NHS
Health Research Authority

Research Ethics Service

East Midlands - Leicester Central Research Ethics Committee

Annual Report

01 April 2016 - 31 March 2017

Part 1 – Committee Membership and Training

Name of REC:	East Midlands - Leicester Central Research Ethics Committee
Type of REC:	REC recognised to review CTIMPS in patients - type iii
Type of Flag:	IRB Registered
Chair:	Mr Ken Willis
Vice-Chair:	Mr Murthy Nyasavajjala
Alternate Vice-Chair:	Miss Alison Armstrong
REC Manager:	Ellen Swainston (to end January 2017) Helen Poole (from February 2017)
REC Assistant:	Nicola Kohut (to end July 2016) Various cover (August-January 2017) Joanne O'Neil (from February 2017)
Committee Address:	The Old Chapel Royal Standard Place Nottingham NG1 6FS
Telephone:	0207 104 8115
Email:	nrescommittee.eastmidlands-leicestercentral@nhs.net

Chair's overview of the past year:

Firstly I must say that it has been a privilege to chair a committee with such a diverse background, which brings a wealth of knowledge and experience to the table. The committee have been efficiently supported by the REC management team which changed from Ellen Swainston and Nicola Kohut to Helen Poole and Joanne O'Neil in January 2017

We have also changed venue and the committee are pleased with the new venue which is in close proximity to the train station, and therefore aids travel options for members and attendees.

The structure of the committee has also changed with the loss of two very experienced members; one of whom, John Baker, was the Vice Chair as well as being our radiation expert. The other long standing member was Sandra Hall who was our pharmacy expert. Both of these members came to the end of their tenure. On the flip side we have gained some new members who have gelled with the committee almost seamlessly.

One of our members expressed an interest in the vacant Vice Chair role and was successful in the interview process. I am pleased to be supported by Murthy Nyasavajjala as the Vice Chair.
With the exception of some PR applications, we have managed to keep on track with regard to the timelines. We are always conscious of meeting time schedules and I am pleased to say that the majority of applicants' time slots have been punctual.

As a committee our meeting plan has evolved into exception reporting. This maximises the time that we can spend on important ethical issues as well as maximising the face to face time that we spend with applicants. Feedback from the applicants has been positive, which is reassuring.

Application forms continue with the same kind of errors and omissions, mostly involving issues around independent complaints contact numbers and neglecting to state the correct REC name. Many of the errors could be quite easily be resolved prior to review by having the applications and patient information sheets proof read, possibly by someone not directly involved in the research. This would certainly increase the number of approved applications.

We have dealt with many applications that have the potential to improve patient care and quality of life for a broad range of situations. I hope that we can look forward to many more exciting applications that make you feel honoured to be supporting and in some cases adding value to research.

Finally I would like to express my thanks to the committee and the REC management team for their continued support, and also to all the research applicants for making our role interesting.

East Midlands - Leicester Central Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Mr Ken Willis	Medical Devices Manager - retired	Lay Plus	01/01/2015	
Mr Murthy Nyasavajjala	Specialist Registrar- General Surgery	Expert	18/08/2014	
Miss Alison Armstrong	Consultant Orthopaedic Surgeon	Expert	08/05/2008	
Dr Paul Beeson	Senior Lecturer	Expert	07/12/2012	
Dr Alan Cudworth	Retired Senior Lecturer	Lay Plus	04/04/2016	
Mrs Lynne Fryatt	Retired Assistant Chief Nurse	Lay	25/01/2016	
Dr Nicola James	Independent Research Consultant	Lay Plus	10/01/2014	
Mr Michael Jones	Medical Statistician	Expert	26/02/2016	
Mrs Rita Patel	Contracts and Innovation Manager	Lay	01/01/2017 Transferred from Nottingham 1 REC	
Mr John Warden	Clinical Trials Data and Information Systems Manager	Lay	25/01/2016	14/06/2016
Mr John Baker	Radiation Protection Advisor and Senior Lecturer (retired)	Lay Plus	06/10/2006	06/10/2016
Mrs Sandra Hall	Principal Lecturer in Clinical Pharmacy & Pharmacy Practice	Expert	20/10/2006	20/10/2016

East Midlands - Leicester Central Research Ethics Committee: Deputy Members

None

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

Name	Profession	Status	Meeting date attended
Dr Ian Ross	Retired Consultant Physician	Expert	01/04/2016 04/11/2016
Mr John Aldridge	Retired Senior Lecturer in Nursing	Lay	02/09/2016
Mrs Anne Walker	Voluntary Worker in Health Care	Lay Plus	01/04/2016
Mr Chris Foy	Medical Statistician	Expert	03/02/2017
Mrs Lynne Gray	Senior Biomedical Scientist	Expert	03/03/2017
Dr Nigel Langford	Consultant Clinical Pharmacologist & General Physician	Expert	06/01/2017 03/02/2017
Mrs Rita Patel	Contracts and Innovation Manager	Lay	05/08/2016

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

Name	Declaration of Interest	Date
Dr Alan Cudworth	None declared	16/05/2016
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.	13/04/2016
Mr Michael Jones	Medical Statistician for Derby Teaching Hospitals NHS Foundation Trust. Expert Reviewer for NIHR funding programs. DMEC member for the TARGET-DLE study (REC Number 15/YH/0257).	01/12/2016
Mrs Rita Patel	Employee at University Hospitals of Leicester NHS Trust - role is Contracts and Innovation Manager - Research'.	01/01/2017
Dr Paul Beeson	Member of University of Northampton Faculty Health & Society research ethics committee and Science Research Degree Board.	01/12/2016
Mr Ken Willis	None declared.	01/12/2016
Mr Murthy Nyasavajjala	None declared.	01/12/2016
Dr Nicola James	Shareholdings in Glaxo Smith Kline and Shire Pharmaceuticals. Willing to offer expert advice in research study design.	01/12/2016

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

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

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

10 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	01/04/2016	2
April	15/04/2016	3
April	25/04/2016	2
May	06/05/2016	3
May	20/05/2016	3
May	23/05/2016	3
June	03/06/2016	3
June	10/06/2016	3
June	17/06/2016	3
July	01/07/2016	2
July	15/07/2016	2
August	05/08/2016	2

August	19/08/2016	2
September	09/09/2016	2
September	26/09/2016	2
October	07/10/2016	2
October	21/10/2016	2
November	04/11/2016	2
November	18/11/2016	2
December	02/12/2016	2
December	16/12/2016	2
January	06/01/2017	2
January	20/01/2017	2
February	03/02/2017	2
February	17/02/2017	2
March	03/03/2017	2
March	17/03/2017	2

27 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 Ken Willis	8
Dr Alan Cudworth	7
Mrs Lynne Fryatt	9
Dr Nicola James	6
Mr Michael Jones	9
Mr Murthy Nyasavajjala	8
Miss Alison Armstrong	5
Dr Paul Beeson	3
Mrs Rita Patel	2

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

Name	Number of Meetings Attended
Miss Alison Armstrong	2
Dr Paul Beeson	2
Dr Alan Cudworth	1
Mrs Lynne Fryatt	1
Dr Nicola James	2
Mr Michael Jones	2
Mr Murthy Nyasavajjala	6
Mr Ken Willis	8

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

Name	Number of Meetings Attended
Miss Alison Armstrong	1
Mr John Baker	10
Dr Paul Beeson	6
Mrs Lynne Fryatt	2
Mrs Sandra Hall	4
Dr Nicola James	2
Mr Murthy Nyasavajjala	14
Mr Ken Willis	22

Training 01 April 2016 - 31 March 2017

Name of Member	Date	Event(s) attended
Miss Alison Armstrong	23/09/2016	Members Regional Training Day
Dr Paul Beeson	23/09/2016	Members' Regional Training Day
Dr Paul Beeson	29/11/2016	Read Article: placebo surgery as control in clinical trials
Dr Paul Beeson	30/11/2016	Read Article: Sense and Sensibility, readability issues in Participant Informaiton Sheets
Dr Paul Beeson	30/11/2016	Read information on generic risk statements on ionising radiation for Partiicpant Information Sheets and IRAS forms
Dr Paul Beeson	02/12/2016	Read article: Must research benefit human subjects if it is to be permissible
Dr Paul Beeson	02/12/2016	Read Article; understanding the therapeutic misconception from the Research Participants perspective
Dr Paul Beeson	08/02/2017	Communicating the Impact of Research
Dr Paul Beeson	08/02/2017	Developing Research on a Shoe String
Dr Paul Beeson	30/03/2017	Faculty Health and Society Ethics Panel - Ongoing member
Dr Alan Cudworth	15/09/2016	Committee Members' Induction
Dr Alan Cudworth	23/09/2016	Members Regional Training Event
Mrs Lynne Fryatt	08/06/2016	New member induction
Mrs Lynne Fryatt	22/06/2016	E&D
Mrs Lynne Fryatt	23/09/2016	Members' Regional Training Day
Dr Nicola James	23/09/2016	Members Regional Training Day
Dr Nicola James	27/09/2016	Human Tissue Act Training - introductory level
Mr Michael Jones	15/09/2016	Committee Members' Induction
Mr Michael Jones	23/09/2016	Members' Regional Training Day
Mr Murthy Nyasavajjala	03/10/2016	Equality and Diversity
Mr Murthy Nyasavajjala	03/10/2016	Information Governance
Mr Murthy Nyasavajjala	04/10/2016	Safeguarding Levels 1, 2 and 3 - Children and Adults
Mrs Rita Patel	23/09/2016	Local Training Day Leicester
Mrs Rita Patel	23/09/2016	Local Members' Training Day - Regional
Mrs Rita Patel	19/10/2016	HARP Member's Portal Webinar
Mrs Rita Patel	08/12/2016	Online Equality and Diversity
Mrs Rita Patel	16/02/2017	National Members' Training Day
Mr Ken Willis	23/09/2016	Members' Regional Training day

PART 2: REC WORKLOAD AND ACTIVITY DURING THE REPORTING PERIOD

Table 1: Applications assigned to a full committee meeting held within the reporting period:

Applications for full ethical review – Study Type	Number	%
Clinical Trial of Investigational Medicinal Product	14	29.17
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	2	4.17
Others	32	66.67
Total Applications Reviewed	**48**	**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	4
Number of device applications reviewed	3
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	4
Number of qualitative applications reviewed	5

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

Decisions taken at meetings following review of applications	Number	%
Favourable Opinion with Standard Conditions	3	6.25
Favourable Opinion with Additional Conditions	4	8.33
Unfavourable Opinion	0	0.00
Provisional Opinion	41	85.42
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	**48**	**100**
Number of studies sent back to full committee meeting for final opinion	0	

Table 4: **Summary of current status of applications reviewed during the reporting period**

Status of applications at date of generation of report	Number	%
Further Information Favourable Opinion with Standard Conditions	38	79.17
Further Information Favourable Opinion with Additional Conditions	2	4.17
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	3	6.25
Favourable Opinion with Additional Conditions	4	8.33
Unfavourable Opinion	0	0.00
Provisional Opinion	1	2.08
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	**48**	**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	3
Number of studies withdrawn prior to the meeting	0
Number of student applications reviewed	14
Number of paediatric applications reviewed	2
Number of device applications reviewed	0
Number of qualitative applications reviewed	8

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	8	24.24
Favourable Opinion with Additional Conditions	9	27.27
No Opinion transfer to full committee for review	1	3.03
Provisional Opinion	15	45.45
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	4.25
Number of completed applications for full ethical review	48
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	3
Number of completed applications over 40 days as a % of total	6.25%
Number of days taken to final decision – average (mean)	30

Number of completed proportionate review applications for ethical review	32
Number of completed proportionate review applications for ethical review over 14 days (Please note, the timeline for the review of PR applications was extended from 14 to 21 calendar days in December 2016)	7
Number of completed proportionate review applications for ethical review over 21 days	3
Number of completed proportionate review applications over 14 days as a % of total	21.88%

Number of SSAs (non-Phase 1) reviewed	7
Number of completed applications for SSA review over 25 days	1
Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs	14.29%

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	152
Number of completed substantial amendments over 35 days	0
Number of completed substantial amendments over 35 days as a % of total substantial amendments	0.00%
Number of completed substantial amendments over 28 days	7
Number of completed substantial amendments over 28 days as a % of total substantial amendments	4.61%

Number of modified amendments reviewed	2
Number of completed modified amendments over 14 days	0
Number of completed modified amendments over 14 days as a % of total modified amendments	0.00%

Number of non substantial amendments received	138

Number of substantial amendments received for information	1
Number of substantial amendments received for new sites/PIs	28
Number of annual progress reports received	99
Number of safety reports received	59
Number of Serious Adverse Events received	0
Number of final reports received	23

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/0135	Effect on contact lens use on the shape of the cornea	25
16/EM/0149	A Core Outcome Set for Comorbid Diabetes and Severe Mental Illness	30
16/EM/0186	STAR-TReC	32
16/EM/0190	Carers – their role and informational needs in vasculitis' (CAREVASC)	24
16/EM/0193	The dal-GenE trial	27
16/EM/0198	GO30081 Atezolizumab in patients with untreated extensive-stage SCLC	29
16/EM/0202	Bariatric patients' experience of loose skin	26
16/EM/0269	REVEAL-Vasc	31
16/EM/0275	Recovery From Late Onset Psychosis: A Narrative Approach	38
16/EM/0278	DIUR-006	29
16/EM/0280	How consent is constructed and negotiated by men who have sex with men	35
16/EM/0308	Placental MRI (PiP-Ox)_ Version 1	32
16/EM/0322	Tenecteplase in Wake-up Ischaemic Stroke Trial	28
16/EM/0325	Understanding 999 use & hospital admissions of Case Managed patients	31
16/EM/0337	Preventing progressive pacemaker-induced remodelling	27
16/EM/0338	Evaluation of the CP1000 Sound Processor and Compatible Products : V3	45
16/EM/0382	PERSPECTIVE	26
16/EM/0383	Sustaining psychological wellbeing in working family carers	29
16/EM/0384	Phase 3b AUGUSTUS study	49
16/EM/0386	CAMG334A2301 in episodic migraine phase 3b	27
16/EM/0439	NOVELTY	36
16/EM/0456	Diagnostic evaluation of a rapid test for children with suspected RSV	24
16/EM/0457	Long term outcome after accidental dural puncture in obstetric populat	26
16/EM/0459	A Phase 2b study for adults with Respiratory Syncytial Virus.	36
16/EM/0460	The effect of exercise on articular cartilage and bone.	25
17/EM/0006	ALD403 for Chronic Migraine Prevention	27
17/EM/0011	SOLVE	39
17/EM/0013	HVC study to qualify molecular biomarkers associated with flu	39
17/EM/0028	CADBIO	37
17/EM/0029	Promoting engagement in physical activity in rheumatoid arthritis	38
17/EM/0044	Nintedanib and placebo in patients with PF-ILD.	25
17/EM/0046	Experiences of women following treatment for invasive breast cancer	24

17/EM/0056	Intervention to Increase Compliance to a Gluten Free Diet	23
17/EM/0058	1245.110 EMPEROR-Preserved Study	41
17/EM/0059	1245.121 EMPEROR-Reduced Study	34
17/EM/0083	3rd Generation Study - Six Year Follow-Up	28
17/EM/0087	Spinal Imaging in Neuropathy of Diabetes: Longitudinal Evaluation	32
17/EM/0092	Questionnaire to measure levels of self-conscious emotions in COPD	18

Further Information Favourable Opinion with Additional Conditions		
REC Reference	**Title**	**Number of Days on Clock**
16/EM/0134	NEON: Nurture Early for Optimal Nutrition	37
16/EM/0142	aTTom-Extended Version 1.0, 15th March 2016	39

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**
16/EM/0121	CRICKET: CRT Improved Clinical Response UK Trial	25
4867	Long-term outcome of respiratory symptoms in pre-school children	31
5005	Second cross-sectional survey of respiratory symptoms in pre-school	31

Favourable Opinion with Additional Conditions		
REC Reference	**Title**	**Number of Days on Clock**
16/EM/0315	LCC-CKD Cohort	24
16/EM/0385	The Relationship Between Trauma and Substance Misuse V1.0	24
17/EM/0015	UK LAM Registry	21
17/EM/0020	The Jockey Study	26

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

None		

Provisional Opinion		
REC Reference	**Title**	**Number of Days on Clock**
16/EM/0287	UK POEM Registry	n/a

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**
None		

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

Further Information Favourable Opinion with Standard Conditions		
REC Reference	**Title**	**Number of Days on Clock**
16/EM/0145	An exploration of women's experience of holistic needs assessment	14
16/EM/0205	Why A&E? A Qualitative Study	10
16/EM/0252	An observational, Quality of Life study in Lemtrada MS patients	25
16/EM/0294	Salivary cortisol and salivary cortisone in children on hydrocortisone	10
16/EM/0295	INSPIRE 1	12
16/EM/0345	Impact of antibiotic administration route on GIT microbiome	26
16/EM/0348	The Back of the Brain Project (BoB)	32

16/EM/0352	A-CAT: Accessing Child Anxiety Treatment Version 1	14
16/EM/0395	Microcirculatory function in peritoneal dialysis V1(1)	10
16/EM/0397	ASSOCIATION BETWEEN PROPRIONIBACTERIUM ACNES AND PREVIOUS SURGERY	9
17/EM/0052	Parents of children with autism's views of child psychotherapy #1	21
17/EM/0054	Coping styles, resilience and self-blame following a traumatic event.	19
17/EM/0057	Role of bradykinin in the diagnosis and management of angioedema	16

Further Information Favourable Opinion with Additional Conditions		
REC Reference	**Title**	**Number of Days on Clock**
16/EM/0200	Cervical Screening Study	13

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**
16/EM/0143	Colon CTC	14
16/EM/0195	Global cVAD Registry	10
16/EM/0197	Molecular Characterisation of CTCs in NSCLC (ref 16/EM/0197)	8
16/EM/0497	Collagen Markers in Hypopharyngeal Cancer. A retrospective study.	8
16/EM/0503	Triple-D Targets: The UK-Philippines Dengue Diagnostic and Drug Target	10
17/EM/0097	Whole Genome Epistasis Analysis Using New Mathematics v1.0	11
17/EM/0098	Stoma Patients, leakages and thoughts about lipomodeling	15
17/EM/0100	CVST-IMAGING STUDY	11

Favourable Opinion with Additional Conditions		
REC Reference	**Title**	**Number of Days on Clock**
16/EM/0250	Patients' Views of Pain Management Programmes	10
16/EM/0297	Quality of Life after Cytoreductive Surgery and HIPEC for Pseudomyxoma	8
16/EM/0394	Peritoneal drain fluid lactate and pH after colorectal surgery - v1	11
16/EM/0468	Exploring Endotypes in Chronic Rhinosinusitis (ExpRess)	7

16/EM/0469	Optical Coherence Tomography Angiography NEtwork (OCTANE) Study	10
16/EM/0470	CAPTURE JIA	11
16/EM/0498	Monopeptide Follow-up	8
17/EM/0051	Patient accounts of pressure ulcer prevention following fractured hip	11
17/EM/0099	An Exploration of How Older People Experience Mindfulness	9

Unfavourable Opinion		
REC Reference	**Title**	**Number of Days on Clock**
None		

Provisional Opinion		
REC Reference	**Title**	**Number of Days on Clock**
16/EM/0392	Optimal Embryo Implantation Site	n/a

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**
08/H0406/189/AM17	An open study of biomarkers in asthma and COPD	SA#16	04/04/2016	11
08/H0406/189/AM18	An open study of biomarkers in asthma and COPD	SA17	09/06/2016	12
08/H0406/223/AM14	Donation of tissue for research from patients at LOROS, L	SA#12 - 11.04.16	10/05/2016	13
08/H0406/223/AM15	Donation of tissue for research from patients at LOROS, L	Substantial Amendment Number 1	11/10/2016	13
09/H0406/114/AM20	Sample and data collection for cardiovascular research	SA19	12/04/2016	16
09/H0406/119/AM28	The United Kingdom Aneurysm Growth Study	SA9	08/04/2016	16
09/H0406/73/AM05	Living with Nystagmus	Substantial Amendment 5	08/09/2016	14
09/H0406/86/AM17	TANDEM: RCT of high and low dose Avastin for MD in East Midlands v1.0	SA#15	21/03/2016	15
09/H0406/86/AM18	TANDEM: RCT of high and low dose Avastin for MD in East Midlands v1.0	16	07/11/2016	19
09/H0406/86/AM19	TANDEM: RCT of high and low dose Avastin for MD in East Midlands v1.0	17	31/01/2017	20
10/H0406/34/AM21	BO22589 T-DM1 +/- Pertuzumab vs Herceptin/Taxane in 1st Line MBC	SA13	31/05/2016	18
11/EM/0180/AM14	WA25204 RA with CV outcomes (ENTRACTE Study)	SA06	16/03/2016	20
11/EM/0225/AM12	R-CHOP vs G-CHOP in previously untreated patients with DLBCL	SA#8	31/03/2016	15
11/EM/0225/AM14	R-CHOP vs G-CHOP in previously untreated patients with DLBCL	9	18/11/2016	14
11/EM/0326/AM15	Body Composition assessment using DEXA	DEXA 1Protocol 2	15/08/2016	19
11/EM/0326/AM16	Body Composition assessment using DEXA	SA32/02/16	15/09/2016	12
11/EM/0327/AM19	Body Composition assessment using DEXA - submission 2	SA327/02/16 - 24th March 2016	24/03/2016	15
11/EM/0327/AM20	Body Composition assessment using DEXA - submission 2	SA327/03/16 - 1st April 2016	01/04/2016	15
11/EM/0327/AM21	Body Composition assessment using DEXA - submission 2	Generic DEXA 2 version 2	15/08/2016	19

11/EM/0327/AM22	Body Composition assessment using DEXA - submission 2	Substantial Amendment SA327/04	24/11/2016	20
11/EM/0327/AM23	Body Composition assessment using DEXA - submission 2	SA0327/05/16	01/12/2016	18
11/EM/0434/AM10	Helicobacter Eradication Aspirin Trial (HEAT)	SA9	17/03/2016	24
12/EM/0018/AM36	CANTOS:CACZ885M2301 Canakinumab in postMI patients with raised hsCRP	SA - Study Patient Survey	20/04/2016	33
12/EM/0018/AM38	CANTOS:CACZ885M2301 Canakinumab in postMI patients with raised hsCRP	Version 1	08/09/2016	13
12/EM/0018/AM40	CANTOS:CACZ885M2301 Canakinumab in postMI patients with raised hsCRP	Protocol amendment 9	28/10/2016	21
12/EM/0151/AM16	PROPELS	11	11/08/2016	23
12/EM/0223/AM08	Bone health and body composition measurement by DXA	SA8	06/04/2016	16
12/EM/0223/AM09	Bone health and body composition measurement by DXA	SA9	13/04/2016	18
12/EM/0223/AM10	Bone health and body composition measurement by DXA	10	29/07/2016	31
12/EM/0284/AM14	A longterm Safety study for asthmatic subjects	SA10	31/08/2016	17
12/EM/0291/AM17	HELIOS - PCI-32765CLL3001	SA12	08/06/2016	11
12/EM/0291/AM19	HELIOS - PCI-32765CLL3001	SA13	21/02/2017	14
12/EM/0453/AM09	Pixantrone in the treatment of Non Hodgkin Lymphoma (2)	SA7	28/06/2016	21
13/EM/0015/AM12	CAN3001 version 1.0	SA#7	10/06/2016	25
13/EM/0015/AM14	CAN3001 version 1.0	SA8	22/06/2016	13
13/EM/0061/AM07	Predicting poor outcome following total hip and knee arthroplasty	SA #7 (18.02.16)	15/03/2016	27
13/EM/0061/AM08	Predicting poor outcome following total hip and knee arthroplasty	8	23/12/2016	14
13/EM/0123/AM05	Community Liver Biomarkers Cohort	SA5	21/04/2016	13
13/EM/0259/AM04	PREVIEW	SA - version 2 29.04.16	04/05/2016	19
13/EM/0263/AM12	LIME Study (LFB IVIG MMN Efficacy Study)	SA10	04/08/2016	28
13/EM/0323/AM08	Asthma-Tailored Pulmonary Rehabilitation	SA7	26/05/2016	19
13/EM/0323/AM10	Asthma-Tailored Pulmonary Rehabilitation	SA8	28/02/2017	27
13/EM/0339/AM06	Hematopoietic Stem Cell Therapy for Inflammatory MS	SA#05	25/10/2016	25
13/EM/0340/AM08	ABT-199 Monotherapy in Relapsed/Refractory CLL With the 17p Deletion	SA - IB update (Edition 7)	11/03/2016	28
13/EM/0340/AM11	ABT-199 Monotherapy in Relapsed/Refractory CLL With the 17p Deletion	SA - Protocol amendment 4	16/05/2016	25

13/EM/0340/AM12	ABT-199 Monotherapy in Relapsed/Refractory CLL With the 17p Deletion	Substantial Amendment 2016/06/	01/06/2016	31
13/EM/0340/AM13	ABT-199 Monotherapy in Relapsed/Refractory CLL With the 17p Deletion	IB7 Addendum 3	13/09/2106	13
13/EM/0340/AM14	ABT-199 Monotherapy in Relapsed/Refractory CLL With the 17p Deletion	Substantial Amendment Protocol	08/09/2016	19
13/EM/0354/AM04	Helium thermocoagulation versus electrosurgery for endometriosis.	SA 2.0	11/07/2016	22
13/EM/0373/AM05	C16017 Ph2 Study of Oral MLN9708 in Patients with Follicular Lymphoma	Ib Addendum IB 10	23/09/2016	20
13/EM/0404/AM17	Serelaxin vs standard of care in acute heart failure patients	15	22/11/2016	13
13/EM/0404/AM18	Serelaxin vs standard of care in acute heart failure patients	Substantial Amendment 16	19/01/2017	19
14/EM/0024/AM13	Efficacy and safety of secukinumab in pts with Psoriatic Arthritis	SA10	21/06/2016	20
14/EM/0034/AM07	GO28667 - PH III, OPEN-LABEL, IN RELAPSED/REFRACTORY PATIENTS WITH CLL	SA#7	11/04/2016	16
14/EM/0034/AM09	GO28667 - PH III, OPEN-LABEL, IN RELAPSED/REFRACTORY PATIENTS WITH CLL	8	23/12/2016	19
14/EM/0129/AM12	Receptors Inc: Efficacy and Safety of Oral RPC1063 in RMS Patients	SA6	06/04/2016	20
14/EM/0129/AM13	Receptors Inc: Efficacy and Safety of Oral RPC1063 in RMS Patients	SA7	30/06/2016	20
14/EM/0129/AM14	Receptors Inc: Efficacy and Safety of Oral RPC1063 in RMS Patients	8	14/12/2016	28
14/EM/0129/AM15	Receptors Inc: Efficacy and Safety of Oral RPC1063 in RMS Patients	SA9	20/02/2017	15
14/EM/0169/AM07	A Study of the Dural Venous Vasculature in Infants Version 1	SA5	04/08/2016	27
14/EM/0215/AM09	M12-914 Phase III Veliparib/Placebo + C/P Breast Cancer Study	SA03	13/07/2016	14
14/EM/1005/AM13	Phase 3 Masitinib/Placebo + Docetaxel in Metastatic Prostate Cancer V1	13	23/08/2016	26
14/EM/1005/AM14	Phase 3 Masitinib/Placebo + Docetaxel in Metastatic Prostate Cancer V1	Substantial Amendment	01/10/2016	16

		Combined		
14/EM/1061/AM02	RCT ABI v Dry needling for plantar fasciitis - v2	SA1 - Amendment 02	21/07/2016	18
14/EM/1068/AM05	Open label, phase 3 trial comparing Mylans Glargine with Lantus	5	29/06/2016	20
14/EM/1137/AM05	ECU-MG-302 Phase III Study of Eculizumab in Subjects with GMG	SA#4	04/04/2016	23
14/EM/1137/AM06	ECU-MG-302 Phase III Study of Eculizumab in Subjects with GMG	SA5	22/02/2017	13
14/EM/1141/AM22	ISIS 304801 in Patients With Familial Chylomicronemia Syndrome	Protocol amendment 4.0+5.0+6.0	06/06/2016	21
14/EM/1141/AM23	ISIS 304801 in Patients With Familial Chylomicronemia Syndrome	SA - Update IB - Rev 7.0	29/06/2016	22
14/EM/1141/AM24	ISIS 304801 in Patients With Familial Chylomicronemia Syndrome	Substantial Amendment 4	19/08/2016	18
14/EM/1141/AM25	ISIS 304801 in Patients With Familial Chylomicronemia Syndrome	Substantial Amendment 7.1	22/09/2016	14
14/EM/1141/AM26	ISIS 304801 in Patients With Familial Chylomicronemia Syndrome	Substantial Amendment 3	01/10/2016	6
14/EM/1141/AM27	ISIS 304801 in Patients With Familial Chylomicronemia Syndrome	7.2	20/12/2016	22
14/EM/1174/AM02	PD-HF	SA02	21/07/2016	15
14/EM/1218/AM02	Effect of DPP4 inhibitor on EPC and SDF-1a in type 2 diabetes (IGLOOS)	2	29/07/2016	28
14/EM/1284/AM09	Neo-AEGIS	SA008	22/03/2016	20
14/EM/1284/AM11	Neo-AEGIS	SA009	29/07/2016	16
14/EM/1286/AM05	Ruxolitinib in Combination With Regorafenib in Metastatic Colorectal Cancer	SA2	31/05/2016	21
14/EM/1295/AM03	Two cluster RCTs to evaluate feedback in blood transfusion audits	3	06/07/2016	11
15/EM/0014/AM06	The BEADS Feasibility Pilot Trial	Amendment 4 - 06.05.16	09/05/2016	14
15/EM/0048/AM05	Ticagrelor for prevention of tumour cell-induced platelet aggregation	Substantial Amendment 5	14/09/2016	7
15/EM/0131/AM01	Re-referral to musculoskeletal outpatient physiotherapy	SA1	24/03/2016	15

	departments			
15/EM/0135/AM10	Phase 2 Study in Mantle Cell Lymphoma ACE-LY-004	8	18/08/2016	28
15/EM/0247/AM06	Effect of Tralokinumab on airway inflammation in asthma	SA 26.07.16	26/07/2016	14
15/EM/0247/AM09	Effect of Tralokinumab on airway inflammation in asthma	Substantial Amendment	10/10/2016	18
15/EM/0270/AM04	Antibiotic Resistance in the Microbiome OxfoRd (ARMORd) Study	SA03 - 12.07.16	12/07/2016	26
15/EM/0291/AM05	WREN Study	substantial Amendment 3	02/09/2016	22
15/EM/0298/AM02	INDICATE-P	SA2	11/05/2016	12
15/EM/0300/AM03	WO29636 ImVigor 010 - Atezolizumab in Bladder Cancer after Cystectomy	SA#3	06/07/2016	8
15/EM/0300/AM05	WO29636 ImVigor 010 - Atezolizumab in Bladder Cancer after Cystectomy	SA4	10/08/2016	28
15/EM/0300/AM08	WO29636 ImVigor 010 - Atezolizumab in Bladder Cancer after Cystectomy	Substantial Amendment 5 2016/1	11/11/2016	10
15/EM/0313/AM05	Gene expression profiling in asthma	Substantial Amendment 1 2016/1	18/11/2016	11
15/EM/0324/AM03	Open label study of BI 655066 in patients with Crohn's disease.	SA#2	14/03/2016	27
15/EM/0324/AM06	Open label study of BI 655066 in patients with Crohn's disease.	SA#03	25/10/2016	27
15/EM/0341/AM03	The Sleep Study	3	13/03/2016	25
15/EM/0341/AM05	The Sleep Study	Substantial Amendment 4.	08/08/2016	28
15/EM/0342/AM03	A Long-term Access Programme (LAP) for Subjects with Severe Asthma	SA1	06/09/2016	20
15/EM/0342/AM05	A Long-term Access Programme (LAP) for Subjects with Severe Asthma	SA2	17/02/2017	34
15/EM/0344/AM04	MORAb009-201 Amatuximab in Unresectable Malignant Pleural Mesothelioma	SA4	17/02/2017	18
15/EM/0399/AM01	Endobarrier in diabetes with obstructive sleep apneoa	SA#01	29/06/2016	16
15/EM/0400/AM05	The SOPHIA Study	SA#3	28/04/2016	20
15/EM/0400/AM06	The SOPHIA Study	4	06/07/2016	16

15/EM/0400/AM07	The SOPHIA Study	Substantial Amendment 5	23/09/2016	20
15/EM/0400/AM08	The SOPHIA Study	Country-specific Addendum 2.0	08/11/2016	11
15/EM/0401/AM04	An open label study of Tocilizumab in PAH	SA02	27/06/2016	28
15/EM/0430/AM06	D1690R00009: The DECIDE Study	SA4	06/05/2016	17
15/EM/0430/AM09	D1690R00009: The DECIDE Study	Substantial Amendment 7	05/08/2016	32
15/EM/0430/AM10	D1690R00009: The DECIDE Study	8	22/12/2016	20
15/EM/0433/AM04	COPD-SEAT (Sitting and ExacerbAtions Trial)	SA2	23/03/2016	30
15/EM/0437/AM06	COLUMBUS-AMD	Substantial Amendment Protocol	18/01/2017	10
15/EM/0439/AM01	POM Study - Version 1	1	18/07/2016	24
15/EM/0439/AM02	POM Study - Version 1	2	07/10/2016	19
15/EM/0443/AM06	Open-Label Extension Trial of RPC1063 in Relapsing Multiple Sclerosis	SA3	30/06/2016	19
15/EM/0443/AM08	Open-Label Extension Trial of RPC1063 in Relapsing Multiple Sclerosis	Substantial Amendment 4	14/12/2016	28
15/EM/0498/AM03	TC Members' Evaluations of a Learning Disability Therapeutic Community	SA1	15/02/2017	11
15/EM/0510/AM02	OBSERV-GBA v1.0	SA#1	30/03/2016	15
15/EM/0510/AM03	OBSERV-GBA v1.0	SA#2	31/05/2016	12
15/EM/0532/AM01	Cambridge Brain and Behaviour Study (CamBABS)	Substantial Amendment 1	15/06/2016	13
15/EM/0546/AM03	MEDI4736 and Tremelimumab for 1st line head and neck cancer	SA3 - Global CSP Amendment 4	19/05/2016	18
15/EM/0546/AM04	MEDI4736 and Tremelimumab for 1st line head and neck cancer	Substantial Amendment 1	03/08/2016	34
15/EM/0546/AM05	MEDI4736 and Tremelimumab for 1st line head and neck cancer	Safety notification 1	22/09/2016	20
15/EM/0546/AM06	MEDI4736 and Tremelimumab for 1st line head and neck cancer	6	02/12/2016	17
15/EM/0547/AM01	Caloric Vestibular Stimulation in Parkinson's Disease	SA#1	20/05/2016	3
15/EM/0547/AM02	Caloric Vestibular Stimulation in Parkinson's Disease	2	28/07/2016	26
16/EM/0029/AM02	Parents' Experiences of Array CGH test_Version1.0	SA1	10/06/2016	11

16/EM/0094/AM03	Effect of IV Cangrelor vs PO Ticagrelor on myocardial damage in STEMI	SA1	13/01/2016	27
16/EM/0096/AM01	AusCOR	SA 1.0 - REC & HRA	05/07/2016	27
16/EM/0098/AM01	Decision making regarding prophylactic mastectomy	1	05/01/2017	14
16/EM/0110/AM01	ASD in children with MPS III	SA1	22/07/2016	27
16/EM/0110/AM02	ASD in children with MPS III	2	12/01/2017	7
16/EM/0121/AM02	CRICKET: CRT Improved Clinical Response UK Trial	SA1	17/05/2016	18
16/EM/0142/AM05	aTTom-Extended Version 1.0, 15th March 2016	Substantial Amendment 01	12/12/2016	15
16/EM/0143/AM02	Colon CTC	1	19/07/2016	24
16/EM/0193/AM07	The dal-GenE trial	Substantial Amendment 3 2016/1	25/11/2016	8
16/EM/0197/AM01	Molecular Characterisation of CTCs in NSCLC (ref 16/EM/0197)	SA1	13/02/2017	12
16/EM/0198/AM01	GO30081 Atezolizumab in patients with untreated extensive-stage SCLC	SA1 - Protocol version 2.0	23/06/2016	12
16/EM/0198/AM03	GO30081 Atezolizumab in patients with untreated extensive-stage SCLC	Substantial Amendment 3	29/09/2016	14
16/EM/0252/AM01	An observational, Quality of Life study in Lemtrada MS patients	SA1	10/08/2016	26
16/EM/0252/AM05	An observational, Quality of Life study in Lemtrada MS patients	2	06/02/2017	12
16/EM/0295/AM01	INSPIRE 1	Substantial Amendment 01	28/11/2016	28
16/EM/0382/AM05	PERSPECTIVE	2	30/01/2017	14
16/EM/0386/AM01	CAMG334A2301 in episodic migraine phase 3b	SA1	10/11/2016	11
16/EM/0386/AM02	CAMG334A2301 in episodic migraine phase 3b	Substantial Amendment 2	21/12/2016	16
16/EM/0395/AM01	Microcirculatory function in peritoneal dialysis V1(1)	Substantial Amendment 1	21/10/2016	18
16/EM/0395/AM02	Microcirculatory function in peritoneal dialysis V1(1)	Substantial Amendment 2	17/01/2017	7
16/EM/0439/AM02	NOVELTY	SA1	16/02/2017	19
16/EM/0459/AM01	A Phase 2b study for adults with Respiratory Syncytial Virus.	SA1	27/02/2017	19
16/EM/0469/AM01	Optical Coherence Tomography Angiography Network (OCTANE) Study	Substantial Amendment 1	22/12/2016	20

4867/AM01	Long-term outcome of respiratory symptoms in pre-school children	1	23/03/2016	13
5005/AM01	Second cross-sectional survey of respiratory symptoms in pre-school	1	23/03/2016	13

Unfavourable opinion				
Amendment REC Reference	**Title**	**Version**	**Date**	**Number of Days on Clock**
15/EM/0401/AM06	An open label study of Tocilizumab in PAH	SA#03	31/10/2016	25
16/EM/0112/AM01	Measuring The Effect of Pringle Manoeuvre on NIRS Values	Amendment 2 (05/04/2016)	20/04/2016	18

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**
15/EM/0401/AM06/1	An open label study of Tocilizumab in PAH	Modified Amendment 06.12.2016	06/12/2016	1
16/EM/0112/AM01/1	Measuring The Effect of Pringle Manoeuvre on NIRS Values	Modified Amendment	02/06/2016	10

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

Table 11: **Items exceeding timelines**

Full applications for ethical review over 60 day timeline		
REC Reference	**Title**	**Number of Days on Clock**
None		

Proportionate review applications for ethical review over 21 day timeline		
REC Reference	**Title**	**Number of Days on Clock**
16/EM/0252	An observational, Quality of Life study in Lemtrada MS patients	25
16/EM/0345	Impact of antibiotic administration route on GIT microbiome	26
16/EM/0348	The Back of the Brain Project (BoB)	32

SSAs (non Phase 1) over 25 day timeline		
REC Reference	**Title**	**Number of Days on Clock**
16/EM/0354	A randomized, double-blind, placebo-controlled, event-driven trial of quarterly subcutaneous canakinumab in the prevention of recurrent cardiovascular events among stable post-myocardial infarction patients with elevated hsCRP	39

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				