDP: Development of a PRO Strategy	8
16/EM/0106	Understanding the determinants of medication adherence in hypertension	8

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
None		

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

Favourable Opinion with Standard Conditions

REC Reference	Title	Number of Days on Clock
15/EM/0260	Informing the development of care pathways for psychiatric emergencies	8
15/EM/0262	Cardiff Congenital Hearts (CCHIRPP)	8
15/EM/0503	GI complications following cardiac surgery in children	8
16/EM/0103	Social factors influencing uptake of free eye examinations	8
16/EM/0108	Risk Stratification tools to identify patients with advanced COPD	7

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/EM/0414	Living with long-term conditions: validation of the LTCQ	6

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
15/EM/0417	EpiMET	6
16/EM/0021	Objective Measurement of Eyelid Margin Lissamine Green Staining	14
16/EM/0023	PEVES V1	14

Provisional Opinion

REC Reference	Title	Number of Days on Clock
None		

Further information response not complete

REC Reference	Title	Number of Days on Clock
None		

Withdrawn after the meeting

REC Reference	Title	Number of Days on Clock
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
01/4/061/AM13	novel treatment strategies in progressing prostate cancer	SA#09	12/06/2015	16
01/4/087/AM18	High risk Neuroblastoma Study 1 of SIOP Europe	SA#21	13/07/2015	10
03/4/021/AM04	Q RESEARCH	Amendment 3	10/08/2015	34
03/4/093/AM03	The CAP (Comparison Arm to ProtecT) study	Substantial Amendment 7	18/11/2015	14
03/4/093/AM04	The CAP (Comparison Arm to ProtecT) study	Amendment 8	02/12/2015	9
04/MRE04/41/AM14	Functional Imaging of Tumours	SA#05	11/03/2015	21
04/MRE04/70/AM12	Genetics and skin barrier function in atopic eczema	SA13	22/07/2015	14
04/MRE04/79/AM31	EURAMOS 1 treatment strategies in resectable osteosarcoma (v 0.1)	12/05/2015	12/05/2015	13
05/MRE04/13/AM17	EpSSG RMS 2005 - Final January 2005	CRCTU SA 17	03/07/2015	16
05/MRE04/37/AM13	EpSSG NRSTS 2005 - UK Final Version 2.0 June 2005	11.08.14	12/03/2015	26
05/MRE04/78/AM04	The CAP (Comparison Arm for ProtecT) Study: part II v.2	Amendment 7	17/11/2015	20
05/MRE04/87/AM07	CPRD: anonymised data for use in observational research (Version 1)	SA New CI	19/06/2015	19
06/MRE04/18/AM16	Extension to efficacy and safety of laquinimod in patients with RR-MS	15.09.2015	15/09/2015	30
06/MRE04/19/AM22	PI dasatinib childhood leukaemia study CA180-018	SA #22	02/09/2015	23
06/MRE04/22/AM01	Placental site tumour database (Version 3)	SA#01	20/04/2015	21
06/MRE04/36/AM11	Interfant-06 (UK Final Version 1.0 May 2006)	SA11	15/07/2015	28
06/MRE04/65/AM16	Bladder Cancer Prognosis Programme (incorporating SELENIB Trial)	Substantial amendment 16	08/05/2015	19
07/H0405/70/AM41	20060289 - Denosumab (AMG162) in postmenopausal osteoporosis	Substantial amendment 32	12/05/2015	15
07/MRE04/31/AM04	Identification and propagation of conjunctival stem cell-rich sites.	SA#4	25/07/2015	21
07/MRE04/37/AM15	SIOPEL 6	SA#11	10/03/2015	20
08/H0401/63/AM16	Human colorectal tissue studies	Amendment 6	21/06/2015	25
08/h0405/22+5/AM01	Children's Cancer and Leukaemia Group (CCLG) Tissue Bank	26/06/2015	26/06/2015	9

09/H0405/44/AM27	Neratinib after Trastuzumab in early stage breast cancer.	SA - Site Call Script	18/03/2015	19
09/H0405/44/AM28	Neratinib after Trastuzumab in early stage breast cancer.	SA - Extension Study	26/05/2015	9
09/H0405/51/AM21	CA180226: PII childhood leukaemia dasatinib study (version 1 9/Jul/08)	SA#17	20/08/2015	14
09/H0405/9/AM21	DMD-Heart Protection Trial	17	17/12/2015	21
10/H0401/16/AM14	Questionnaire for assessing everyday processing in children, version 2	Amendment 4	21/02/2016	11
10/H0401/16/AM15	Questionnaire for assessing everyday processing in children, version 2	Amendment 5	26/02/2016	27
10/H0401/60/AM05	Exploring the role of glycaemic instability in sudden cardiac death.	SA#3	24/08/2015	10
10/H0401/70/AM06	(duplicate) Experiencing Seizures	Substantial amendment 2	07/05/2015	15
10/H0405/56/AM09	Genetic and epigenetic factors in RA pathogenesis (Version 1.0)	Substantial Amendment 7	10/12/2015	33
10/H0405/90/AM26	The seAFood Polyp Prevention Trial	05.05.2015	05/05/2015	22
10/H0405/90/AM28	The seAFood Polyp Prevention Trial	SA#18	29/06/2015	21
11/EM/0263/AM07	FOLFOX plus curcumin in patients with inoperable colorectal cancer V1	SA#06	11/05/2015	21
11/EM/0263/AM10	FOLFOX plus curcumin in patients with inoperable colorectal cancer V1	Substantial Amendment 5	05/11/2015	14
11/EM/0314/AM14	HCV Research UK V1	SA#6	24/06/2015	16
11/EM/0314/AM16	HCV Research UK V1	Substantial Amendment 7	09/12/2015	25
11/EM/0323/AM12	HCV Research UK Tissue Bank V1	Substantial Amendment 5	09/12/2015	25
11/EM/0353/AM13	HCV Research UK Clinical Research Database V1	SA#6	19/06/2015	16
11/EM/0353/AM14	HCV Research UK Clinical Research Database V1	Substantial Amendment 7	09/12/2015	25
11/EM/0358/AM08	EuroNet PHL-LP1	Substantial Amendment SA-06	17/11/2015	15
11/EM/0393/AM11	RADICAL, v1.0	Substantial Amendment 7	07/10/2015	17
11/EM/0398/AM18	MK-0431A in Pediatric Patients with Type 2 Diabetes Mellitus	Substantial	12/05/2015	20

		amendment 12		
11/EM/0398/AM21	MK-0431A in Pediatric Patients with Type 2 Diabetes Mellitus	SA 13	03/12/2015	17
12/EM/0010/AM07	ACTIVATE	SA#02	30/03/2015	22
12/EM/0073/AM05	HHT and other medical conditions	SA#02	17/03/2015	21
12/EM/0088/AM08	Testosterone and glycaemic control in hypogonadal men. Version 1	AM03 (alert card)	11/06/2015	32
12/EM/0088/AM09	Testosterone and glycaemic control in hypogonadal men. Version 1	Revised protocol 1.6	18/09/2015	16
12/EM/0270/AM04	A genomic study in Soweto, South Africa (the Birth to Twenty Cohort)	01.07.15	15/07/2015	22
12/EM/0308/AM06	SCULPTURE extension study	09.07.15	30/06/2015	13
12/EM/0308/AM08	SCULPTURE extension study	SA#5	18/08/2015	6
12/EM/0309/AM05	Secukinumab - efficacy and long term safety in Ankylosing Spondylitis	SA#04	27/03/2015	25
12/EM/0309/AM06	Secukinumab - efficacy and long term safety in Ankylosing Spondylitis	01 December 2015	01/12/2015	20
12/EM/0312/AM07	Investigation and Prevention of Alzheimer's disease - Version 1	SA#1.5	19/05/2015	16
12/EM/0341/AM08	Respiratory virus transmission to health care workers. Version 1	Amendment 5	02/03/2016	21
12/EM/0376/AM02	Leicester NIHR BioResource	Amendment 2	15/02/2016	8
12/EM/0407/AM10	The Remediation of Oculomotor and Attentional Deficits in ADHD	Amendment 7	23/11/2015	33
12/EM/0426/AM06	Donate for Research Initiative (DRI)	SA#2	02/09/2015	23
12/EM/0426/AM07	Donate for Research Initiative (DRI)	Amendment 11.02.2016	11/02/2016	14
12/EM/0441/AM02	ARID Main Study	Substantial Amendment 1.4	01/12/2015	25
12/EM/0448/AM09	MESO-02	Amendment 5	30/09/2015	20
13/EM/0011/AM02	Investigating the Genome-Phenome Correlations for Human Vascular Disease	Amendment 3	17/11/2015	19
13/EM/0069/AM05	Intravenous iron in the management of anaemia in palliative UGI cancer	12GA029	07/10/2015	28
13/EM/0154/AM13	Scaphoid Waist Internal Fixation for Fractures (SWIFFT) Trial (v1)	3	20/10/2015	23
13/EM/0190/AM02	Ovarian cancer biomarker case-control study	Amendment 1	22/12/2015	20
13/EM/0196/AM03	The University of Leicester Cancer Research Biobank.	SA#2	19/08/2015	23

13/EM/0275/AM03	HCV Community Study Version 1	Substantial amendment 3	10/05/2015	26
13/EM/0283/AM03	Colorectal and lung cancer biomarker studies	Amendment 2	22/12/2015	19
13/EM/0314/AM02	Treatments for uro-gynaecological problems and patient self-reports v1	SA#1	26/08/2015	22
13/EM/0395/AM12	Treatment of Advanced Glaucoma Study (TAGS)	SA#04	16/04/2015	25
13/EM/0395/AM13	Treatment of Advanced Glaucoma Study (TAGS)	SA#13	02/07/2015	14
13/EM/0398/AM02	EPIVIN trial (v 1.0)	SA#02	28/05/2015	34
13/EM/0398/AM03	EPIVIN trial (v 1.0)	SA#3	13/08/2015	11
13/EM/0398/AM04	EPIVIN trial (v 1.0)	AM04	06/10/2015	14
13/EM/0398/AM05	EPIVIN trial (v 1.0)	5.0	18/01/2016	17
13/EM/0398/AM06	EPIVIN trial (v 1.0)	AM06	25/02/2016	23
13/EM/0411/AM01	TMAO levels and CAD Risk	SA 1	20/08/2015	30
13/EM/0431/AM01	Carers' experiences of supporting a person with heart failure	SA#1	13/05/2015	21
14/EM/0017/AM06	GS-US-337-0124: Sofosbuvir/Ledipasvir Fixed-Dose Combination+Ribavirin	SA#03	03/06/2015	28
14/EM/0047/AM01	Component Analysis of Acceptance and Commitment Therapy	Substantial Amendment 1	27/11/2015	31
14/EM/0069/AM07	NU:LEVEL	SA#02	02/04/2015	19
14/EM/0160/AM08	AEGIS-I, Phase II, dose ranging study of CSL112 in Acute MI	09/06/2015	09/06/2015	27
14/EM/0160/AM09	AEGIS-I, Phase II, dose ranging study of CSL112 in Acute MI	Global Amendment 03	29/09/2015	22
14/EM/0174/AM04	Anti-FGF23 antibody, KRN23, in pediatric patients with XLH	SA#04	14/05/2015	8
14/EM/0174/AM05	Anti-FGF23 antibody, KRN23, in pediatric patients with XLH	Amendment 5	08/10/2015	28
14/EM/0200/AM01	Understanding the rehabilitation needs of people who have lung cancer	Substantial Amendment 1	13/08/2015	13
14/EM/0203/AM06	109MS306, Paediatric Relapsing MS (10 - <18 years), BG00012	SA6	30/06/2015	21
14/EM/0203/AM07	109MS306, Paediatric Relapsing MS (10 - <18 years), BG00012	SA #7	23/12/2015	21
14/EM/0220/AM02	Skin surveillance in paediatric transplant patients. Ver 3, 16/4/14	2nd Amendment	19/09/2015	28
14/EM/1024/AM02	Validating the CAIDS-Q in a paediatric setting	SA#2	04/11/2015	22
14/EM/1049/AM03	COCO Tx	3	23/11/2015	21
14/EM/1051/AM01	Ultrasound measurement of patients undergoing venesection	19/08/2015	19/08/2015	14
14/EM/1105/AM03	Inter-SPACE COPD self-management project	1.0	21/12/2015	17

14/EM/1111/AM01	Understanding the effects of acne	Amendment 1	30/10/2015	18
14/EM/1113/AM05	MOCAM	SA#3	03/09/2015	20
14/EM/1113/AM06	MOCAM	Amendment 4	18/02/2016	20
14/EM/1130/AM02	Biomarkers to inform ACL operations: version-1.0	Amendment 1.2	15/01/2016	17
14/EM/1131/AM03	High intensity exercise training in older colorectal cancer patients	Amendment 1	20/01/2016	25
14/EM/1139/AM02	AP26113 in patients with Non-Small Cell Lung Cancer	SA - pregnant partner	07/04/2015	14
14/EM/1139/AM03	AP26113 in patients with Non-Small Cell Lung Cancer	SA#3	26/08/2015	8
14/EM/1139/AM04	AP26113 in patients with Non-Small Cell Lung Cancer	Substantial amendment 14.10.15	14/10/2015	26
14/EM/1173/AM02	HI-Light Vitiligo Trial	SA#01	16/03/2015	20
14/EM/1173/AM07	HI-Light Vitiligo Trial	Amendment SA03	30/09/2015	24
14/EM/1176/AM01	Histopathological characterisation of NHL using novel T-cell markers	SA#01	16/04/2015	25
14/EM/1179/AM01	Point of Care Thromboelastogram Device Development	Substantial Amendment 1	24/11/2015	27
14/EM/1261/AM02	4Ms Study Version 6, Date 29 October 2014	SA#1	20/07/2015	29
14/EM/1272/AM03	BUTEO: A clinical trial of BTT1023 in patients with PSC	Substantial Amendment 2	17/12/2015	25
14/EM/1280/AM01	TEB vs PVB In reducing chronic post thoracotomy pain	SA#01	29/04/2015	28
14/EM/1280/AM04	TEB vs PVB In reducing chronic post thoracotomy pain	Amendment 2	28/08/2015	16
14/EM/1289/AM01	Morbidity of pneumonia after discharge	Substantial amendment 1	06/03/2015	14
14/EM/1290/AM02	UK Inflammatory Bowel Disease Inception Cohort Study	SA#2	20/08/2015	14
14/EM/1290/AM06	UK Inflammatory Bowel Disease Inception Cohort Study	Amendment 3	12/02/2016	28
15/EM/0002/AM05	An Investigation of Arousal and Escape Behaviour in Fragile X Syndrome	SA#1	07/08/2015	17
15/EM/0004/AM01	A 34-week Follow-up to: MK-0431A in Pediatric Patients with Type 2 Diabetes Mellitus	SA#02	18/05/2015	14
15/EM/0004/AM04	A 34-week Follow-up to: MK-0431A in Pediatric Patients with Type 2 Diabetes Mellitus	SA #03	03/12/2015	17
15/EM/0045/AM01	Anthony Nolan Research Tissue Bank Renewal 2015	Amendment 2	18/01/2016	7
15/EM/0066/AM02	Paediatric Study with Blinatumomab in Acute Lymphoblastic Leukaemia	Substantial amendment 1	07/05/2015	19

15/EM/0066/AM03	Paediatric Study with Blinatumomab in Acute Lymphoblastic Leukaemia	Amendment 2	12/02/2016	14
15/EM/0069/AM01	CLL14 - study of GDC-0199 in CLL	SA#01	14/04/2015	7
15/EM/0069/AM04	CLL14 - study of GDC-0199 in CLL	SA#04	29/07/2015	8
15/EM/0069/AM06	CLL14 - study of GDC-0199 in CLL	SA# 5	02/11/2015	25
15/EM/0075/AM01	Parental Perspective of Transitional Care (Version 1)	02.08.15	26/08/2015	17
15/EM/0116/AM01	Animal Assisted Activities and their impact on Trauma Factors	SA#01	27/05/2015	8
15/EM/0116/AM02	Animal Assisted Activities and their impact on Trauma Factors	Amendment 3	23/12/2015	21
15/EM/0196/AM01	Robot Assisted Physiotherapy Exercises With REX.	Substantial Amendment 01	30/09/2015	14
15/EM/0197/AM01	A feasibility study of treatments for Dupuytren's Contracture	SA#1		26
15/EM/0236/AM01	'Our care through our eyes' study	SA#1	24/08/2015	10
15/EM/0236/AM02	'Our care through our eyes' study	Amendment 2	29/01/2016	22
15/EM/0244/AM01	OMMIT 2	Substantial Amendment 1	26/08/2015	33
15/EM/0244/AM02	OMMIT 2	Amendment 2	03/12/2015	14
15/EM/0251/AM01	High-flow nasal oxygen in high risk cardiac surgical patients	Amendment 1	12/10/2015	24
15/EM/0280/AM02	Left Ventricular Myocardial Fibrosis in early CKD	First substantial amendment	17/09/2015	21
15/EM/0284/AM02	PRISM-2 Study	Amendment 1	30/09/2015	28
15/EM/0284/AM04	PRISM-2 Study	Substantial Amendment 2	11/11/2015	15
15/EM/0284/AM06	PRISM-2 Study	Substantial Amendment 3	15/12/2015	25
15/EM/0284/AM07	PRISM-2 Study	4.0	07/01/2016	18
15/EM/0340/AM01	Role of Surgical Centralisation on Renal Cancer Survival	Substantial Amendment 12.12.15	12/12/2015	28
15/EM/0358/AM01	Feasibility Study of a Mobile App for Preconception Care of Women v 1	24/09/2015	24/09/2015	23
15/EM/0358/AM02	Feasibility Study of a Mobile App for Preconception Care of Women v 1	Amendment 01.03.2016	01/03/2016	21
15/EM/0360/AM02	mHealth to assist with the self-management of asthma	Substantial Amendment 1	25/11/2015	7
15/EM/0361/AM01	A Positive Psychology Group for Stroke Survivors and Carers.	14.09.15	14/09/2015	23
15/EM/0361/AM02	A Positive Psychology Group for Stroke Survivors and Carers.	Amendment 2	25/11/2015	25

15/EM/0391/AM01	PINK	Substantial Amendment SA 1	16/11/2015	15
15/EM/0414/AM01	Living with long-term conditions: validation of the LTCQ	Substantial Amendment 1	16/10/2015	18
15/EM/0480/AM01	Sitagliptin vs. Dapagliflozin As Add-on to Metformin in Subjects with Mild Renal Impairment	SA#1	06/01/2016	18
15/EM/0487/AM02	M13-594 - Study in Subjects with Genotype 3 Chronic HCV infection	Amendment 1, 2, 3 and 4	22/02/2016	10
15/EM/0559/AM01	Lifestyle	Amendment 1	09/02/2016	18
16/EM/0008/AM01	ALXN1101 in Newborns with molybdenum cofactor deficiency	SA#1	07/03/2016	17

Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
05/MRE04/19/AM13	The Neonatal Survey	SA#11	06/03/2015	28
09/H0405/44/AM30	Neratinib after Trastuzumab in early stage breast cancer.	26.11.2015	26/11/2015	24

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
09/H0405/44/AM30/1	Neratinib after Trastuzumab in early stage breast cancer.	Modified Amendment in response	26/02/2016	14

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 14 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				