NHS
Health Research Authority

Research Ethics Service

East Midlands - Leicester South Research Ethics Committee

Annual Report

01 April 2016 - 31 March 2017

Part 1 – Committee Membership and Training

Name of REC:	East Midlands - Leicester South Research Ethics Committee
Type of REC:	RECs recognised to review CTIMPS in patients - type iii
Type of Flag:	None
Chair:	Mr John Aldridge
Vice-Chair:	Ms Elizabeth Gibbons
Alternate Vice-Chair:	Mr Alan Caswell
REC Manager:	Miss Rebecca Morledge
REC Assistant:	Mr George R. Martin
Committee Address:	The Old Chapel Royal Standard Place Nottingham NG1 6FS
Telephone:	0207 104 8104
Email:	NRESCommittee.EastMidlands-LeicesterSouth@nhs.net

Chair's overview of the past year:

Venue
We have been meeting at the Three Swan in Market Harborough for over a year and it appears to suit our purposes well, being within easy reach of the railway station and main roads. The venue is comfortable and welcoming for researchers and our meeting room is commodious.

Main committee meetings
Our agenda has been full for most meetings during the past year and we appear to be generally able to work within the set time frame. Researchers are not usually kept waiting for more than five minutes.
We now have two new members in the committee, which has broadened our skill base and ensured that we are generally quorate without difficulty.
We have had one study recently that has presented a severe test for the committee and that has polarized opinion. However, I believe that the committee has dealt fairly with the study to reach an objective ethical opinion.

Proportionate Reviews
These meetings are now held 'virtually', with most members being confident to use the HARP Portal. Comments are either left on HARP or emailed to the Chair, who then collates the Opinion and emails this to the REC Manager. This part of the Committee's business is consistently conducted well within set time limits.

General comments
The committee is generally able to deal with all business within the required time limits and is, I believe, highly efficient. I would like to offer my thanks to committee members, REC managers and HRA staff for their support in discharging the committee's responsibilities.

John Aldridge
25.3.17

East Midlands - Leicester South Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Mr John Aldridge	Retired Senior Lecturer in Nursing	Lay	24/04/2008	
Mr Derek Butters	Industrial Pharmacy Consultant and Locum Pharmacist	Expert	01/02/2012	
Mr Alan Caswell	Retired Nurse	Lay	01/12/2011	
Mrs Jeanne-Anne Charly	Staff Nurse	Expert	08/07/2013	
Dr Belinda Cupid	Head of Research -MND Association	Lay	20/12/2012	
Ms Elizabeth Gibbons	Senior Research Scientist	Expert	13/07/2011	
Mrs Sarah Hamill	Cardiology Research Nurse	Expert	20/03/2014	
Dr Brendan Laverty	Retired Head of Research Governance	Lay	11/03/2014	
Mrs Jill Marshall	Retired Training and Development Manager, HRA	Lay Plus	04/04/2016	
Ms Rachel Neilan	Former Executive Editor at BioMed Central	Lay Plus	22/05/2014	
Mrs Sarah Elizabeth Westwater-Wood	Lecturer	Expert	20/12/2012	
Dr Joanna Wood	Academic Clinical Lecturer in Medical Oncology	Expert	04/04/2016	

East Midlands - Leicester South Research Ethics Committee: Deputy Members

None

East Midlands - Leicester South Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended
Dr Brian Hands	Retired General Practitioner	Expert	16/02/2017

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

Name	Declaration of Interest	Date
Mr John Aldridge	None declared	01/12/2016
Mr Derek Butters	Managing Director - DSB Pharma LTD.	30/12/2016
Mr Alan Caswell	Member of PPI group Nottingham University - Dementia, Frail older people and palliative care	30/12/2016
Mrs Jeanne-Anne Charly	None declared	02/01/2017
Dr Belinda Cupid	Head of Research at Motor Neurone Disease Association. The Association funds medical research.	31/12/2016
Ms Elizabeth Gibbons	Occasional Peer review of funding for research applications	30/12/2016
Mrs Sarah Hamill	Cardiology Research Nurse - Peterborough + Stamford NHS Foundation Trust member of R&D committee. Participates in commercial/non commercial trial within cardiology.	30/12/2016
Dr Brendan Laverty	Director of Brendan Laverty Consulting Limited, Expert Reviewer for Energy Efficiency Projects for European Commission, Expert Reviewer for Ethical screening of projects for European Commission.	30/12/2016
Mrs Jill Marshall	None declared	30/12/2016
Ms Rachel Neilan	None declared	30/12/2016
Mrs Sarah Elizabeth Westwater-Wood	National committee member of the APCP however they do not do primary research. Is a member of staff at the University of Nottingham however it is declared and withdraws if it arises	30/12/2016
Dr Joanna Wood	None declared	18/04/2016

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

Month	Date	Number of Members Present at Meeting
April	21/04/2016	10
May	19/05/2016	8
June	16/06/2016	9
July	21/07/2016	11
September	15/09/2016	10
October	20/10/2016	9
December	15/12/2016	10
February	16/02/2017	7
March	16/03/2017	9

9 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	05/04/2016	3
May	06/05/2016	3
June	09/06/2016	3
July	08/07/2016	3
August	05/08/2016	3
September	09/09/2016	3
September	15/09/2016	3
October	07/10/2016	3
November	11/11/2016	3
December	12/12/2016	3
February	09/02/2017	3
March	10/03/2017	3

12 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	12/04/2016	2
April	26/04/2016	2
May	10/05/2016	2
May	13/05/2016	2
May	24/05/2016	2
June	07/06/2016	2
June	16/06/2016	3
July	05/07/2016	2

July	15/07/2016	2
August	02/08/2016	2
August	16/08/2016	2
August	30/08/2016	2
September	13/09/2016	2
October	13/10/2016	2
October	27/10/2016	2
November	07/11/2016	2
November	18/11/2016	2
December	05/12/2016	2
December	20/12/2016	2
January	17/01/2017	2
January	27/01/2017	2
February	13/02/2017	2
February	27/02/2017	2
March	16/03/2017	2
March	24/03/2017	2

25 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
Mr John Aldridge	9
Mr Derek Butters	7
Mr Alan Caswell	7
Mrs Jeanne-Anne Charly	6
Dr Belinda Cupid	7
Ms Elizabeth Gibbons	5
Mrs Sarah Hamill	4
Dr Brendan Laverty	9
Mrs Jill Marshall	7
Ms Rachel Neilan	8
Mrs Sarah Elizabeth Westwater-Wood	7
Dr Joanna Wood	5

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

Name	Number of Meetings Attended
Mr John Aldridge	12
Mrs Jeanne-Anne Charly	8
Dr Belinda Cupid	3
Ms Elizabeth Gibbons	10
Mrs Sarah Hamill	1
Dr Brendan Laverty	2

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

Name	Number of Meetings Attended
Mr John Aldridge	25
Mr Derek Butters	1
Mrs Jeanne-Anne Charly	1
Ms Elizabeth Gibbons	24

Training 01 April 2016 - 31 March 2017

Name of Member	Date	Event(s) attended
Mr John Aldridge	18/11/2016	Chairs Meeting
Mr John Aldridge	01/12/2016	National Training Day for Committee Chairs
Mr John Aldridge	21/02/2017	Equality & Diversity
Mr Derek Butters	16/02/2017	National Members Training Day
Mr Alan Caswell	18/11/2016	Regional Chairs Meeting
Mr Alan Caswell	07/12/2016	Workshop on Research Ethics
Mrs Jeanne-Anne Charly	16/02/2017	National Members Training Day
Dr Belinda Cupid	23/09/2016	Regional Training Day
Ms Elizabeth Gibbons	18/11/2016	Regional Chairs Meeting
Ms Elizabeth Gibbons	08/03/2017	Equality & Diversity
Mrs Sarah Hamill	27/04/2016	E&D and Human rights
Mrs Sarah Hamill	01/12/2016	Mentor to new member
Dr Brendan Laverty	24/05/2016	Training - Introduction to Phase 1 Research - Trials & Regulation
Dr Brendan Laverty	04/07/2016	CTIMP Training Day
Dr Brendan Laverty	28/02/2017	Equality & Diversity
Mrs Jill Marshall	28/04/2016	Members Induction
Mrs Jill Marshall	29/05/2016	Equality & Diversity online
Ms Rachel Neilan	23/09/2016	Local Training Day - Regional
Mrs Sarah Elizabeth Westwater-Wood	23/09/2016	Regional Training Day
Dr Joanna Wood	23/05/2016	Mandatory REC Training
Dr Joanna Wood	30/11/2016	Committee Member Induction
Dr Joanna Wood	04/01/2017	Equality & Diversity

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	19	44.19
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	0	0.00
Others	24	55.81
Total Applications Reviewed	**43**	**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	11
Number of paediatric applications reviewed	6
Number of device applications reviewed	1
Number of prisoner applications reviewed	1
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	0	0.00
Favourable Opinion with Additional Conditions	2	4.65
Unfavourable Opinion	5	11.63
Provisional Opinion	36	83.72
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	**43**	**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	33	76.74
Further Information Favourable Opinion with Additional Conditions	3	6.98
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	2	4.65
Unfavourable Opinion	5	11.63
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	**43**	**100**

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

Total Applications Reviewed	**33**

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	15
Number of paediatric applications reviewed	7
Number of device applications reviewed	3
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	7	21.21
Favourable Opinion with Additional Conditions	4	12.12
No Opinion transfer to full committee for review	1	3.03
Provisional Opinion	21	63.64
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	4.78
Number of completed applications for full ethical review	43
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	0
Number of completed applications over 40 days as a % of total	0.00%
Number of days taken to final decision – average (mean)	26

Number of completed proportionate review applications for ethical review	32
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	3
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	9.38%

Number of SSAs (non-Phase 1) reviewed	10
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	128
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	4.69%

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	115
Number of substantial amendments received for information	1
Number of substantial amendments received for new sites/PIs	34
Number of annual progress reports received	79
Number of safety reports received	44
Number of Serious Adverse Events received	2
Number of final reports received	16

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/0159	COMBAT-ID 2	28
16/EM/0163	CMR Airway Disease	13
16/EM/0165	A Phase 3 Multicenter Open-label Study of Brigatinib versus Crizotinib	33
16/EM/0166	Back pain prevention in multiple myeloma using a spinal brace (MAPP)	30
16/EM/0167	Assessing Efficacy & Safety of PT010 versus PT003 & PT009 in COPD	27
16/EM/0172	NOAH - AFNET 6	30
16/EM/0207	SPAaRC	32
16/EM/0219	FAST	32
16/EM/0220	Randomized parallel group phase III trial for patients with NSCLC	35
16/EM/0221	PRE-STARt Phase 2	32
16/EM/0254	Impact of locked, low, & medium security inpatient adolescent services	21
16/EM/0259	Masitinib in Metastatic Colorectal Cancer phase II-III V1.2	25
16/EM/0260	RASP Bronchoscopy Study	27
16/EM/0312	Safety And Efficacy Of Orally Administered DS102 In NAFLD Patients	21
16/EM/0317	The ExPO Trial (Exercise Prior to Oesophagectomy)	25
16/EM/0319	Clinical Protocol 204503 - Cognitive Function & Mobility Pain Study	23
16/EM/0320	Trastuzumab emtansine in combination with atezolizumab in HER2+ non-op	22
16/EM/0321	Eisai/ E7080-G000-211	32
16/EM/0400	SHIPS	21
16/EM/0436	ALXN1210 IN PATIENTS WITH ATYPICAL HEMOLYTIC UREMIC SYNDROME (aHUS)	26
16/EM/0443	SFX-01 in the Treatment of ER positive Metastatic Breast Cancer - V1.0	24
16/EM/0446	Exploring the 'alcoholic' in ALD - version 1.0	21
16/EM/0476	Effect of gas plasma (charged gas) on infected diabetic foot ulcers	35
16/EM/0504	SEEKS Study: Exploring the Experiences of Klinefelter's Syndrome	29
16/EM/0506	Social cognition in adults with mild-mod intellectual disabilities	29
16/EM/0507	Radicalisation and General Practice	33
16/EM/0512	CO39262 - Atezolizumab in patients with untreated advanced melanoma	35
17/EM/0063	Gilteritinib as Maintenance After Induction/Consolidation in CR1 AML	23
17/EM/0075	High Energy, High Protein Tube Feed Study	15
17/EM/0076	A biomarker of spinally-driven pain in diabetes	18
17/EM/0101	Neural Correlates of Memory in Non-Healthy Ageing	28
17/EM/0108	Clinical features in persistent rhinitis in preschool children.	28

17/EM/0116	TOZ-CL06 Tozadenant in patients with Parkinson's Disease	24

Further Information Favourable Opinion with Additional Conditions		
REC Reference	**Title**	**Number of Days on Clock**
16/EM/0411	Goal-setting in care planning for people with multimorbidity v1.0	20
17/EM/0117	To evaluate the change in weight after 24 weeks treatment with LIK066	29
17/EM/0118	STUDY ON THE EFFECTIVENESS OF METABOLIC MEDICINES FOR CANCER	32

Further Information Unfavourable Opinion		
REC Reference	**Title**	**Number of Days on Clock**

Favourable Opinion with Standard Conditions		
REC Reference	**Title**	**Number of Days on Clock**

Favourable Opinion with Additional Conditions		
REC Reference	**Title**	**Number of Days on Clock**
16/EM/0199	Using urinalysis test strips to detect bacterial skin infections	8
16/EM/0242	EPIC: Effect on ePcs by the Implantation of Cardiac closure devices	22

Unfavourable Opinion		
REC Reference	**Title**	**Number of Days on Clock**
16/EM/0189	Justifications for withdrawing treatment from critically ill neonates	29
16/EM/0270	Manual Drawing in the Clinical Consultation: a pilot study	32
16/EM/0406	Dignity and Human Rights in Community Nursing	22
16/EM/0444	Study on the effectiveness of metabolic medicines for cancer	21
16/EM/0487	Study on the effectiveness of metabolic medicines for cancer	27

Provisional Opinion		
REC Reference	**Title**	**Number of Days on Clock**

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

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

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

Table 9.2: **Breakdown of current status of all PRS applications reviewed within the reporting period**

Further Information Favourable Opinion with Standard Conditions		
REC Reference	**Title**	**Number of Days on Clock**
16/EM/0152	An evaluation of the process of consent in neonatal medicine	8
16/EM/0153	Factor VIII-associated cellular stress	20
16/EM/0194	MIAA Validation Study - protocol version 1	14
16/EM/0196	Effectiveness of a relaxation session for anxious pregnant women.	10
16/EM/0201	Immunological and microRNA profile in GBM - v.1.0	11
16/EM/0305	Developing optimal pathways of care for Heart Failure patients	9
16/EM/0306	Cellulitis study	10
16/EM/0349	ACTICOAT for the treatment of burns and chronic wounds	12
16/EM/0353	Liquorice effect on salivary cortisol	13
16/EM/0402	Pain processing in Autism Spectrum Disorder Version 1.1	13
16/EM/0403	Exploration of the cardinal symptoms of overactive bladder	11
16/EM/0418	The impact of information and support on people with Nystagmus	11
16/EM/0419	Assessment of the MEST criteria in childhood HSP nephritis	13
16/EM/0433	MR Assessment of Perianal Crohn's disease	10
16/EM/0514	A new look at respiratory mechanics	11
17/EM/0064	Neural mechanisms of touch processing in adults with ASD (v1)	14
17/EM/0067	IRIT-A Stage 1 (Version 1.0)	14
17/EM/0068	FICUS Control - faecal incontinence cost utilisation study	12

Further Information Favourable Opinion with Additional Conditions		
REC Reference	**Title**	**Number of Days on Clock**
16/EM/0154	A Paediatric Classification Tool to Determine Assessment for APD	18
16/EM/0420	Behavioural Activation for depression in young people	13

Further Information Unfavourable Opinion		
REC Reference	**Title**	**Number of Days on Clock**

Favourable Opinion with Standard Conditions		
REC Reference	**Title**	**Number of Days on Clock**
16/EM/0156	Molecular pathology investigation of post mortem change	7
16/EM/0263	Long-term storage of faecal samples	8
16/EM/0304	Study of coffee consumption in liver disease	10
16/EM/0309	WHO Checklist and Surgical Mortality in Scotland	8
16/EM/0478	Edinburgh Foreign Accent Syndrome Survey	6
16/EM/0508	Variant presentation of dementia & dysphagia in the acute setting	5
17/EM/0105	BOSU Study on Essential Infantile Esotropia	11

Favourable Opinion with Additional Conditions		
REC Reference	**Title**	**Number of Days on Clock**
16/EM/0262	Assessment of handgrip strength in adults with IBD	7
16/EM/0351	Acute postnatal transfer and mortality in very preterm babies	11
16/EM/0416	Accuracy of the Brief Pain Inventory in identifying sleep disturbances	11
17/EM/0103	WOODCAST	16

Unfavourable Opinion		
REC Reference	**Title**	**Number of Days on Clock**

Provisional Opinion		
REC Reference	**Title**	**Number of Days on Clock**
17/EM/0104	Digitally enhanced educational toys for children with type-1 diabetes	n/a

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

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

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**
09/H0402/101/AM36	The Effects of JNJ-28431754 on Cardiovascular Outcomes (CANVAS Study)	28	07/04/2016	5
09/H0402/101/AM38	The Effects of JNJ-28431754 on Cardiovascular Outcomes (CANVAS Study)	29	11/05/2016	12
09/H0402/101/AM39	The Effects of JNJ-28431754 on Cardiovascular Outcomes (CANVAS Study)	30	14/06/2016	3
09/H0402/101/AM40	The Effects of JNJ-28431754 on Cardiovascular Outcomes (CANVAS Study)	31	14/10/2016	12
09/H0402/101/AM41	The Effects of JNJ-28431754 on Cardiovascular Outcomes (CANVAS Study)	32	18/11/2016	18
09/H0402/96/AM13	Open label extension to the ALLEGRO study	Global Amendment 3	25/04/2016	16
09/H0402/96/AM14	Open label extension to the ALLEGRO study	4	10/10/2016	16
11/EM/0415/AM06	The role of peripheral and central vision in postural stability.	5	29/11/2016	4
12/EM/0197/AM15	1199.33 - Extension trial of long term safety of BIBF 1120 in IPF	9	29/07/2016	24
12/EM/0197/AM17	1199.33 - Extension trial of long term safety of BIBF 1120 in IPF	10	13/02/2017	14
12/EM/0197/AM18	1199.33 - Extension trial of long term safety of BIBF 1120 in IPF	11	02/03/2017	14
12/EM/0269/AM01	Macular abnormality in both eyes of children who have strabismus.	2	14/03/2016	13
12/EM/0304/AM08	DREAM Study (Daily Remote Ischaemic Conditioning following AMI)	8	21/11/2016	25
13/EM/0112/AM15	AKT inhibitor in breast cancer (STAKT study)	8	03/06/2016	3
13/EM/0195/AM07	HGS1006-C1112 Phase 3/4 Study of Belimumab in Black Race SLE Patients	8	11/08/2016	11
13/EM/0195/AM08	HGS1006-C1112 Phase 3/4 Study of Belimumab in Black Race SLE Patients	7	05/07/2016	7
13/EM/0266/AM09	Low dose cyclophosphamide +/- nintedanib in advanced ovarian cancer	9	08/11/2016	10

13/EM/0344/AM04	ExTra CKD	3	26/04/2016	12
13/EM/0349/AM11	MANTA	12	08/07/2016	7
13/EM/0414/AM07	Study of Eosinophilic Granulomatosis with Polyangiitis and Mepolizumab	4	06/07/2016	8
13/EM/0424/AM11	Study of Pridopidine to reduce symptoms in patients with Huntington's	Version 5	28/04/2016	13
13/EM/0460/AM16	Study of Adjuvant Kadcyla vs Herceptin, HER2+ve Primary Breast Cancer	10	20/07/2016	12
13/EM/0460/AM19	Study of Adjuvant Kadcyla vs Herceptin, HER2+ve Primary Breast Cancer	12	25/11/2016	7
13/EM/0460/AM20	Study of Adjuvant Kadcyla vs Herceptin, HER2+ve Primary Breast Cancer	13	18/01/2017	8
13/EM/0462/AM07	RomiCar	7	26/08/2016	13
14/EM/0029/AM04	ECU-NMO-301 Phase3 study:Eculizumab for Relapsing Neuromyelitis Optica	4	28/07/2016	24
14/EM/0029/AM05	ECU-NMO-301 Phase3 study:Eculizumab for Relapsing Neuromyelitis Optica	5	03/02/2017	10
14/EM/0030/AM07	ECU-NMO-302 Phase 3 Open-Label Extension Study of Eculizumab for NMO	5	12/08/2016	18
14/EM/0030/AM09	ECU-NMO-302 Phase 3 Open-Label Extension Study of Eculizumab for NMO	6	05/01/2017	2
14/EM/0086/AM04	Secukinumab in Ankylosing Spondylitis	3	18/04/2016	7
14/EM/0089/AM12	Niraparib vs. physician choice in HER2 negative breast cancer	06/06/2016	06/06/2016	11
14/EM/0089/AM15	Niraparib vs. physician choice in HER2 negative breast cancer	27/02/2017	27/02/2017	17
14/EM/0124/AM04	GOLMePsA	SA3	05/05/2016	18
14/EM/0134/AM01	Pre-clinical evaluation of novel anti-leukemia therapies	1	05/04/2016	6
14/EM/0202/AM15	Ertugliflozin in subjects w/ T2DM & poor glycemic control on metformin	Informed Consent Form V5.0	20/01/2017	18
14/EM/0217/AM05	Fast Track Faecal Calprotectin	5	21/12/2016	13
14/EM/1042/AM02	CMR Sequence Development - SGUL	3	29/04/2016	14
14/EM/1060/AM11	049 FIT (Fostamatinib for Immune Thrombocytopenia) Extension Study	2	08/11/2016	6
14/EM/1060/AM12	049 FIT (Fostamatinib for Immune Thrombocytopenia) Extension Study	3	22/02/2017	15
14/EM/1067/AM03	A feasibility study for cardiac rehabilitation in stroke patients	3	26/02/2016	6
14/EM/1071/AM13	D5136C00007 Ticagrelor for sickle cell disease in paediatric	3	11/04/2016	14

	patients			
14/EM/1071/AM15	D5136C00007 Ticagrelor for sickle cell disease in paediatric patients	24.05.2016	24/05/2016	10
14/EM/1074/AM02	Effect of local anaesthesia at vaginal hysterectomy on post-op pain	2	01/11/2016	11
14/EM/1163/AM04	Defining Outcome Measures in Ocular Inflammatory Disease (DOMINO ID)	3	07/12/2016	13
14/EM/1172/AM03	CamBMT1	3	12/01/2017	9
14/EM/1211/AM01	Pilot Study for validation of the MDS-NMS Rater-Administered Scale	1	25/07/2016	26
14/EM/1267/AM06	LCZ696 in patients from Paradigm HF study	28/04/2016	10/05/2016	13
14/EM/1306/AM05	Pilot Study of FFP104 Dose Escalation in PBC Subjects	3	26/08/2016	18
14/EM/1306/AM06	Pilot Study of FFP104 Dose Escalation in PBC Subjects	4	03/11/2016	4
14/EM/1314/AM04	Phase 2 Veliparib or Placebo, plus FOLFIRI Â± Bevacizumab in mCRC	3	31/05/2016	18
14/EM/1314/AM05	Phase 2 Veliparib or Placebo, plus FOLFIRI Â± Bevacizumab in mCRC	Substantial Amendment 04	14/07/2016	21
15/EM/0071/AM05	Carbetocin RTS A65870	SA07	18/05/2016	5
15/EM/0071/AM09	Carbetocin RTS A65870	9	26/01/2017	20
15/EM/0071/AM10	Carbetocin RTS A65870	10	06/02/2017	17
15/EM/0077/AM06	Long-term Access Programme for Subjects who Participated in MEA115921	3	16/08/2016	14
15/EM/0101/AM05	Triple P for Parents of Children with a diagnosis of cancer	2	05/03/2016	22
15/EM/0122/AM04	RCT - ESWT v minimal dose ESWT for tendinopathies	2	21/07/2016	10
15/EM/0230/AM10	Knee flare up study	8	31/03/2016	12
15/EM/0230/AM11	Knee flare up study	9	07/04/2016	17
15/EM/0230/AM14	Knee flare up study	11	20/05/2016	28
15/EM/0238/AM03	Efficacy and safety of intravenous neridronic acid in CRPSI	2	20/05/2016	28
15/EM/0305/AM03	GTx G200901 - GTx-024(Enobosarm) on AR+ Triple Negative Breast Cancer	2	18/02/2016	20
15/EM/0305/AM04	GTx G200901 - GTx-024(Enobosarm) on AR+ Triple Negative Breast Cancer	3	14/06/2016	8
15/EM/0308/AM03	The Metabolic Effect of Hypoxia and Steroid Signalling	3	05/05/2016	18
15/EM/0310/AM03	Is morphine an effective analgesic for procedural pain in infants?	3	11/04/2016	30
15/EM/0310/AM04	Is morphine an effective analgesic for procedural pain in	4	22/07/2016	22

	infants?			
15/EM/0310/AM06	Is morphine an effective analgesic for procedural pain in infants?	6.0	08/02/2017	7
15/EM/0312/AM02	Ceritinib in ALK postive NSCLC patients with brain metastases	1	29/03/2016	13
15/EM/0312/AM04	Ceritinib in ALK postive NSCLC patients with brain metastases	3	11/08/2016	18
15/EM/0312/AM06	Ceritinib in ALK postive NSCLC patients with brain metastases	4	22/09/2016	22
15/EM/0312/AM07	Ceritinib in ALK postive NSCLC patients with brain metastases	5	21/11/2016	7
15/EM/0393/AM02	Open PRIdopidine Dose Evaluation in Huntington's Disease	Protocol amendment 2	29/04/2016	12
15/EM/0393/AM03	Open PRIdopidine Dose Evaluation in Huntington's Disease	3	29/06/2016	27
15/EM/0393/AM05	Open PRIdopidine Dose Evaluation in Huntington's Disease	2	31/03/2016	29
15/EM/0424/AM06	Efficacy and safety of Tanezumab in patients with bone metastasis	5	27/10/2016	11
15/EM/0424/AM07	Efficacy and safety of Tanezumab in patients with bone metastasis	6	28/02/2017	9
15/EM/0432/AM05	Effectiveness of MBCT in improving anxiety, depression & HbA1c	2	31/05/2016	8
15/EM/0432/AM06	Effectiveness of MBCT in improving anxiety, depression & HbA1c	3	13/12/2016	14
15/EM/0500/AM02	QAW039 vs. placebo in patients with uncontrolled severe asthma	2	16/06/2016	20
15/EM/0500/AM04	QAW039 vs. placebo in patients with uncontrolled severe asthma	4	07/09/2016	12
15/EM/0501/AM01	Community sport and type 2 diabetes	1	20/12/2016	29
15/EM/0552/AM03	The CIRCLE Study	2	14/12/2016	6
16/EM/0045/AM01	Demand for Pre exposure prophylaxis for HIV (PrEP) in Scotland	18/4/16	29/04/2016	12
16/EM/0073/AM01	Low exhaled NO and inhaled corticosteroids in suspected asthma	1	04/04/2016	15
16/EM/0073/AM03	Low exhaled NO and inhaled corticosteroids in suspected asthma	2	10/08/2016	12
16/EM/0076/AM01	Study of E/C/F/TAF in HIV-1 patients on Chronic Haemodialysis	1	28/11/2016	12
16/EM/0078/AM01	Safety, blood levels and effects of GLPG1690 in subjects with IPF (2)	1	17/05/2016	6
16/EM/0078/AM03	Safety, blood levels and effects of GLPG1690 in subjects with	2	02/08/2016	6

	IPF (2)			
16/EM/0078/AM05	Safety, blood levels and effects of GLPG1690 in subjects with IPF (2)	3	15/11/2016	6
16/EM/0079/AM01	High intensity interval training in UK cardiac rehabilitation - v1	1	03/06/2016	14
16/EM/0116/AM01	LASER-48	1	04/05/2016	19
16/EM/0127/AM01	PLEO-CMT	1	01/08/2016	22
16/EM/0127/AM02	PLEO-CMT	3	22/09/2016	23
16/EM/0130/AM02	The Therapeutic Alliance in EMDR.	1	06/09/2016	18
16/EM/0132/AM02	Gender Dysphoria in People with Autism: A Qualitative Study	1	09/12/2016	6
16/EM/0153/AM01	Factor VIII-associated cellular stress	1	01/06/2016	16
16/EM/0159/AM01	COMBAT-ID 2	1	30/08/2016	18
16/EM/0165/AM02	A Phase 3 Multicenter Open-label Study of Brigatinib versus Crizotinib	1	10/08/2016	14
16/EM/0165/AM04	A Phase 3 Multicenter Open-label Study of Brigatinib versus Crizotinib	2	30/11/2016	4
16/EM/0165/AM06	A Phase 3 Multicenter Open-label Study of Brigatinib versus Crizotinib	3	15/02/2017	12
16/EM/0167/AM01	Assessing Efficacy & Safety of PT010 versus PT003 & PT009 in COPD	1	02/06/2016	15
16/EM/0167/AM05	Assessing Efficacy & Safety of PT010 versus PT003 & PT009 in COPD	6	14/11/2016	6
16/EM/0167/AM06	Assessing Efficacy & Safety of PT010 versus PT003 & PT009 in COPD	3	09/12/2016	29
16/EM/0194/AM02	MIAA Validation Study - protocol version 1	1	14/10/2016	8
16/EM/0194/AM03	MIAA Validation Study - protocol version 1	2	26/01/2017	20
16/EM/0196/AM01	Effectiveness of a relaxation session for anxious pregnant women.	1	07/07/2016	10
16/EM/0201/AM01	Immunological and microRNA profile in GBM - v.1.0	1	27/05/2016	24
16/EM/0207/AM01	SPAaRC	1	07/11/2016	9
16/EM/0219/AM01	FAST	1	01/11/2016	17
16/EM/0220/AM02	Randomized parallel group phase III trial for patients with NSCLC	3	07/03/2017	9
16/EM/0221/AM01	PRE-STARt Phase 2	2.0	14/10/2016	5
16/EM/0242/AM01	EPIC: Effect on ePcs by the Implantation of Cardiac closure devices	1	15/08/2016	4
16/EM/0259/AM01	Masitinib in Metastatic Colorectal Cancer phase II-III V1.2	1.0	01/10/2016	7

16/EM/0259/AM02	Masitinib in Metastatic Colorectal Cancer phase II-III V1.2	2.0	08/12/2016	14
16/EM/0260/AM01	RASP Bronchoscopy Study	1	10/11/2016	7
16/EM/0305/AM04	Developing optimal pathways of care for Heart Failure patients	1	28/11/2016	6
16/EM/0319/AM02	Clinical Protocol 204503 - Cognitive Function & Mobility Pain Study	1	07/12/2016	15
16/EM/0319/AM03	Clinical Protocol 204503 - Cognitive Function & Mobility Pain Study	2	07/12/2016	5
16/EM/0320/AM02	Trastuzumab emtansine in combination with atezolizumab in HER2+ non-op	2	24/10/2016	7
16/EM/0320/AM03	Trastuzumab emtansine in combination with atezolizumab in HER2+ non-op	4	11/11/2016	7
16/EM/0320/AM06	Trastuzumab emtansine in combination with atezolizumab in HER2+ non-op	6	19/12/2016	30
16/EM/0320/AM07	Trastuzumab emtansine in combination with atezolizumab in HER2+ non-op	7	10/02/2017	17
16/EM/0349/AM01	ACTICOATâ„¢ for the treatment of burns and chronic wounds	1	10/01/2017	9
16/EM/0403/AM01	Exploration of the cardinal symptoms of overactive bladder	1	29/11/2016	14
16/EM/0418/AM01	The impact of information and support on people with Nystagmus	1	17/11/2016	28
16/EM/0506/AM01	Social cognition in adults with mild-mod intellectual disabilities	1	02/03/2017	10
16/EM/0512/AM02	CO39262 - Atezolizumab in patients with untreated advanced melanoma	1	08/02/2017	17

Unfavourable opinion				
Amendment REC Reference	**Title**	**Version**	**Date**	**Number of Days on Clock**
14/EM/0030/AM08	ECU-NMO-302 Phase 3 Open-Label Extension Study of Eculizumab for NMO	6	29/07/2016	30

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**

Unfavourable opinion timeline				
Amendment REC Reference	**Title**	**Version**	**Date**	**Number of Days on Clock**

Table 11: **Items exceeding timelines**

Full applications for ethical review over 60 day timeline		
REC Reference	**Title**	**Number of Days on Clock**

Proportionate review applications for ethical review over 21 day timeline		
REC Reference	**Title**	**Number of Days on Clock**

SSAs (non Phase 1) over 25 day timeline		
REC Reference	**Title**	**Number of Days on Clock**

SSAs (Phase 1) over 14 day timeline		
REC Reference	**Title**	**Number of Days on Clock**

Substantial Amendments over 35 day timeline				
Amendment REC Reference	**Title**	**Version**	**Date**	**Number of Days on Clock**

Modified Amendments over 14 day timeline				
Amendment REC Reference	**Title**	**Version**	**Date**	**Number of Days on Clock**