NHS
Health Research Authority

Research Ethics Service

East Midlands - Leicester Central Research Ethics Committee

Annual Report

01 April 2015 - 31 March 2016

Part 1 – Committee Membership and Training

Name of REC:	East Midlands - Leicester Central Research Ethics Committee
Type of REC:	Recognised to review CTIMPs in patients – Type III
Type of Flag:	IRB – Independent Review Board
Chair:	Mr Ken Willis
Vice-Chair:	Mr John Baker
Alternate Vice-Chair:	Miss Alison Armstrong
REC Manager:	Ms Ellen Swainston
REC Assistant:	Miss Joanne Unsworth to 31 May 2015 Mr Tad Jones from 1 June to 28 August 2015 Miss Nicola Kohut 1 February to 31 March 2016
Committee Address:	The Old Chapel Royal Standard Place Nottingham NG1 6FS
Telephone:	0207 104 8107
Email:	nrescommittee.eastmidlands-leicestercentral@nhs.net

Chair's overview of the past year:

I would like to start by wholeheartedly thanking the committee for their continued efforts and for accepting me into their ranks without question. Over the past twelve months we have evolved into an effective unit that has rapidly developed a mutual understanding of which I am very proud.

We have had numerous changes in membership, however these changes have been accepted and adopted in a way that ensured that the committee core business continued in an efficient and effective manner,
My thanks go out for the support from the REC management team and to other committee members when co-opted members have been required.

We have dealt with a wide range of interesting and diverse applications which have all brought their challenges during the review process. Many applications would have been granted a favourable opinion at first review, if the HRA guidelines regarding documentation had been more effectively followed. The majority of applications that have received a provisional opinion are in my opinion due to the researcher failing to look at the documentation package from a participant's viewpoint in order to ensure that all facts are given in an easily understandable format. Representing the research project as a journey from the participant's perspective, where the starting and end points are detailed, along with the timed itinerary of the various stages, may help overall understanding.

Feedback from researchers has been encouraging as it defines the approval process as a positive experience that has been of benefit, rather than trial by committee. I have been pleased to have welcomed several observers from student research, I hope that they have gained an in depth knowledge of the process, which will hopefully influence their prospective submissions.

We have reviewed some novel and interesting topics as well as clinical research intended to reduce suffering and improve the quality of people's lives, and I hope that as a committee we support research by helping to allay doubt and resolve any ethical issues prior to research commencement. I look forward to meeting next year's challenges as well as the opportunity to discuss the research proposals with the research representatives at forthcoming meetings.

I can't understate the effort of all the members as well the REC team for ensuring that all the correct information is reviewed in a timely fashion to enable effective meetings.

Thank You!

East Midlands - Leicester Central Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Miss Sue Ainsworth	Retired Teacher/Social Worker	Lay	18/02/2014	06/11/2015
Miss Alison Armstrong	Consultant Orthopaedic Surgeon	Expert	08/05/2008	
Mr John Baker	Radiation Protection Advisor and Senior Lecturer (retired)	Lay Plus	06/10/2006	
Dr Paul Beeson	Senior Lecturer	Expert	07/12/2012	
Dr Nigel Birch	Retired from Rolls-Royce	Lay Plus	12/05/2014	30/09/2015
Professor Jayne Brown	Professor of Palliative Care	Expert	30/01/2014	01/01/2015
Dr Margherita Carucci	Clinical Trial Coordinator	Lay	03/02/2014	21/09/2015
Mrs Lynne Fryatt	Retired Assistant Chief Nurse	Lay	25/01/2016	
Mrs Sandra Hall	Principal Lecturer in Clinical Pharmacy & Pharmacy Practice	Expert	20/10/2006	
Dr Nicola James	Independent Research Consultant	Lay Plus	10/01/2014	
Mr Michael Jones	Medical Statistician	Expert	26/02/2016	
Mr Murthy Nyasavajjala	Specialist Registrar - General Surgery	Expert	18/08/2014	
Mr John Warden	Clinical Trials Data and Information Systems Manager - retired	Lay	25/01/2016	
Mr Ken Willis	Medical Devices Manager	Lay Plus	01/01/2015	

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

Name	Profession	Status	Meeting date attended
Mrs Jeanne-Anne Charly	Staff Nurse	Expert	10/04/2015
Dr Margaret Stone	Senior Research Fellow	Lay	04/12/2015
Ms Margaret Vince	Translator	Lay Plus	04/12/2015
Reverend Keith Lackenby	Lay member	Lay Plus	10/04/2015

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

Name	Declaration of Interest	Date
Miss Alison Armstrong	1. Research and Innovation lead for MSK and spinal surgery. 2. PI for two research studies (portfolio) 3. Research lead for MSK surgery Shares may be held in organisation(s) involved with research but unknown as managed by stockbroker.	11/12/2015
Mr John Baker	None declared	14/12/2015
Dr Paul Beeson	None declared	11/12/2015
Professor Jayne Brown	1. Occasional review of NIHR proposals 2. Research Chair 3. Co-chair of the Centre for Excellence in Palliative Care 4. Member of Aging Institute at De Montfort University	11/12/2015
Mrs Lynne Fryatt	None declared	10/02/2016
Mrs Sandra Hall	None declared	11/12/2015
Dr Nicola James	approximately 200 shares in GSK plc	11/12/2015
Mr Murthy Nyasavajjala	Editor of peer-review journals. Member of various peer-review bodies - not related to ethics role. I am an editor for a gastroenterology and surgery journal. I am a peer-reviewer for a few medical and surgical journals.	11/12/2015
Mr Ken Willis	None declared	11/12/2015
Mr John Warden	None declared	29/02/2016
Mr Michael Jones	Medical statistician employed in Research, Innovation and Development Department at Derby Teaching Hospital NHSFT. Occasionally reviews NIHR funding applications as an expert reviewer.	31/03/2016

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

Month	Date	Number of Members Present at Meeting
April	10/04/2015	8
May	01/05/2015	10
July	03/07/2015	9
August	07/08/2015	9
September	04/09/2015	8
October	02/10/2015	8
November	06/11/2015	8
December	04/12/2015	9
March	04/03/2016	9

9 full committee meetings were held during the reporting period.

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

Month	Date	Number of Members Present at Meeting
April	10/04/2015	3
April	29/04/2015	3
May	01/05/2015	7 (Additional PR mtg following full mtg)
June	05/06/2015	3
August	07/08/2015	3
September	04/09/2015	3
October	02/10/2015	3
November	06/11/2015	3
December	04/12/2015	3
January	08/01/2016	3
February	05/02/2016	3
March	04/03/2016	3

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

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

Month	Date	Number of Members Present at Meeting
April	10/04/2015	3
April	24/04/2015	2
May	15/05/2015	2
June	05/06/2015	2
June	19/06/2015	2
July	03/07/2015	2
July	17/07/2015	2
July	24/07/2015	2
August	07/08/2015	3

August	21/08/2015	3
August	28/08/2015	2
September	04/09/2015	3
September	18/09/2015	2
October	02/10/2015	3
October	16/10/2015	3
October	30/10/2015	3
November	06/11/2015	3
November	13/11/2015	3
November	20/11/2015	3
December	04/12/2015	3
December	18/12/2015	3
January	08/01/2016	2
January	22/01/2016	3
February	05/02/2016	2
February	19/02/2016	2
March	04/03/2016	3
March	18/03/2016	2

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

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

Name	Number of Meetings Attended
Miss Sue Ainsworth	7
Miss Alison Armstrong	7
Mr John Baker	9
Dr Paul Beeson	6
Dr Nigel Birch	6
Professor Jayne Brown	4
Dr Margherita Carucci	3
Mrs Lynne Fryatt	1
Mrs Sandra Hall	7
Dr Nicola James	8
Mr Murthy Nyasavajjala	7
Mr John Warden	1
Mr Ken Willis	8

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

Name	Number of Meetings Attended
Miss Sue Ainsworth	1
Miss Alison Armstrong	5
Mr John Baker	7
Dr Paul Beeson	2
Dr Nigel Birch	2
Professor Jayne Brown	1
Dr Margherita Carucci	2
Mrs Sandra Hall	3
Dr Nicola James	3
Mr Murthy Nyasavajjala	5
Mr Ken Willis	7

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

Name	Number of Meetings Attended
Miss Alison Armstrong	3
Mr John Baker	24
Dr Paul Beeson	3
Mrs Sandra Hall	2
Dr Nicola James	1
Mr Murthy Nyasavajjala	14
Mr Ken Willis	21

Training 01 April 2015 - 31 March 2016

Name of Member	Date	Event(s) attended
Miss Sue Ainsworth	25/09/2015	Members Regional Training Day
Miss Alison Armstrong	16/07/2015	GCP Training
Miss Alison Armstrong	23/07/2015	Consent DOLs, MCA and MHA
Miss Alison Armstrong	27/01/2016	Consent Training - especially when capacity is limited
Miss Alison Armstrong	04/02/2016	Equality and Diversity
Mr John Baker	15/05/2015	NREAP Meeting
Mr John Baker	25/09/2015	Members Regional Training Day
Dr Paul Beeson	22/04/2015	Diversity in the Workplace
Dr Paul Beeson	25/09/2015	Members Regional Training Day
Dr Nigel Birch	25/09/2015	Members Regional Training Day
Mrs Sandra Hall	25/09/2015	Members Regional Training Day
Mrs Sandra Hall	31/03/2016	Equality and Diversity
Dr Nicola James	25/09/2015	Members Regional Training Day
Dr Nicola James	01/02/2016	Equality and Diversity
Mr Murthy Nyasavajjala	15/06/2015	REC Members Induction
Mr Ken Willis	30/06/2015	Discovery of Grounded Theory, Glaser B and Straves A
Mr Ken Willis	30/11/2015	Good Research Guide, Open University Press, Denscombe M
Mr Ken Willis	26/02/2016	Equality and 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	16	39.02
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	25	60.98
Total Applications Reviewed	**41**	**100**

Table 2: Breakdown of full applications and other activity during reporting period

Number of applications made invalid by the REC Manager	3
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	12
Number of paediatric applications reviewed	1
Number of device applications reviewed	4
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	1
Number of qualitative applications reviewed	2

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	4.88
Favourable Opinion with Additional Conditions	4	9.76
Unfavourable Opinion	2	4.88
Provisional Opinion	33	80.49
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	**41**	**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	28	68.29
Further Information Favourable Opinion with Additional Conditions	5	12.20
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	2	4.88
Favourable Opinion with Additional Conditions	4	9.76
Unfavourable Opinion	2	4.88
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	**41**	**100**

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

Total Applications Reviewed	**43**

Table 6: **Breakdown of PRS applications and other activity during reporting period:**

Number of applications made invalid by the REC Manager	7
Number of studies withdrawn prior to the meeting	1
Number of student applications reviewed	22
Number of paediatric applications reviewed	5
Number of device applications reviewed	2
Number of qualitative applications reviewed	6

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	11	25.58
Favourable Opinion with Additional Conditions	6	13.95
No Opinion transfer to full committee for review	3	6.98
Provisional Opinion	21	48.84
Unfavourable Opinion	2	4.65
Total	**43**	**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	4.56
Number of completed applications for full ethical review	41
Number of completed applications for full ethical review over 60 days	0
Number of completed applications over 60 days as a % of total	0.00%
Number of completed applications for full ethical review over 40 days	1
Number of completed applications over 40 days as a % of total	2.44%
Number of days taken to final decision – average (mean)	26

Number of completed proportionate review applications for ethical review	40
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	5
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	169
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	8
Number of completed substantial amendments over 28 days as a % of total substantial amendments	4.73%

Number of modified amendments reviewed	4
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	141
Number of substantial amendments received for information	0
Number of substantial amendments received for new sites/PIs	32
Number of annual progress reports received	122

Number of safety reports received	68
Number of Serious Adverse Events received	1
Number of final reports received	34

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/0135	Phase 2 Study in Mantle Cell Lymphoma ACE-LY-004	27
15/EM/0185	Dietary manipulation in cystic fibrosis-related diabetes	26
15/EM/0291	WREN Study	25
15/EM/0298	INDICATE-P	27
15/EM/0299	A Study of the Prevalence and Causes of Anaemia in Aortic Stenosis	27
15/EM/0300	WO29636 ‹ImVigor 010 - Atezolizumab in Bladder Cancer after Cystectomy	32
15/EM/0313	Gene expression profiling in asthma	29
15/EM/0324	Open label study of BI 655066 in patients with Crohn's disease.	33
15/EM/0328	Effects of machine perfusion on cadaveric kidneys for transplantation.	29
15/EM/0342	A Long-term Access Programme (LAP) for Subjects with Severe Asthma	34
15/EM/0344	MORAb009-201 Amatuximab in Unresectable Malignant Pleural Mesothelioma	29
15/EM/0398	SV vs. PPV for lung biopsy under GA in patients with ILD	28
15/EM/0399	Endobarrier in diabetes with obstructive sleep apneoa	30
15/EM/0400	The SOPHIA Study	30
15/EM/0401	An open label study of Tocilizumab in PAH	29
15/EM/0430	D1690R00009: The DECIDE Study	21
15/EM/0433	COPD-SEAT (Sitting and ExacerbAtions Trial)	21
15/EM/0437	COLUMBUS-AMD	24
15/EM/0443	Open-Label Extension Trial of RPC1063 in Relapsing Multiple Sclerosis	42
15/EM/0494	Novel Accelerometer use in Sleepwalking (NREM Parasomnia)	33
15/EM/0496	Evaluation of three care pathways following hearing aid fitting. V.1.7	29
15/EM/0532	Cambridge Brain and Behaviour Study (CamBABS)	36
15/EM/0546	MEDI4736 and Tremelimumab for 1st line head and neck cancer	28
15/EM/0547	Caloric Vestibular Stimulation in Parkinson's Disease	28
16/EM/0094	Effect of IV Cangrelor vs PO Ticagrelor on myocardial damage in STEMI	25
16/EM/0096	AusCOR	24
16/EM/0098	Decision making regarding prophylactic mastectomy	19
16/EM/0099	Laser Treatment for Stress Incontinence	28

Further Information Favourable Opinion with Additional Conditions		
REC Reference	**Title**	**Number of Days on Clock**

15/EM/0180	Pre-emptive Rehabilitation to Prevent Dialysis-Associated Morbidity	24
15/EM/0247	Effect of Tralokinumab on airway inflammation in asthma	27
15/EM/0294	INN-TOP-005- Gentamicin- Collagen Sponge in Diabetic Foot Ulcers	26
15/EM/0439	POM Study - Version 1	22
15/EM/0498	TC Members' Evaluations of a Learning Disability Therapeutic Community	29

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**
15/EM/0163	Clinician Screening of 999 calls for Overdose	17
6721	Do genetic changes cause congenital heart disorders?	14

Favourable Opinion with Additional Conditions		
REC Reference	**Title**	**Number of Days on Clock**
15/EM/0188	PRECISION	20
15/EM/0341	The Sleep Study	16
15/EM/0346	The ED-AKI-P Study	16
15/EM/0550	HCV seroprevalence: un-linked anonymous testing - version 1.0	31

Unfavourable Opinion		
REC Reference	**Title**	**Number of Days on Clock**
15/EM/0389	Developing a text message intervention to support positive parenting	26
15/EM/0548	Traumatic brain injury follow up study	24

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**
15/EM/0164	Dietary behaviour change in haemodialysis patients	13
15/EM/0171	Magnetic resonance imaging and renal transplant function and prognosis	8
15/EM/0205	Ethnicity, Religion and Amputation	6
15/EM/0209	Towards the validation of the SASIT-E60 as a diagnostic test for SLI.	7
15/EM/0211	Survey of self-management and support preferences for men with RA	6
15/EM/0215	Pharmacist impact on AKI discharge communication	11
15/EM/0265	Biological mechanisms of skin integrity and regeneration	14
15/EM/0270	Antibiotic Resistance in the Microbiome OxfoRd (ARMORd) Study	14
15/EM/0363	Metabolism of Renal cells in Alkaptonuria	9
15/EM/0418	Investigating SLE related muscle fatigue	12
15/EM/0463	Making sense of non-specific low back pain: a grounded theory approach	14
15/EM/0466	A pilot study comparing non-invasive and invasive tests	10
15/EM/0509	Supervised vs. non-supervised exercise in knee osteoarthritis	12
15/EM/0510	OBSERV-GBA v1.0	8
15/EM/0554	A pilot study to investigate the effect of Krill oil on skin function	14
16/EM/0029	Parents' Experiences of Array CGH test_Version1.0	6
16/EM/0064	REFLX	14
16/EM/0109	Service User Experiences of Peer Support Workers.	11
16/EM/0110	ASD in children with MPS III	9

Further Information Favourable Opinion with Additional Conditions		
REC Reference	**Title**	**Number of Days on Clock**
15/EM/0362	Effects of food intake regulating hormones on pain perception	14
15/EM/0465	The DESMA Study	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**
15/EM/0217	Home tonometry for monitoring glaucoma: a pilot study	8
15/EM/0264	Troponin use in PICU	13
15/EM/0367	TORSO	11
15/EM/0420	HeartModel A.I. Multicenter Registry	8
15/EM/0421	Innocoll Pharmacoeconomic Study	7
15/EM/0561	ASCEND2	7
16/EM/0028	Enhancing Gypsy/Travellers' trust in mainstream health services v1	4
16/EM/0033	In vitro sonothrombolysis with microbubbles and the Ekos catheter	4
16/EM/0067	Physical activity intervention in AAASP population	12
16/EM/0112	Measuring The Effect of Pringle Manoeuvre on NIRS Values	7

Favourable Opinion with Additional Conditions		
REC Reference	**Title**	**Number of Days on Clock**
15/EM/0167	The perceptual effects of crowding in amblyopic and developing vision	3
15/EM/0212	Knowledge and attitude of the MDT towards epilepsy in LD service v2	5
15/EM/0372	Multi-Centre Clinical Evaluation of Two Reusable Soft Contact Lenses	10
15/EM/0506	Measuring Physiotherapists Physical Behaviour (Version 1)	7
15/EM/0562	Exploring exercise participation in people with RA.1	7
16/EM/0031	Urinary micronutrient profile after renal transplantation	4
16/EM/0111	Finding Mechanisms of Immunity to Salmonella	7

Unfavourable Opinion		
REC Reference	**Title**	**Number of Days on Clock**
15/EM/0216	Patient expectations and outcomes of orthodontic treatment	9
15/EM/0560	Antibiotic stewardship, nutrition & vitamin D level in HAP	13

Provisional Opinion		
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 10.1: **Breakdown of current status of all substantial amendments reviewed within the reporting period**

Favourable opinion				
Amendment REC Reference	**Title**	**Version**	**Date**	**Number of Days on Clock**
04/Q2501/114/AM23	Alveolar development in childhood	SA#21	09/10/2015	25
04/Q2501/64/AM09	Less Invasive Autopsy (version 1)	Substantial Amendment 8	30/04/2015	15
04/Q2501/64/AM10	Less Invasive Autopsy (version 1)	SA#09	04/08/2015	21
06/Q2501/122/AM09	Generic Tissue Bank for Haematologic Malignancies.	SA#7	11/09/2015	28
06/Q2501/124/AM02	Development of new therapies for B cell malignancies	SA#2	11/09/2015	23
07/Q2501/58/AM04	Studies on specimens from patients with suspected or confirmed tuberculosis	Substantial Amendment 4	26/08/2015	21
07/Q2501/58/AM06	Studies on specimens from patients with suspected or confirmed tuberculosis	SA5	10/03/2016	11
08/H0406/189/AM16	An open study of biomarkers in asthma and COPD	SA#15	30/09/2015	27
08/H0406/226/AM02	Investigating lung cancer progression and therapy - version 2	Substantial Amendment 1	18/03/2015	24
09/H0406/117/AM05	The PSP-CKD Study	SA2	05/11/2015	14
09/H0406/119/AM24	The United Kingdom Aneurysm Growth Study	Substantial amendment 20.05.20	15/05/2015	22
09/H0406/86/AM15	TANDEM: RCT of high and low dose Avastin for MD in East Midlands v1.0	SA#14	29/10/2015	20
10/H0406/27/AM11	ADMYRE: Aplidin – Dexamethasone in RElapsed/Refractory MYeloma	SA - New CI	12/02/2016	14
10/H0406/34/AM20	BO22589 T-DM1 +/- Pertuzumab vs Herceptin/Taxane in 1st Line MBC	Substantial amendment #12	09/07/2015	33
10/H0406/47/AM33	Long Term Safety and Efficacy of Adalimumab in Non-infectious Uveitis	SA11	28/07/2015	13
10/H0406/47/AM36	Long Term Safety and Efficacy of Adalimumab in Non-infectious Uveitis	SA - GP Letter - 23.02.16	03/03/2016	17
10/H0406/75/AM26	C21004:Study of Orteronel with prednisone for prostate cancer	Substantial	31/03/2015	13

	patients	Amendment 31 March		
10/H0406/75/AM27	C21004:Study of Orteronel with prednisone for prostate cancer patients	Substantial Amendment 14.04.2015	14/04/2015	10
10/H0406/76/AM27	C21005:Study of Orteronel with prednisone for prostate cancer patients	Substantial amendment 31.03.2015	31/03/2015	13
10/H0406/76/AM28	C21005:Study of Orteronel with prednisone for prostate cancer patients	Substantial Amendment 14.04.2015	14/04/2015	10
11/EM/0225/AM10	R-CHOP vs G-CHOP in previously untreated patients with DLBCL	SA#6	03/12/2015	18
11/EM/0321/AM21	Fulvestrant with GDC-0941/ GDC-0980 in Metastatic Breast cancer	SA 30.10.2015	30/09/2015	20
11/EM/0326/AM12	Body Composition assessment using DEXA	SA326/01/15	17/09/2015	16
11/EM/0326/AM13	Body Composition assessment using DEXA	SA326/02/15	21/10/2015	21
11/EM/0326/AM14	Body Composition assessment using DEXA	SA326/01/16 11.02.16	11/02/2016	13
11/EM/0327/AM14	Body Composition assessment using DEXA - submission 2	SA327/03/15	21/10/2015	14
11/EM/0327/AM15	Body Composition assessment using DEXA - submission 2	SA327/01/15	20/10/2015	22
11/EM/0327/AM16	Body Composition assessment using DEXA - submission 2	SA327/02/15	20/10/2015	22
11/EM/0327/AM17	Body Composition assessment using DEXA - submission 2	Substantial Amendment 03/11/15	03/11/2015	22
11/EM/0327/AM18	Body Composition assessment using DEXA - submission 2	SA327/01/16 11.02.16	11/02/2016	14
11/EM/0434/AM07	Helicobacter Eradication Aspirin Trial (HEAT)	Substantial Amendment 6	15/06/2015	12
11/EM/0434/AM08	Helicobacter Eradication Aspirin Trial (HEAT)	SA7	28/08/2015	34
11/EM/0434/AM09	Helicobacter Eradication Aspirin Trial (HEAT)	SA8	25/11/2015	15
11/H0406/1/AM09	Longterm effects of grass tablet sublingual immunotherapy	Substantial Amendment 7	25/08/2015	28
11/H0406/10/AM23	ASPIRE - A Study Promoting the Influenza Response in the Elderly v1	SA 01.10.2015	28/09/2015	15
11/H0406/4/AM16	BO22334/A	Substantial	28/04/2015	16

		Amendment 6		
12/EM/0012/AM16	Adolescents and Adults Living with Perinatal HIV Cohort (AALPHI)	SA#9	14/10/2015	20
12/EM/0014/AM14	Preloading Trial	Substantial amendment 1 July 2	30/06/2015	21
12/EM/0018/AM33	CANTOS:CACZ885M2301 Canakinumab in postMI patients with raised hsCRP	Substantial Amendment 08.05.2015	08/05/2015	30
12/EM/0018/AM34	CANTOS:CACZ885M2301 Canakinumab in postMI patients with raised hsCRP	Substantial amendment 27.05.2015	21/05/2015	15
12/EM/0051/AM07	Effectiveness of S78454 in NHL and CLL	SA#9	07/08/2015	18
12/EM/0051/AM08	Effectiveness of S78454 in NHL and CLL	SA#10	07/08/2015	15
12/EM/0051/AM09	Effectiveness of S78454 in NHL and CLL	SA 10.11.15	06/11/2015	16
12/EM/0151/AM13	PROPELS	SA9	16/11/2015	22
12/EM/0151/AM15	PROPELS	Amendment 10 (substantial)	02/03/2016	26
12/EM/0228/AM03	Evaluation of the Health Foundation's Safer Clinical Systems Phase 2	SA2 - Further extension	23/02/2016	13
12/EM/0284/AM09	A longterm Safety study for asthmatic subjects	SA#08	30/07/2015	21
12/EM/0291/AM11	HELIOS - PCI-32765CLL3001	Substantial amendment 8	27/05/2015	15
12/EM/0291/AM14	HELIOS - PCI-32765CLL3001	9	28/09/2015	18
12/EM/0291/AM15	HELIOS - PCI-32765CLL3001	SA#10	09/12/2015	12
12/EM/0292/AM13	RAPID	Substantial Amendment 8	11/08/2015	19
12/EM/0363/AM04	Cab B1	2.0	24/12/2015	15
12/EM/0370/AM09	Phenotyping bronchiectasis over 2 years including a macrolide trial	Substantial Amendment 8	15/07/2015	21
12/EM/0395/AM09	EUCLID – Examining use of ticagrelor in PAD patients	Substantial amendment 9	01/04/2015	11
12/EM/0395/AM10	EUCLID – Examining use of ticagrelor in PAD patients	Substantial Amendment 19 May 2015	19/05/2015	23
12/EM/0395/AM13	EUCLID – Examining use of ticagrelor in PAD patients	SA 7 IB Edition 20	24/12/2015	18

12/EM/0453/AM06	Pixantrone in the treatment of Non Hodgkin Lymphoma (2)	5	17/07/2015	15
12/EM/0453/AM07	Pixantrone in the treatment of Non Hodgkin Lymphoma (2)	SA#6	12/10/2015	22
13/EM/0015/AM08	CAN3001 version 1.0	SA#5	28/09/2015	15
13/EM/0015/AM09	CAN3001 version 1.0	SA#6	07/12/2015	13
13/EM/0061/AM04	Predicting poor outcome following total hip and knee arthroplasty	Substantial Amendment 27.04.2015	24/04/2015	18
13/EM/0123/AM04	Community Liver Biomarkers Cohort	Substantial Amendment 4	02/07/2015	16
13/EM/0226/AM06	Extended cohort for e-health, environment and DNA (EXCEED) Study	Substantial Amendment 2	31/03/2015	13
13/EM/0226/AM07	Extended cohort for e-health, environment and DNA (EXCEED) Study	3	01/10/2015	15
13/EM/0254/AM05	Visual impairment due to VEGF driven Macular Oedema	Substantial Amendment 2	27/04/2015	21
13/EM/0259/AM03	PREVIEW	1.4	04/12/2015	12
13/EM/0263/AM09	LIME Study (LFB IVIG MMN Efficacy Study)	Substantial amendment 7	31/07/2015	26
13/EM/0263/AM10	LIME Study (LFB IVIG MMN Efficacy Study)	SA8	09/11/2105	17
13/EM/0263/AM11	LIME Study (LFB IVIG MMN Efficacy Study)	SA9	10/03/2016	18
13/EM/0317/AM04	SLS Follow-up Interviews	SA02	08/02/2016	16
13/EM/0323/AM05	Asthma-Tailored Pulmonary Rehabilitation	Substantial Amendment 4	17/06/2015	14
13/EM/0323/AM06	Asthma-Tailored Pulmonary Rehabilitation	SA5	07/01/2016	19
13/EM/0323/AM07	Asthma-Tailored Pulmonary Rehabilitation	SA6	10/03/2016	18
13/EM/0339/AM03	Hematopoietic Stem Cell Therapy for Inflammatory MS	SA3	14/10/2015	21
13/EM/0339/AM05	Hematopoietic Stem Cell Therapy for Inflammatory MS	SA4		26
13/EM/0340/AM07	ABT-199 Monotherapy in Relapsed/Refractory CLL With the 17p Deletion	Substantial Amendment 5	05/05/2015	13
13/EM/0373/AM04	C16017 Ph2 Study of Oral MLN9708 in Patients with Follicular Lymphoma	Substantial Amendment 4	22/06/2015	18
13/EM/0397/AM02	Virtual Reality for Risk Assessment after Stroke	SA#1/2015	18/12/2015	21
13/EM/0404/AM10	Serelaxin vs standard of care in acute heart failure patients	Substantial Amendment 9	07/04/2015	15
13/EM/0404/AM11	Serelaxin vs standard of care in acute heart failure patients	SA#10	04/08/2015	22
13/EM/0404/AM12	Serelaxin vs standard of care in acute heart failure patients	SA#11	20/11/2015	19

13/EM/0469/AM04	Developing and testing a tool to measure Therapeutic Engagement (TE)	Substantial Amendment 1	12/05/2015	30
13/EM/0469/AM05	Developing and testing a tool to measure Therapeutic Engagement (TE)	SA2; 22.02.16	22/02/2016	10
14/EM/0001/AM06	TREND	Substantial Amendment 27 April	27/04/2015	18
14/EM/0001/AM08	TREND	Substantial Amendment Change o	19/06/2015	19
14/EM/0024/AM09	Efficacy and safety of secukinumab in pts with Psoriatic Arthritis	Substantial Amendment 27 March	27/03/2015	17
14/EM/0024/AM10	Efficacy and safety of secukinumab in pts with Psoriatic Arthritis	Substantial Amendment 09.04.20	09/04/2015	15
14/EM/0034/AM05	GO28667 - PH III, OPEN-LABEL, IN RELAPSED/REFRACTORY PATIENTS WITH CLL	Substantial Amendment 5	17/03/2015	27
14/EM/0034/AM06	GO28667 - PH III, OPEN-LABEL, IN RELAPSED/REFRACTORY PATIENTS WITH CLL	SA#06	11/06/2015	18
14/EM/0129/AM09	Receptors Inc: Efficacy and Safety of Oral RPC1063 in RMS Patients	Substantial Amendment 4	17/06/2015	21
14/EM/0129/AM11	Receptors Inc: Efficacy and Safety of Oral RPC1063 in RMS Patients	SA05	05/02/2016	20
14/EM/0169/AM03	A Study of the Dural Venous Vasculature in Infants Version 1	Substantial amendment 28.05.20	22/05/2015	14
14/EM/0169/AM04	A Study of the Dural Venous Vasculature in Infants Version 1	SA4	28/01/2016	12
14/EM/0186/AM03	A Phase 3 Study of Pacritinib in Patients with Myelofibrosis	SA003 - 18.02.16 - Temporary H	18/02/2016	18
14/EM/0215/AM07	M12-914 Phase III Veliparib/Placebo + C/P Breast Cancer Study	SA#02	06/08/2015	16
14/EM/1003/AM09	Study to evaluate safety & efficacy of Blisibimod in IgA Nephropathy	Substantial amendment 1 June 2	29/05/2015	23
14/EM/1005/AM08	Phase 3 Masitinib/Placebo + Docetaxel in Metastatic Prostate	SA7	21/09/2015	16

	Cancer V1			
14/EM/1005/AM11	Phase 3 Masitinib/Placebo + Docetaxel in Metastatic Prostate Cancer V1	Amendment 11 (Substantial)	15/02/2016	21
14/EM/1008/AM02	The impact of Joint Hypermobility Syndrome.	Substantial Amendment 1	01/06/2015	18
14/EM/1058/AM02	Administration of subcut depo provera by the community pharmacy	Substantial amendment 09.07.2015	09/07/2015	27
14/EM/1065/AM10	Study of 18 mg SelincroÂ® As-needed Use in Alcohol Dependent Patients	SA05	24/12/2015	14
14/EM/1068/AM03	Open label, phase 3 trial comparing Mylans Glargine with Lantus	SA2	01/10/2015	22
14/EM/1068/AM04	Open label, phase 3 trial comparing Mylans Glargine with Lantus	SA3	11/11/2015	15
14/EM/1137/AM03	ECU-MG-302 Phase III Study of Eculizumab in Subjects with GMG	2	09/09/2015	28
14/EM/1137/AM04	ECU-MG-302 Phase III Study of Eculizumab in Subjects with GMG	SA#3	21/12/2015	21
14/EM/1138/AM01	Sleep Disturbance and The Experience of Chronic Pain	Substantial amendment 31.07.15	31/07/2015	26
14/EM/1141/AM09	ISIS 304801 in Patients With Familial Chylomicronemia Syndrome	Substantial Amendment 3	18/03/2015	26
14/EM/1141/AM11	ISIS 304801 in Patients With Familial Chylomicronemia Syndrome	Substantial Amendment 4	22/05/2015	20
14/EM/1141/AM13	ISIS 304801 in Patients With Familial Chylomicronemia Syndrome	SA#05	23/07/2015	20
14/EM/1141/AM16	ISIS 304801 in Patients With Familial Chylomicronemia Syndrome	Substantial Amendment 08.09.2	08/09/2015	30
14/EM/1141/AM19	ISIS 304801 in Patients With Familial Chylomicronemia Syndrome	SA 21.12.2015	21/12/2015	21
14/EM/1141/AM21	ISIS 304801 in Patients With Familial Chylomicronemia Syndrome	SA - 04.02.16	04/02/2016	21
14/EM/1145/AM02	Birth Outcomes of In Vitro Fertilisation- Conceived Children	SA#01	18/08/2015	18
14/EM/1174/AM01	PD-HF	Substantial	12/05/2015	27

		Amendment 1		
14/EM/1183/AM02	The role of health beliefs in predicting lifestyle choices within CF	SA1	21/09/2015	18
14/EM/1183/AM03	The role of health beliefs in predicting lifestyle choices within CF	SA#2	07/01/2016	15
14/EM/1184/AM03	Surgery for recurrent stress urinary incontinence. The Three S study.	Substantial Amendment 2	08/04/2015	10
14/EM/1214/AM01	SNAPSHOT	Substantial amendment 1 July 2	24/06/2015	26
14/EM/1218/AM01	Effect of DPP4 inhibitor on EPC and SDF-1a in type 2 diabetes (IGLOOS)	Substantial amendment 1	06/05/2015	10
14/EM/1286/AM02	Ruxolitinib in Combination With Regorafenib in Metastatic Colorectal Cancer	Substantial Amendment 1	09/04/2015	18
14/EM/1287/AM01	Antimicrobial Agent for Reducing Bacteria in Aerosols and Oral Cavity	Substantial Amendment 1	27/04/2015	21
14/EM/1287/AM02	Antimicrobial Agent for Reducing Bacteria in Aerosols and Oral Cavity	Substantial amendment 2.1	07/09/2015	14
14/EM/1295/AM01	Two cluster RCTs to evaluate feedback in blood transfusion audits	Substantial amendment 1	07/09/2015	15
14/EM/1295/AM02	Two cluster RCTs to evaluate feedback in blood transfusion audits	2.0	01/12/2015	20
15/EM/0001/AM01	Rowing Away from Diabetes	Substantial amendment 14 July	14/07/2015	29
15/EM/0014/AM01	The BEADS Feasibility Pilot Trial	Amendment 1	20/03/2015	24
15/EM/0014/AM03	The BEADS Feasibility Pilot Trial	Substantial Amendment 2	26/06/2015	12
15/EM/0014/AM04	The BEADS Feasibility Pilot Trial	Substantial Amendment 3	19/08/2015	17
15/EM/0021/AM05	TopicalÂ OxygenÂ andÂ DiabeticÂ FootÂ Ulcers 2 (TODFU2)	Substantial Amendment 1	25/06/2015	12
15/EM/0021/AM06	TopicalÂ OxygenÂ andÂ DiabeticÂ FootÂ Ulcers 2 (TODFU2)	Substantial Amendment 2	17/08/2015	8
15/EM/0048/AM01	Ticagrelor for prevention of tumour cell-induced platelet aggregation	Amendment 1	19/03/2015	24
15/EM/0048/AM03	Ticagrelor for prevention of tumour cell-induced platelet	Substantial	04/08/2015	26

	aggregation	Amendment 3		
15/EM/0135/AM01	Phase 2 Study in Mantle Cell Lymphoma ACE-LY-004	Substantial Amendment 1	12/05/2015	30
15/EM/0135/AM04	Phase 2 Study in Mantle Cell Lymphoma ACE-LY-004	Substantial Amendment 4	22/06/2015	16
15/EM/0135/AM05	Phase 2 Study in Mantle Cell Lymphoma ACE-LY-004	SA#5	26/08/2015	15
15/EM/0135/AM06	Phase 2 Study in Mantle Cell Lymphoma ACE-LY-004	6.0	03/12/2015	18
15/EM/0135/AM08	Phase 2 Study in Mantle Cell Lymphoma ACE-LY-004	SA07	10/02/2016	15
15/EM/0185/AM01	Dietary manipulation in cystic fibrosis-related diabetes	SA1	30/09/2015	16
15/EM/0188/AM01	PRECISION	Substantial amendment 1	03/09/2015	20
15/EM/0209/AM02	Towards the validation of the SASIT-E60 as a diagnostic test for SLI.	SA1	02/10/2015	16
15/EM/0247/AM02	Effect of Tralokinumab on airway inflammation in asthma	SA 14.10.15	14/10/2015	20
15/EM/0247/AM04	Effect of Tralokinumab on airway inflammation in asthma	SA 14.01.16	12/01/2016	12
15/EM/0270/AM01	Antibiotic Resistance in the Microbiome OxfoRd (ARMORd) Study	Substantial Amendment 1	06/08/2015	21
15/EM/0270/AM03	Antibiotic Resistance in the Microbiome OxfoRd (ARMORd) Study	2.0	28/01/2016	12
15/EM/0291/AM01	WREN Study	SA#1	02/10/2015	14
15/EM/0291/AM03	WREN Study	SA#2	09/12/2015	11
15/EM/0294/AM07	INN-TOP-005- Gentamicin- Collagen Sponge in Diabetic Foot Ulcers	SA4	30/09/2015	16
15/EM/0294/AM10	INN-TOP-005- Gentamicin- Collagen Sponge in Diabetic Foot Ulcers	SA#6	29/10/2015	13
15/EM/0294/AM11	INN-TOP-005- Gentamicin- Collagen Sponge in Diabetic Foot Ulcers	07	24/11/2015	15
15/EM/0294/AM13	INN-TOP-005- Gentamicin- Collagen Sponge in Diabetic Foot Ulcers	SA8	13/01/2016	13
15/EM/0298/AM01	INDICATE-P	SA1	02/11/2105	23
15/EM/0300/AM02	WO29636 â€‹ImVigor 010 - Atezolizumab in Bladder Cancer after Cystectomy	SA#2	26/10/2015	16
15/EM/0324/AM02	Open label study of BI 655066 in patients with Crohn's disease.	SA#1	27/10/2015	14
15/EM/0341/AM01	The Sleep Study	1	10/09/2015	28
15/EM/0341/AM02	The Sleep Study	2.0	08/01/2016	18

15/EM/0372/AM01	Multi-Centre Clinical Evaluation of Two Reusable Soft Contact Lenses	SA1	21/08/2015	14
15/EM/0400/AM02	The SOPHIA Study	SA#1	30/10/2015	26
15/EM/0400/AM04	The SOPHIA Study	SA#2	18/12/2015	24
15/EM/0401/AM01	An open label study of Tocilizumab in PAH	SA01	02/11/2015	28
15/EM/0418/AM01	Investigating SLE related muscle fatigue	SA1	28/01/2016	24
15/EM/0433/AM01	COPD-SEAT (Sitting and ExacerbAtions Trial)	SA1	07/12/2015	10
15/EM/0437/AM02	COLUMBUS-AMD	16.12.15	16/12/2015	24
15/EM/0443/AM03	Open-Label Extension Trial of RPC1063 in Relapsing Multiple Sclerosis	SA01	04/02/2016	21
15/EM/0443/AM04	Open-Label Extension Trial of RPC1063 in Relapsing Multiple Sclerosis	SA2	11/03/2016	17
15/EM/0546/AM01	MEDI4736 and Tremelimumab for 1st line head and neck cancer	Global CSP Amend 3	12/01/2016	18
6463/AM08	The GRAPHIC2 Study	SA#4	25/02/2016	31
7254/AM04	ADDITION	170915	17/09/2015	11

Unfavourable opinion				
Amendment REC Reference	**Title**	**Version**	**Date**	**Number of Days on Clock**
13/EM/0061/AM06	Predicting poor outcome following total hip and knee arthroplasty	SA#4	05/10/2015	11
15/EM/0270/AM02	Antibiotic Resistance in the Microbiome OxfoRd (ARMORd) Study	SA#2	12/01/2016	13

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**
04/Q2501/114/AM20/1	Alveolar development in childhood	Modified Amendment of Amendment	02/04/2015	7

13/EM/0061/AM06/2	Predicting poor outcome following total hip and knee arthroplasty	SA#6	06/01/2016	5
13/EM/0323/AM03/1	Asthma-Tailored Pulmonary Rehabilitation	Modified Amendment of Substantial	24/03/2015	6

Unfavourable opinion timeline				
Amendment REC Reference	**Title**	**Version**	**Date**	**Number of Days on Clock**
13/EM/0061/AM06/1	Predicting poor outcome following total hip and knee arthroplasty	SA#4	09/11/2015	9

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 14 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**