

**East Midlands - Leicester South Research Ethics
Committee**

Annual Report

01 April 2015 - 31 March 2016



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:	CTIMP in patients – iii
Chair:	Mr John Aldridge
Vice-Chair:	Ms Elizabeth Gibbons
Alternate Vice-Chair:	Mr Alan Caswell
REC Manager:	Miss Rebecca Morledge
REC Assistant:	George Martin
Committee Address:	The Old Chapel Royal Standard Place Nottingham NG1 6FS
Telephone:	0207 104 8104
Email:	NRESCcommittee.EastMidlands-LeicesterSouth@nhs.net

Chair's overview of the past year:

NRES Committee East Midlands – South Leicester Chairman's Report April 2015 to March 2016

Venue

It is now almost one year since the decision was made to change the title of the committee to Leicester South and to move the meeting venue to the Three Swans in Market Harborough. These changes appear to have been very successful and we consistently have full agendas for the meetings, which seem to fill quite quickly. The venue appears to be popular with those researchers who opt to attend meetings. Access to the venue is good from both road and rail routes.

Meetings

Main meetings

Soon after moving to our new venue the committee made the decision to make greater efforts to keep strictly to the meeting timetable in order not to inconvenience researchers and to ensure that members are able to return to their afternoon responsibilities. This has been achieved by:

- a) Exception reporting. Lead Reviewers only comment on issues of ethical concern, rather than describing all aspects of a study. A quick 'round table' request for comments is then made.
- b) The above part of each paper's review is strictly timed (using a kitchen timer) to take no more than 15 minutes.
- c) This leaves a further 15 minutes in which to ask questions of the researchers, which is usually adequate.

This strategy appears to be working well, with most researchers being invited into the meeting within 5 minutes of their timed 'slot'. Members have also commented favorably on the timing of meetings. There have only been three meetings this year when we have needed to co-opt a member from another committee.

Proportionate Review meetings

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.

Response to Provisional Opinions

Responses to P.O. are usually emailed to the Chair and any other member who has agreed to be involved. Studies involving a large number of papers are sometimes dealt with on HARP. With very few exceptions these studies are dealt with on the same day, but always within set time limits.

Membership

Membership of the committee has been very stable over the past year. Our Alternate Vice Chair, Mr. Alan Caswell, has had to take some time off for health reasons but has now returned.

We have recently been able to recruit two new members to the committee. Mrs Jill Marshall is a retired REC Project Team Manager and Dr Joanna Wood is a Clinical Lecturer in Medical Oncology. Both new members are very welcomed for their expertise.

John Aldridge (Chair)

12.5.16

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	
Ms Sarah Hamill	Cardiology Research Nurse	Expert	20/03/2014	
Dr Brendan Laverty	Retired Head of Research governance	Lay	11/03/2014	
Ms Rachel Neilan	Former Executive Editor at BioMed Central	Lay Plus	22/05/2014	
Mrs Sarah Elizabeth Westwater-Wood	Lecturer	Expert	20/12/2012	

East Midlands - Leicester South Research Ethics Committee: Deputy Members

Name	Profession	Status	Meeting date attended
none			

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

Name	Profession	Status	Meeting date attended
Mr John Baker	Radiation Protection Advisor and Senior Lecturer (retired)	Lay Plus	17/12/2015
Dr Rebecca Harmston	Scientific Officer	Lay Plus	17/03/2016
Mr John Warden	Clinical Trials Data and Information Systems Manager	Lay	17/03/2016

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

Name	Declaration of Interest	Date
Mr John Aldridge	None Declared	31/12/2015
Mrs Jeanne-Anne Charly	None Declared	31/12/2015
Dr Belinda Cupid	Member of staff (Head of Research) at the Motor Neurone Disease Association, registered charity number 294354.	31/12/2015
Ms Elizabeth Gibbons	None Declared	31/12/2015
Ms Sarah Hamill	Cardiology Research Nurse - Peterborough and Stamford NHS Foundation Trust member of R&D committee. Participates in commercial/non-commercial trial within cardiology.	31/12/2015
Ms Rachel Neilan	None Declared	31/12/2015
Mrs Sarah Elizabeth Westwater-Wood	National committee member of the APCP however they do not undertake primary research. Is a member of staff at the University of Nottingham.	31/12/2015
Mr Derek Butters	Pharmanova (Europe LTD)	23/03/2016
Alan Caswell	Member of PPI group Nottingham University/dementia frail older people and palliative care	16/03/2016
Dr Brendan Laverty	Review of application to the Europe Commission for research support. These normally cover Energy & Eco-Innovation, waste and are unlikely to have anything to do with research involving the HRA. One exception to this was a recent (Dec 2015) application regarding the use at a micro-organism as a 'medical device' which was probably outside the formal scope for the EC call for proposals	15/12/2015

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

Month	Date	Number of Members Present at Meeting
April	16/04/2015	8
May	21/05/2015	8
June	18/06/2015	9
July	16/07/2015	7
September	17/09/2015	9
October	15/10/2015	9
November	19/11/2015	8
December	17/12/2015	7
February	18/02/2016	8
March	17/03/2016	7

10 full committee meetings were held during the reporting period.

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

Month	Date	Number of Members Present at Meeting
April	16/04/2015	8
May	21/05/2015	3
June	18/06/2015	3
July	14/07/2015	3
August	13/08/2015	3
September	17/09/2015	3
November	19/11/2015	3
January	21/01/2016	3
February	17/02/2016	3
March	07/03/2016	3

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

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

Month	Date	Number of Members Present at Meeting
April	10/04/2015	2
April	23/04/2015	2
May	11/05/2015	2
May	25/05/2015	2
June	05/06/2015	2
June	19/06/2015	2
July	06/07/2015	2
July	20/07/2015	2
July	30/07/2015	2
August	13/08/2015	2
August	27/08/2015	2

September	14/09/2015	2
September	29/09/2015	2
October	08/10/2015	2
October	27/10/2015	2
November	05/11/2015	2
November	26/11/2015	2
December	03/12/2015	2
December	17/12/2015	2
December	31/12/2015	2
January	19/01/2016	2
February	02/02/2016	2
February	11/02/2016	2
March	01/03/2016	2
March	16/03/2016	2
March	29/03/2016	2

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

Details of inquorate meeting held:01 April 2015 - 31 March 2016

Date	Reason	Action taken
none		

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

Name	Number of Meetings Attended
Mr John Aldridge	10
Mr Derek Butters	9
Mr Alan Caswell	5
Mrs Jeanne-Anne Charly	9
Dr Belinda Cupid	6
Ms Elizabeth Gibbons	8
Ms Sarah Hamill	6
Dr Brendan Lavery	10
Ms Rachel Neilan	10
Mrs Sarah Elizabeth Westwater-Wood	6

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

Name	Number of Meetings Attended
Mr John Aldridge	10
Mr Derek Butters	1
Mr Alan Caswell	1
Mrs Jeanne-Anne Charly	5
Dr Belinda Cupid	2
Ms Elizabeth Gibbons	8
Ms Sarah Hamill	3
Dr Brendan Lavery	2
Ms Rachel Neilan	3

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

Name	Number of Meetings Attended
Mr John Aldridge	24
Mr Alan Caswell	1
Mrs Jeanne-Anne Charly	4
Ms Elizabeth Gibbons	22
Dr Brendan Lavery	1

Training 01 April 2015 - 31 March 2016

Name of Member	Date	Event(s) attended
Mr John Aldridge	15/05/2015	NREAP Meeting
Mr John Aldridge	25/09/2015	Members Regional Training Day- Speaker
Mr John Aldridge	09/12/2015	National Training Day for Committee Chairs
Mr Derek Butters	25/09/2015	Members Regional Training Day
Mr Alan Caswell	15/05/2015	NREAP Meeting
Mrs Jeanne-Anne Charly	07/05/2015	Phase 1 Introduction Training
Mrs Jeanne-Anne Charly	30/06/2015	Human Tissue Act
Dr Belinda Cupid	07/05/2015	Phase 1 Introduction Training
Dr Belinda Cupid	22/07/2015	Qualitative Research and Ethical Review
Dr Belinda Cupid	25/09/2015	Members Regional Training Day
Ms Sarah Hamill	24/09/2015	On-line induction for new committee members
Ms Sarah Hamill	25/09/2015	Members Regional Training Day
Dr Brendan Lavery	25/09/2015	Members Regional Training Day
Dr Brendan Lavery	29/09/2015	Genetic and Genomic Research
Dr Brendan Lavery	06/10/2015	Quantitative Research
Dr Brendan Lavery	03/03/2016	Qualitative Research and Ethical Review
Ms Rachel Neilan	25/09/2015	Members Regional Training Day
Mrs Sarah Elizabeth Westwater-Wood	25/09/2015	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	24	47.06
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	27	52.94
Total Applications Reviewed	51	100

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

Number of applications made invalid by the REC Manager	1
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	12
Number of paediatric applications reviewed	4
Number of device applications reviewed	6
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	0
Number of applications reviewed that are funded by the US DHHS	0
Number of qualitative applications reviewed	4

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

Decisions taken at meetings following review of applications	Number	%
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	1	1.96
Unfavourable Opinion	7	13.73
Provisional Opinion	43	84.31
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	51	100
Number of studies sent back to full committee meeting for final opinion	0	

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

Status of applications at date of generation of report	Number	%
Further Information Favourable Opinion with Standard Conditions	41	80.39
Further Information Favourable Opinion with Additional Conditions	0	0.00
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	1	1.96
Unfavourable Opinion	7	13.73
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	2	3.92
Total	51	100

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

Total Applications Reviewed	28
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Table 6: Breakdown of PRS applications and other activity during reporting period:

Number of applications made invalid by the REC Manager	4
Number of studies withdrawn prior to the meeting	0
Number of student applications reviewed	16
Number of paediatric applications reviewed	2
Number of device applications reviewed	4
Number of qualitative applications reviewed	5

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

Decisions taken at proportionate review sub-committee meetings	Number	%
Favourable Opinion with Standard Conditions	6	21.43
Favourable Opinion with Additional Conditions	4	14.29
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	17	60.71
Unfavourable Opinion	1	3.57
Total	28	100

Table 8: Other Management Information based on the number of completed applications for the reporting period:

Average number of applications reviewed per full meeting	5.10
Number of completed applications for full ethical review	49
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)	29
Number of completed proportionate review applications for ethical review	28
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	13
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	119
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	1
Number of completed substantial amendments over 28 days as a % of total substantial amendments	0.84%
Number of modified amendments reviewed	1
Number of completed modified amendments over 14 days	0
Number of completed modified amendments over 14 days as a % of total modified amendments	0.00%
Number of minor amendments received	89
Number of substantial amendments received for information	0
Number of substantial amendments received for new sites/Pis	22
Number of annual progress reports received	109

Number of safety reports received	55
Number of Serious Adverse Events received	2
Number of final reports received	13

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/0139	Discourse Analysis – advance care planning frail older persons	30
15/EM/0170	Characterization of Negative Symptoms in Schizophrenia	20
15/EM/0229	PROFILE (2819-MA-1003) - version 2	27
15/EM/0230	Knee flare up study	21
15/EM/0232	Ambulatory oxygen assessment on discharge from hospital	19
15/EM/0238	Efficacy and safety of intravenous neridronic acid in CRPSI	26
15/EM/0249	Dying of heart failure in hospital, carers perspective	28
15/EM/0268	MIDNIGHT	28
15/EM/0271	Utility of ultrasound imaging in localising the conus medullaris	26
15/EM/0273	Study of rare cutaneous lichenoid, alopecic and scarring variants	24
15/EM/0278	Is sacral nerve stimulation effective following anterior resection?	23
15/EM/0305	GTx G200901 - GTx-024(Enobosarm) on AR+ Triple Negative Breast Cancer	31
15/EM/0307	The effects of RPL554 on top of standard COPD reliever medications	20
15/EM/0308	The Metabolic Effect of Hypoxia and Steroid Signalling	24
15/EM/0310	Is morphine an effective analgesic for procedural pain in infants?	24
15/EM/0312	Ceritinib in ALK positive NSCLC patients with brain metastases	23
15/EM/0357	Measuring Major Trauma Patients Pre-Hospital Lactate Levels	31
15/EM/0393	Open PRIdopidine Dose Evaluation in Huntington's Disease	27
15/EM/0406	RESILIENT EXTENSION STUDY	30
15/EM/0413	Feasibility trial of psychosocial interventions for preventing BBV	31
15/EM/0424	Efficacy and safety of Tanezumab in patients with bone metastasis	32
15/EM/0425	Novel Vascular Manifestations of COPD 2	32
15/EM/0454	The Captivator EMR Registry (EMR=Endoscopic Mucosal Resection)	26
15/EM/0455	SEL-I-METRY	39
15/EM/0467	EXPLORE CKD	36
15/EM/0472	The 3R Study	34
15/EM/0484	EPPHEA- Employment protection and health	31
15/EM/0500	QAW039 vs. placebo in patients with uncontrolled severe asthma	36
15/EM/0501	Community sport and type 2 diabetes	36
15/EM/0552	The CIRCLE Study	24
15/EM/0563	The 'Arming your Health' study	32
16/EM/0047	STATIC Study	33

16/EM/0073	Low exhaled NO and inhaled corticosteroids in suspected asthma	26
16/EM/0076	Study of E/C/F/TAF in HIV-1 patients on Chronic Haemodialysis	32
16/EM/0078	Safety, blood levels and effects of GLPG1690 in subjects with IPF (2)	37
16/EM/0079	High intensity interval training in UK cardiac rehabilitation - v1	28
16/EM/0125	Powered Vascular Stapler Study in Renal Surgery	33
16/EM/0127	PLEO-CMT	37
16/EM/0129	Davol Phasix EU Study DVL-HE-016	33
16/EM/0130	The Therapeutic Alliance in EMDR.	33
16/EM/0132	Gender Dysphoria in People with Autism: A Qualitative Study	33

Further Information Favourable Opinion with Additional Conditions

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

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

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

REC Reference	Title	Number of Days on Clock
15/EM/0551	IRONMAN	21

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
15/EM/0235	EPPHEA- Employment protection and health	18
15/EM/0256	The 3R Study Version 1	26
15/EM/0461	Masitinib in Metastatic Colorectal Cancer phase II V1.0	35
15/EM/0512	Psychological profile of children with functional visual loss	28
15/EM/0553	M15-410: ABT-493/530, Hep C patients who are prior DAA failures	21
15/EM/0555	Safety, blood levels and effects of GLPG1690 in subjects with IPF	21

16/EM/0131	Novel Glyco-tools to Study Human Milk Oligosaccharides	32
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Provisional Opinion

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

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

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

REC Reference	Title	Number of Days on Clock
15/EM/0456	181501 Efficacy and Safety of SM101 in the Treatment of IgA Nephropathy	38
16/EM/0080	Experiences of dissociation in individuals with Psychosis	27

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/0174	Exploring self-monitoring in colorectal cancer survivorship patients	10
15/EM/0176	Non-contact monitoring for breath holding radiotherapy v1.0	10
15/EM/0177	Bra- line perforators of clinical value	11
15/EM/0178	NAL-NL2 versus DSLv5 for Tinnitus 1	10
15/EM/0245	Dyadic illness experience of severe asthma patients and partners	11
15/EM/0322	Acceptability of functional MRI	9
15/EM/0330	Haemodynamic effects of rivaroxaban	8
15/EM/0387	Parental decision making. UHL habilitation. GT feasibility study	12
15/EM/0390	Analysing Current Practice in the Assessment of Paediatric Chest Pain	8

15/EM/0434	Patients' perceptions of their safety within an acute hospital setting	14
15/EM/0435	The effects of discrimination in RA and PsA patients-A pilot study	11
16/EM/0045	Demand for Pre exposure prophylaxis for HIV (PrEP) in Scotland	8
16/EM/0048	SONIC WINDOW	13
16/EM/0049	Effect of a Fresnel Prism on Visual Function	7
16/EM/0085	Do large refractive correction changes increase dizziness? version 1	11
16/EM/0116	LASER-48	7
16/EM/0119	Baha 5 SuperPower Sound Processor & Baha Attract System	8

Further Information Favourable Opinion with Additional Conditions

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

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

REC Reference	Title	Number of Days on Clock
15/EM/0283	Analysis of ISIS2 surface topography pictures in scoliotic subjects	4
15/EM/0326	Reliability of duplex ultrasound in post Endovascular Aneurysm Repair surveillance	7
16/EM/0050	Validating the EssenCES within learning disabled low secure in-patients	7
16/EM/0087	Use of EEG for predicting outcome of unresponsive patients the ITU	8
16/EM/0117	frictional torque with large diameter heads	6
16/EM/0118	Thinnest HCLPE survival and wear	6

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/EM/0246	V1 Decision making process for clipping for an unruptured aneurysm	8
15/EM/0385	Metabolic profiling of multimodal therapy in colorectal cancer	9
15/EM/0432	Effectiveness of MBCT in improving anxiety, depression & HbA1c	11
15/EM/0530	Factors that influence uptake to community health initiatives	13

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
15/EM/0527	Diet and/or clinical interventions on biomarkers in NET and Controls	13

Provisional Opinion

REC Reference	Title	Number of Days on Clock
15/EM/0390	Analysing Current Practice in the Assessment of Paediatric Chest Pain	n/a

Further information response not complete

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

REC Reference	Title	Number of Days on Clock
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Table 10.1: Breakdown of current status of all substantial amendments reviewed within the reporting period

Favourable opinion				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
05/Q2502/80/AM01	Proteomic analysis in human kidney disease	1	03/03/2015	19
09/H0402/101/AM31	The Effects of JNJ-28431754 on Cardiovascular Outcomes (CANVAS Study)	24	31/03/2015	15
09/H0402/101/AM32	The Effects of JNJ-28431754 on Cardiovascular Outcomes (CANVAS Study)	25	03/07/2015	16
09/H0402/101/AM34	The Effects of JNJ-28431754 on Cardiovascular Outcomes (CANVAS Study)	26	14/10/2015	13
09/H0402/101/AM35	The Effects of JNJ-28431754 on Cardiovascular Outcomes (CANVAS Study)	27	08/02/2016	4
09/H0402/74/AM16	IMCL CP12-0606/TRIO-012 version 4.0 18 July 2008	12	02/11/2015	4
09/H0402/96/AM12	Open label extension to the ALLEGRO study	3	25/02/2016	19
10/H0402/30/AM18	1199.35 A roll-over study of oral BIBF 1120 in patients with IPF	11	09/06/2015	7
10/H0402/30/AM20	1199.35 A roll-over study of oral BIBF 1120 in patients with IPF	12	27/08/2015	12
10/H0402/55/AM30	Evaluating 2 Treatment Algorithms in Moderate-severe Crohn's disease	25.06.2015	29/06/2015	7
11/EM/0415/AM04	The role of peripheral and central vision in postural stability.	4	01/05/2015	12
12/EM/0294/AM02	Routine Data Pilot – Dementia (RDP Dem)	2	17/04/2015	3
12/EM/0304/AM05	DREAM Study (Daily Remote Ischaemic Conditioning following AMI)	5.0	11/11/2014	7
12/EM/0304/AM06	DREAM Study (Daily Remote Ischaemic Conditioning following AMI)	6	28/05/2015	13
12/EM/0304/AM07	DREAM Study (Daily Remote Ischaemic Conditioning following AMI)	Substantial amendment 7	19/10/2015	17
12/EM/0351/AM10	A feasibility study for web based PR (full data set)	8	05/08/2015	12
12/EM/0404/AM03	Non-Contact Ultra Wide Field Imaging of Retinopathy of Prematurity	4	27/04/2015	7
13/EM/0095/AM07	(duplicate) Long term safety study of secukinumab in pts with Psoriati	5	10/12/2015	11
13/EM/0112/AM12	AKT inhibitor in breast cancer (STAKT study)	6	14/09/2015	5
13/EM/0112/AM13	AKT inhibitor in breast cancer (STAKT study)	7	02/12/2015	9
13/EM/0125/AM04	Biomarker expression and response to Chemo-radiotherapy in	3	13/08/2015	8

	NSCLC			
13/EM/0195/AM06	HGS1006-C1112 Phase 3/4 Study of Belimumab in Black Race SLE Patients	6	17/03/2015	13
13/EM/0266/AM07	Low dose cyclophosphamide +/- nintedanib in advanced ovarian cancer	15.07.2015	15/07/2015	18
13/EM/0266/AM08	Low dose cyclophosphamide +/- nintedanib in advanced ovarian cancer	05	10/09/2015	5
13/EM/0344/AM03	ExTra CKD	2	11/05/2015	7
13/EM/0349/AM09	MANTA	N/A	11/03/2016	19
13/EM/0383/AM01	The MaRACAS Study	1	04/03/2016	12
13/EM/0423/AM11	GWP42004 in Type 2 diabetes	27.10.2015	27/10/2015	10
13/EM/0424/AM08	Study of Pridopidine to reduce symptoms in patients with Huntington's	05	19/05/2015	9
13/EM/0424/AM09	Study of Pridopidine to reduce symptoms in patients with Huntington's	6	03/09/2015	11
13/EM/0424/AM10	Study of Pridopidine to reduce symptoms in patients with Huntington's	1.0	21/07/2015	9
13/EM/0460/AM11	Study of Adjuvant Kadcyra vs Herceptin, HER2+ve Primary Breast Cancer	6	05/05/2015	6
13/EM/0460/AM12	Study of Adjuvant Kadcyra vs Herceptin, HER2+ve Primary Breast Cancer	6	15/05/2015	13
13/EM/0460/AM13	Study of Adjuvant Kadcyra vs Herceptin, HER2+ve Primary Breast Cancer	8	11/08/2015	7
13/EM/0462/AM04	RomiCar	4	11/12/2015	10
13/EM/0474/AM01	The Easy Read Project Version 1	24/03/2015	27/03/2015	19
14/EM/0030/AM05	ECU-NMO-302 Phase 3 Open-Label Extension Study of Eculizumab for NMO	3	07/08/2015	11
14/EM/0086/AM03	Secukinumab in Ankylosing Spondylitis	2	10/06/2015	13
14/EM/0089/AM06	Niraparib vs. physician choice in HER2 negative breast cancer	08.06.2015	08/06/2015	17
14/EM/0089/AM07	Niraparib vs. physician choice in HER2 negative breast cancer	5	12/01/2016	7
14/EM/0089/AM08	Niraparib vs. physician choice in HER2 negative breast cancer	6	02/02/2016	10
14/EM/0089/AM09	Niraparib vs. physician choice in HER2 negative breast cancer	11/02/2016	11/02/2016	20
14/EM/0124/AM03	GOLMEPsA	2	05/10/2015	7
14/EM/0140/AM01	Music questionnaire development	1	28/07/2015	14
14/EM/0179/AM03	Exploratory study of a binocular therapy for childhood amblyopia	2	18/02/2015	13

14/EM/0179/AM06	Exploratory study of a binocular therapy for childhood amblyopia	3	01/12/2015	35
14/EM/0202/AM08	Ertugliflozin in subjects w/ T2DM & poor glyceic control on metformin	22.04.2015	22/04/2015	21
14/EM/0202/AM09	Ertugliflozin in subjects w/ T2DM & poor glyceic control on metformin	14/05/2015	14/05/2015	14
14/EM/0202/AM11	Ertugliflozin in subjects w/ T2DM & poor glyceic control on metformin	20/07/2015	29/07/2015	5
14/EM/0202/AM12	Ertugliflozin in subjects w/ T2DM & poor glyceic control on metformin	12/11/2015	12/11/2015	15
14/EM/0202/AM13	Ertugliflozin in subjects w/ T2DM & poor glyceic control on metformin	15/02/16	15/02/2016	16
14/EM/0209/AM05	Colourstart® Test 73 mcg Cutaneous Patch. TDL-CS-001 Version 1.0	4, version 4.1	06/05/2015	6
14/EM/0217/AM02	Fast Track Faecal Calprotectin	EMS002	14/07/2015	7
14/EM/0217/AM03	Fast Track Faecal Calprotectin	EMS003	08/10/2015	14
14/EM/0217/AM04	Fast Track Faecal Calprotectin	EMS0004	12/02/2016	15
14/EM/1059/AM08	047 FIT (Fostamatinib for Immune Thrombocytopenia) Study	2	21/10/2015	14
14/EM/1067/AM02	A feasibility study for cardiac rehabilitation in stroke patients	2	04/12/2015	17
14/EM/1070/AM08	A phase 3 study of icatibant in adults with ACE-I-Induced Angioedema	3	09/04/2015	15
14/EM/1070/AM10	A phase 3 study of icatibant in adults with ACE-I-Induced Angioedema	22.05.2015	22/05/2015	19
14/EM/1070/AM12	A phase 3 study of icatibant in adults with ACE-I-Induced Angioedema	15/07/2015	15/07/2015	5
14/EM/1071/AM05	D5136C00007 Ticagrelor for sickle cell disease in paediatric patients	31.03.2015	31/03/2015	15
14/EM/1071/AM07	D5136C00007 Ticagrelor for sickle cell disease in paediatric patients	19.05.2015	19/05/2015	8
14/EM/1071/AM10	D5136C00007 Ticagrelor for sickle cell disease in paediatric patients	08.09.2015	08/09/2015	7
14/EM/1071/AM11	D5136C00007 Ticagrelor for sickle cell disease in paediatric patients	22/09/2015	22/09/2015	7
14/EM/1071/AM12	D5136C00007 Ticagrelor for sickle cell disease in paediatric patients	12/02/2016	12/02/2016	15
14/EM/1074/AM01	Effect of local anaesthesia at vaginal hysterectomy on post-op	1.0	25/08/2015	15

	pain			
14/EM/1153/AM01	The Utility of Routine Pathology Results for Identifying Rare Diseases	1	30/04/2015	7
14/EM/1158/AM02	The link between plasma and endometrial endocannabinoid levels	2	18/02/2015	11
14/EM/1172/AM01	CamBMT1	1 14/10/15	14/10/2015	10
14/EM/1190/AM01	CYCLE-HD	Version 3 15/05/2015	15/05/2015	8
14/EM/1207/AM04	Investigating how women with breast cancer view Tamoxifen	16.04.2015	16/04/2015	6
14/EM/1207/AM05	Investigating how women with breast cancer view Tamoxifen	4 27/10/2015	27/10/2015	16
14/EM/1233/AM01	The expression of the endocannabinoid system at the Implantation Zone	1	16/04/2015	11
14/EM/1266/AM01	Beta-glucans and endotoxins in end-stage kidney disease	#1	15/04/2015	9
14/EM/1267/AM01	LCZ696 in patients from Paradigm HF study	02.06.2015	02/06/2015	7
14/EM/1267/AM03	LCZ696 in patients from Paradigm HF study	3	22/09/2015	7
14/EM/1306/AM01	Pilot Study of FFP104 Dose Escalation in PBC Subjects	31.03.2015	30/03/2015	8
14/EM/1306/AM03	Pilot Study of FFP104 Dose Escalation in PBC Subjects	2	16/12/2015	4
14/EM/1309/AM01	The role of buspirone in LIDs in patients with Parkinson's disease.	1	09/06/2015	12
14/EM/1313/AM03	The Effect of Social Media among Individuals with Anorexia Nervosa	#2	29/04/2015	7
14/EM/1314/AM01	Phase 2 Veliparib or Placebo, plus FOLFIRI ± Bevacizumab in mCRC	1	29/07/2015	18
14/EM/1319/AM01	Ultrasound to prevent leg wound complications in heart bypass- Ver.5.3	09/06/2015	09/06/2015	8
14/EM/1322/AM01	Head-mounted displays for low vision. v1	1	22/04/2015	17
14/EM/1322/AM02	Head-mounted displays for low vision. v1	2	06/01/2016	13
15/EM/0071/AM02	Carbetocin RTS A65870	4	03/07/2015	4
15/EM/0071/AM03	Carbetocin RTS A65870	5	26/08/2015	20
15/EM/0071/AM04	Carbetocin RTS A65870	6	22/10/2015	5
15/EM/0077/AM03	Long-term Access Programme for Subjects who Participated in MEA115921	2	02/09/2015	13
15/EM/0094/AM03	26-Week Extension Study of the Safety and Clinical Effects of EVP-6124	3	25/08/2015	2
15/EM/0094/AM04	26-Week Extension Study of the Safety and Clinical Effects of EVP-6124	4	11/09/2015	18

15/EM/0101/AM04	Triple P for Parents of Children with a diagnosis of cancer	1	16/12/2015	4
15/EM/0110/AM02	Mental health transitions: the move to adult services	1	01/03/2016	10
15/EM/0121/AM01	PRE-STARt Risk Tool	1	07/12/2015	14
15/EM/0177/AM01	Bra- line perforators of clinical value	1	04/12/2015	8
15/EM/0229/AM01	PROFILE (2819-MA-1003) - version 2	17/09/2015	17/09/2015	12
15/EM/0230/AM01	Knee flare up study	1	14/07/2015	6
15/EM/0230/AM04	Knee flare up study	3	29/10/2015	3
15/EM/0230/AM06	Knee flare up study	5	22/12/2015	27
15/EM/0230/AM07	Knee flare up study	6	25/01/2016	7
15/EM/0230/AM09	Knee flare up study	7	18/03/2016	8
15/EM/0238/AM02	Efficacy and safety of intravenous neridronic acid in CRPSI	3.0	15/10/2015	11
15/EM/0245/AM02	Dyadic illness experience of severe asthma patients and partners	1	01/03/2016	10
15/EM/0249/AM01	Dying of heart failure in hospital, carers perspective	1 29/10/15	29/10/2015	17
15/EM/0307/AM01	The effects of RPL554 on top of standard COPD reliever medications	1	24/08/2015	4
15/EM/0308/AM01	The Metabolic Effect of Hypoxia and Steroid Signalling	1	18/08/2015	8
15/EM/0308/AM02	The Metabolic Effect of Hypoxia and Steroid Signalling	2	02/03/2016	9
15/EM/0310/AM01	Is morphine an effective analgesic for procedural pain in infants?	1 03/11/2015	02/11/2015	3
15/EM/0310/AM02	Is morphine an effective analgesic for procedural pain in infants?	2	17/12/2015	18
15/EM/0357/AM01	Measuring Major Trauma Patients Pre-Hospital Lactate Levels	1	25/01/2016	7
15/EM/0393/AM01	Open PRIdopidine Dose Evaluation in Huntington's Disease	new non-NHS SSI	24/02/2016	6
15/EM/0406/AM01	RESILIENT EXTENSION STUDY	1 04/11/2015	02/11/2015	2
15/EM/0424/AM01	Efficacy and safety of Tanezumab in patients with bone metastasis	Substantial Amendment 1	26/10/2015	11
15/EM/0424/AM04	Efficacy and safety of Tanezumab in patients with bone metastasis	2	18/03/2016	12
15/EM/0432/AM03	Effectiveness of MBCT in improving anxiety, depression & HbA1c	1	19/02/2016	11
15/EM/0434/AM02	Patients' perceptions of their safety within an acute hospital setting	1	18/03/2016	12
15/EM/0455/AM01	SEL-I-METRY	1	22/03/2016	8
15/EM/0472/AM01	The 3R Study	1	05/02/2016	7
15/EM/0472/AM02	The 3R Study	2	23/03/2016	7

Unfavourable opinion				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
15/EM/0071/AM01	Carbetocin RTS A65870	SA 01 02 and 03	26/05/2015	15

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/0071/AM01/1	Carbetocin RTS A65870	SA03	24/06/2015	1

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
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Proportionate review applications for ethical review over 14 day timeline

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

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

REC Reference	Title	Number of Days on Clock
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Substantial Amendments over 35 day timeline

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

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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