

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

Annual Report

01 April 2017 - 31 March 2018



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 registered
Chair:	Mr Ken Willis Reverend Keith Lackenby – Acting chair 18.10.2017 – 18.02.2018
Vice-Chair:	Mrs Rita Patel
Alternate Vice-Chair:	Miss Alison Armstrong
REC Manager:	Ms Carolyn Halliwell – March 2018 – present Joanne O’Neil – October 2017 – February 2018 Helen Poole – April 2017 – September 2017
REC Assistant:	Teagan Allen
Committee Address:	The Old Chapel Royal Standard Place Nottingham NG1 6FS
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Chair's overview of the past year:

I would like to thank all committee members who served the Leicester Central Committee for their commitment and resilience in ensuring that ethics applications were reviewed thoroughly and constructive feedback was provided to the researchers.

We have had reduced number of meetings in year 2017/18 due to turnover in membership and chair's absence. However the committee meetings managed to run on quorum and only called upon other committee members to co-opt on 5 occasions. The average number of applications reviewed per full meeting reduced from 4.56 (2016/17) to 3.50 and so has the substantial amendments fallen from 169 to 132 in year.

The majority of applications reviewed received provisional opinion and that has not changed from last year. This indicates that applicants are still not following HRA guidelines; but continue to adopt historical processes.

I look forward to working with committee members in the coming year to review varied research applications put forward to us.

East Midlands - Leicester Central Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Miss Alison Armstrong	Consultant Orthopaedic Surgeon	Expert	08/05/2008	
Dr Paul Beeson	Senior Lecturer	Expert	07/12/2012	07/12/2017
Dr Alan Cudworth	Retired Senior Lecturer	Lay Plus	04/04/2016	
Dr James Dixon	Senior Fellow	Expert	07/08/2017	
Mrs Lynne Fryatt	Retired Assistant Chief Nurse	Lay	25/01/2016	
Mr Saul Hill	Diabetes Research Podiatrist	Expert	21/03/2018	
Dr Nicola James	Independent Research Consultant	Lay Plus	10/01/2014	
Mr Michael Jones	Medical Statistician	Expert	26/02/2016	
Reverend Keith Lackenby	Reverend	Lay Plus	18/10/2017	18/02/2018
Mr Murthy Nyasavajjala	Specialist Registrar-General Surgery	Expert	18/08/2014	01/09/2017
Mrs Rita Patel	Contracts and Innovation Manager	Lay	01/01/2017	
Mr Ken Willis	Medical Devices Manager - retired	Lay Plus	01/01/2015	

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

Name	Profession	Status	Meeting date attended
Ms Yasumati Damodar	Pharmacist	Expert	04/08/17
Mr Chris Foy	Medical Statistician	Expert	07/04/17
Mrs Bernadette Roberts	Retired Finance Manager	Lay Plus	04/08/17
Mrs Anne Walker	Voluntary worker in Health Care	Lay Plus	07/04/17
Mrs Anne Walker	Voluntary worker in Health Care	Lay Plus	05/05/17

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

Name	Declaration of Interest	Date
Miss Alison Armstrong	Research Lead, Clinical management group research lead for musculoskeletal surgery and spinal surgery to lead on research for the management group, for UHL and MSK	29/01/2018
Dr Alan Cudworth	Independent Hospital Manager CYNET Derby. Member of the Grand Lodge of England Free Masonry.	02/02/2018
Dr James Dixon	Consultancy for Locate Therapeutics Medicity, Nottingham. Member of the University Research Group and GM Committee - University of Nottingham.	01/02/2018
Mrs Lynne Fryatt	None declared	31/03/2018
Dr Nicola James	Shareholdings in Glaxo Smith Kline and Shire Pharmaceuticals.	29/01/2018
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).	02/02/2018
Mrs Rita Patel	Employee at University Hospitals of Leicester NHS Trust - role is Research Contracts and Innovation Manager '	02/02/2018
Mr Ken Willis	None declared	31/03/2018

Meetings for Full Ethical Review 01 April 2017 - 31 March 2018:

Month	Date	Number of Members Present at Meeting
April	07/04/2017	7
May	05/05/2017	8
July	07/07/2017	9
August	04/08/2017	7
September	01/09/2017	8
February	02/02/2018	8
March	02/03/2018	7

7 full committee meetings were held during the reporting period.

Proportionate Review Sub-Committee Meetings held during 01 April 2017 - 31 March 2018:

Month	Date	Number of Members Present at Meeting
April	10/04/2017	3
May	05/05/2017	3
June	02/06/2017	3
July	07/07/2017	3
August	04/08/2017	3
September	01/09/2017	3
October	06/10/2017	3
November	03/11/2017	3
December	01/12/2017	3
December	06/12/2017	3
February	02/02/2018	3
March	02/03/2018	3

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

Sub-Committee Meetings held during 01 April 2017 - 31 March 2018:

Month	Date	Number of Members Present at Meeting
April	07/04/2017	2
April	21/04/2017	2
May	05/05/2017	2
May	19/05/2017	2
June	02/06/2017	2
June	16/06/2017	2
July	07/07/2017	2
July	21/07/2017	2
August	04/08/2017	2
August	18/08/2017	2
September	01/09/2017	2
September	15/09/2017	2
October	06/10/2017	2

October	20/10/2017	2
November	03/11/2017	2
November	17/11/2017	2
December	01/12/2017	2
December	13/12/2017	2
January	05/01/2018	2
January	19/01/2018	2
February	02/02/2018	2
February	16/02/2018	2
March	02/03/2018	2
March	16/03/2018	2

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

Details of inquorate meeting held: 01 April 2017 - 31 March 2018

None

Attendance of Members at full committee meetings: 01 April 2017 - 31 March 2018

Name	Number of Meetings Attended
Miss Alison Armstrong	5
Dr Paul Beeson	2
Dr Alan Cudworth	5
Dr James Dixon	3
Mrs Lynne Fryatt	5
Dr Nicola James	7
Mr Michael Jones	6
Reverend Keith Lackenby	2
Mr Murthy Nyasavajjala	4
Mrs Rita Patel	5
Mr Ken Willis	4

Attendance of Members at proportionate review sub-committee meetings: 01 April 2017 - 31 March 2018

Name	Number of Meetings Attended
Miss Alison Armstrong	4
Dr Paul Beeson	4
Dr Alan Cudworth	3
Mrs Lynne Fryatt	5
Dr Nicola James	3
Mr Michael Jones	3
Reverend Keith Lackenby	5
Mr Murthy Nyasavajjala	3
Mrs Rita Patel	3
Mr Ken Willis	3

Attendance of Members at sub-committee meetings: 01 April 2017 - 31 March 2018

Name	Number of Meetings Attended
Miss Alison Armstrong	3
Dr Paul Beeson	3
Dr Alan Cudworth	4
Mrs Lynne Fryatt	5
Dr Nicola James	4
Mr Michael Jones	4
Reverend Keith Lackenby	10
Mr Murthy Nyasavajjala	5
Mrs Rita Patel	5
Mr Ken Willis	5

Training 01 April 2017 - 31 March 2018

Name of Member	Date	Event(s) attended
Miss Alison Armstrong	13/04/2017	Reading - MRC/UCL articles on research design
Dr Paul Beeson	11/04/2017	Reading - MRC/UCL articles on research design
Dr Alan Cudworth	30/06/2017	Equality, Diversity and Human Rights
Dr James Dixon	29/08/2017	Induction for New Research Ethics Service Committee Members
Mrs Lynne Fryatt	05/04/2017	Reading - MRC/UCL articles re. research design
Mrs Lynne Fryatt	19/08/2017	Acting as a Buddy for new member - James Dixon
Mrs Lynne Fryatt	29/09/2017	Regional Training Day - Nottingham
Dr Nicola James	05/04/2017	Reading - MRC/UCL Articles on Research Study Design
Dr Nicola James	29/09/2017	Regional Training Day - Nottingham
Dr Nicola James	17/11/2017	Exploration of Concept of Vulnerability of Pregnant Women
Dr Nicola James	17/11/2017	Reading Multiple Publications
Mrs Rita Patel	12/12/2017	National Members Training Day
Mrs Rita Patel	31/01/2018	Complex Cases
Mr Ken Willis	22/05/2017	Chairs' Meeting
Mr Ken Willis	19/06/2017	Reading: MRC/UCL Briefings - Multi-arm multi-stage (MAMS) trials
Mr Ken Willis	19/06/2017	Reading: MRC/UCL Briefings - Stratified medicine trials
Mr Ken Willis	22/05/2017	Chairs' Meeting – East of England

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	9	32.14
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	19	67.86
Total Applications Reviewed	28	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	9
Number of paediatric applications reviewed	4
Number of device applications reviewed	0
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	2	7.14
Favourable Opinion with Additional Conditions	4	14.29
Unfavourable Opinion	1	3.57
Provisional Opinion	21	75.00
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	28	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	21	75.00
Further Information Favourable Opinion with Additional Conditions	0	0.00
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	2	7.14
Favourable Opinion with Additional Conditions	4	14.29
Unfavourable Opinion	1	3.57
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	28	100

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

Total Applications Reviewed	38
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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	0
Number of studies withdrawn prior to the meeting	0
Number of student applications reviewed	18
Number of paediatric applications reviewed	5
Number of device applications reviewed	0
Number of qualitative applications reviewed	2

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	14	36.84
Favourable Opinion with Additional Conditions	9	23.68
No Opinion transfer to full committee for review	1	2.63
Provisional Opinion	12	31.58
Unfavourable Opinion	2	5.26
Total	38	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	3.50
Number of completed applications for full ethical review	28
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 days taken to final decision – average (mean)	31
Number of completed proportionate review applications for ethical review	37
Number of completed proportionate review applications for ethical review over 21 days	6
Number of completed proportionate review applications over 21 days as a % of total	16.22%
Number of SSAs (non-Phase 1) reviewed	6
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	132
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 modified amendments reviewed	0
Number of completed modified amendments over 14 days	0
Number of completed modified amendments over 14 days as a % of total modified amendments	0.00%
Number of non substantial amendments received	126
Number of substantial amendments received for information	2
Number of substantial amendments received for new sites/PIs	24
Number of annual progress reports received	83
Number of safety reports received	53
Number of Serious Adverse Events received	3
Number of final reports received	21

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
17/EM/0115	Perspectives of people with personality disorder	23
17/EM/0126	Human IBD Enteroid Study(MINIGUT)	27
17/EM/0139	JN1017C - mCRPC - UK	27
17/EM/0146	The MeMO Study (Version 1.2)	29
17/EM/0155	POINT	42
17/EM/0240	Stay One Step Ahead Implementation Study	33
17/EM/0264	Working Backwards Version 1	31
17/EM/0287	What is "palliative care": a questionnaire survey	33
17/EM/0293	D3250C00045, Benralizumab in Patients with Severe Asthma (ANDHI)	29
17/EM/0303	Future Thinking and Medicine Use in Chronically Ill Young People	31
17/EM/0313	Lysin CF-301 for Treatment of Staphylococcus aureus bacteremia	31
17/EM/0319	CMR CHD	49
17/EM/0322	Patient and GP factors affecting referral to oesophageal endoscopy	33
17/EM/0324	Phase III with Octreotide capsules/Placebo in acromegaly patients	58
17/EM/0336	Lived experience of watchful waiting in NHL: A qualitative analysis v1	23
17/EM/0338	ABL001 versus Bositunib in Chronic Myeloid Leukaemia	30
17/EM/0339	Exploratory dose-response study in endometriosis patients	35
18/EM/0035	DSM-5 Personality Traits and Response to Treatment	29
18/EM/0039	Wilson - WTX101-301	26
18/EM/0078	Engaging adults with ASPD in mental health services v.1	32
18/EM/0079	Vaccination for immune recovery following sepsis:The VACIRiSS Trial	32

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

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
17/EM/0125	Tissue biomarker discovery and validation for melanocytic tumours	27
18/EM/0081	NHS AAA Screening Programme data linkage with HES and ONS Datasets	22

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
17/EM/0144	Effect of Heart Transplantation on Sleep Disordered Breathing	22
17/EM/0164	LENTEN	20
17/EM/0260	Gastric Emptying (V1)	25
18/EM/0074	CMR in ACS	27

Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock
18/EM/0038	R475-OA-1688, Efficacy and Safety of Fasinumab	28

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
17/EM/0212	StOIC (Study of Opioid-Induced Constipation) project - version 1.1	20
17/EM/0314	The role of community pharmacy in diabetes prevention	23
17/EM/0343	Development of an objective measure of cochlear implant outcome	27
17/EM/0344	Parental Opinions of Appendicitis	20
17/EM/0393	The association of HPV and Prostate, Bladder and Renal cancers	21
17/EM/0396	Acceptability and Use of Personalised Relaxation Techniques in COPD	20
17/EM/0422	IDEAS - (Identification of DEterminants of Altered circadian rhythms)	21
17/EM/0450	DESMA 2	12
17/EM/0471	NOVEMBR Delphi Study	9
17/EM/0474	Assessing your face in profile	12
18/EM/0084	A critical evaluation of community based integrated care policy v1	26

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
17/EM/0469	INFORM RSV	15

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
17/EM/0128	Validation of a shortened Patient Measure of Safety (PMOS-10)	26
17/EM/0130	Treatment persistence in rivaroxaban versus warfarin therapy	15
17/EM/0176	Mapping Sound Propagation through the Human Lung for Better Diagnosis	13
17/EM/0178	ACCELERATE	13
17/EM/0214	Experiences and outcomes of people receiving immunotherapy for cancer	14
17/EM/0216	Qualitative study of men's experiences of AAA screening	19
17/EM/0218	Remaking the Human Body	13
17/EM/0256	Operative versus Non-Operative Treatment for Achilles Tendon Rupture.	15
17/EM/0258	Valvular Heart Disease (VHD II) Survey	19

17/EM/0263	Physiological Monitoring Using Video Analysis Software - Cardioversion	19
17/EM/0307	Optimising Newborn Nutrition During Therapeutic Hypothermia	18
17/EM/0345	Posterior Ligament Complex Assessment in Thoracolumbar Fractures	23
17/EM/0452	Steroids and HCC	21
17/EM/0454	Effects of PTP1B inhibition on macrophage activity in atherosclerosis	15

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
17/EM/0175	Mi-PART	14
17/EM/0181	A mixed methods evaluation of online provision of oral contraceptives	17
17/EM/0261	Impact of Treatment of Vestibular Schwannoma on Quality of Life	14
17/EM/0349	Malaria antigen presentation in blood dendritic cells	29
17/EM/0456	Experiences of Diabetics with health information in primary care	12
17/EM/0472	Inter-current illness, teething or immunisations and blood phe.	9
17/EM/0473	HPV Sampling Study	14
18/EM/0041	ICCD	20
18/EM/0077	FAST Study 1 (Fluidic Automated Screening for Trisomy Study 1)	20

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
17/EM/0309	Hospital Experiences of Older Black Caribbean Stroke Patients	10
18/EM/0040	Exploring the utility of a mobile application (LiberEat)	15

Provisional Opinion

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
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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
08/H0406/189/AM19	An open study of biomarkers in asthma and COPD	SA18	07/04/2017	18
08/H0406/226/AM05	Investigating lung cancer progression and therapy - version 2	2	11/12/2017	19
09/H0406/114/AM24	Sample and data collection for cardiovascular research	SA20	29/09/2017	35
10/H0406/47/AM42	Long Term Safety and Efficacy of Adalimumab in Non-infectious Uveitis	SA13	15/08/2017	20
11/EM/0326/AM17	Body Composition assessment using DEXA	SA0326/01/17	26/06/2017	28
11/EM/0326/AM18	Body Composition assessment using DEXA	SA0326/02/17	17/07/2017	10
11/EM/0326/AM19	Body Composition assessment using DEXA	SA0326/03/17	30/11/2017	15
11/EM/0327/AM24	Body Composition assessment using DEXA - submission 2	SA0327/01/17	31/03/2017	22
11/EM/0327/AM25	Body Composition assessment using DEXA - submission 2	SA0327/02/17	08/05/2017	14
11/EM/0327/AM26	Body Composition assessment using DEXA - submission 2	SA0327/03/17	11/07/2017	16
11/EM/0327/AM27	Body Composition assessment using DEXA - submission 2	SA0327/04/17	10/07/2017	16
11/EM/0327/AM28	Body Composition assessment using DEXA - submission 2	SA0327/05/17	30/11/2017	15
11/EM/0434/AM14	Helicobacter Eradication Aspirin Trial (HEAT)	SA11	24/11/2017	15
11/H0406/4/AM23	BO22334/A	SA09	27/10/2017	10
12/EM/0012/AM19	Adolescents and Adults Living with Perinatal HIV Cohort (AALPHI)	SA10	26/06/2017	31
12/EM/0018/AM44	CANTOS:CACZ885M2301 Canakinumab in postMI patients with raised hsCRP	22.02.2018	22/02/2018	12
12/EM/0151/AM17	PROPELS	SA12	14/06/2017	28
12/EM/0151/AM18	PROPELS	SA13	02/10/2017	22
12/EM/0280/AM04	D699BC00001 - Ph. III Study for Metastatic Breast Cancer in Women	SA2	15/03/2017	19
12/EM/0280/AM05	D699BC00001 - Ph. III Study for Metastatic Breast Cancer in Women	SA3	15/06/2017	24
12/EM/0280/AM07	D699BC00001 - Ph. III Study for Metastatic Breast Cancer in Women	26.01.18	26/01/2018	13
12/EM/0291/AM21	HELIOS - PCI-32765CLL3001	SA14	12/10/2017	13
12/EM/0291/AM22	HELIOS - PCI-32765CLL3001	15	27/02/2018	27
12/EM/0370/AM10	Phenotyping bronchiectasis over 2 years including a macrolide trial	SA09	08/09/2017	28

12/EM/0453/AM11	Pixantrone in the treatment of Non Hodgkin Lymphoma (2)	SA8	24/03/2017	18
12/EM/0453/AM13	Pixantrone in the treatment of Non Hodgkin Lymphoma (2)	SA9	10/08/2017	11
13/EM/0015/AM15	CAN3001 version 1.0	SA9	12/04/2017	13
13/EM/0226/AM08	Extended cohort for e-health, environment and DNA (EXCEED) Study	SA4	13/06/2017	20
13/EM/0259/AM05	PREVIEW	AM6	19/04/2017	20
13/EM/0340/AM17	ABT-199 Monotherapy in Relapsed/Refractory CLL With the 17p Deletion	6	28/02/2017	28
13/EM/0340/AM18	ABT-199 Monotherapy in Relapsed/Refractory CLL With the 17p Deletion	SA7	13/06/2017	30
13/EM/0404/AM20	Serelaxin vs standard of care in acute heart failure patients	SA18	29/03/2017	13
14/EM/0034/AM10	GO28667 - PH III, OPEN-LABEL, IN RELAPSED/REFRACTORY PATIENTS WITH CLL	SA9	25/07/2017	15
14/EM/0169/AM08	A Study of the Dural Venous Vasculature in Infants Version 1	6	17/03/2017	29
14/EM/0169/AM10	A Study of the Dural Venous Vasculature in Infants Version 1	7	12/02/2018	21
14/EM/0215/AM12	M12-914 Phase III Veliparib/Placebo + C/P Breast Cancer Study	SA4	18/08/2017	17
14/EM/0215/AM13	M12-914 Phase III Veliparib/Placebo + C/P Breast Cancer Study	SA 10 2017/10/10	10/10/2017	22
14/EM/1005/AM15	Phase 3 Masitinib/Placebo + Docetaxel in Metastatic Prostate Cancer V1	2017/06/22	04/07/2017	22
14/EM/1005/AM16	Phase 3 Masitinib/Placebo + Docetaxel in Metastatic Prostate Cancer V1	14	18/12/2017	18
14/EM/1284/AM12	Neo-AEGIS	SA010	31/05/2017	20
15/EM/0048/AM08	Ticagrelor for prevention of tumour cell-induced platelet aggregation	6	30/10/2017	14
15/EM/0135/AM11	Phase 2 Study in Mantle Cell Lymphoma ACE-LY-004	SA9	01/06/2017	19
15/EM/0135/AM12	Phase 2 Study in Mantle Cell Lymphoma ACE-LY-004	SA10	29/08/2017	19
15/EM/0135/AM14	Phase 2 Study in Mantle Cell Lymphoma ACE-LY-004	SA11	02/11/2017	19
15/EM/0135/AM16	Phase 2 Study in Mantle Cell Lymphoma ACE-LY-004	12	20/02/2018	14
15/EM/0270/AM06	Antibiotic Resistance in the Microbiome OxfoRd (ARMORd) Study	SA4	06/07/2017	20
15/EM/0300/AM09	WO29636 â€‹ImVigor 010 - Atezolizumab in Bladder Cancer after Cystectomy	SA6	17/07/2017	10
15/EM/0300/AM10	WO29636 â€‹ImVigor 010 - Atezolizumab in Bladder Cancer after Cystectomy	SA7	27/11/2017	16

15/EM/0324/AM08	Open label study of BI 655066 in patients with Crohn's disease.	SA#4	08/05/2017	13
15/EM/0324/AM09	Open label study of BI 655066 in patients with Crohn's disease.	SA05	12/09/2017	27
15/EM/0324/AM10	Open label study of BI 655066 in patients with Crohn's disease.	SA6	08/12/2017	5
15/EM/0398/AM02	SV vs. PPV for lung biopsy under GA in patients with ILD	SA01	15/05/2017	14
15/EM/0400/AM10	The SOPHIA Study	8	09/02/2017	28
15/EM/0400/AM11	The SOPHIA Study	SA9	22/08/2017	13
15/EM/0430/AM13	D1690R00009: The DECIDE Study	SA10	22/08/2017	13
15/EM/0437/AM07	COLUMBUS-AMD	SA5	10/04/2017	15
15/EM/0443/AM09	Open-Label Extension Trial of RPC1063 in Relapsing Multiple Sclerosis	SA5	19/05/2017	17
15/EM/0443/AM10	Open-Label Extension Trial of RPC1063 in Relapsing Multiple Sclerosis	SA6	19/06/2017	24
15/EM/0443/AM11	Open-Label Extension Trial of RPC1063 in Relapsing Multiple Sclerosis	SA7	20/09/2017	20
15/EM/0532/AM02	Cambridge Brain and Behaviour Study (CamBABS)	2	12/12/2017	22
15/EM/0546/AM07	MEDI4736 and Tremelimumab for 1st line head and neck cancer	7	17/03/2017	20
15/EM/0546/AM09	MEDI4736 and Tremelimumab for 1st line head and neck cancer	SA8	23/05/2017	21
15/EM/0546/AM10	MEDI4736 and Tremelimumab for 1st line head and neck cancer	SA9	07/09/2017	11
15/EM/0546/AM11	MEDI4736 and Tremelimumab for 1st line head and neck cancer	11	30/01/2018	21
15/EM/0547/AM03	Caloric Vestibular Stimulation in Parkinson's Disease	SA3	07/07/2017	14
15/EM/0547/AM04	Caloric Vestibular Stimulation in Parkinson's Disease	SA4	02/10/2017	29
15/EM/0547/AM05	Caloric Vestibular Stimulation in Parkinson's Disease	5.0	31/01/2018	20
16/EM/0099/AM01	Laser Treatment for Stress Incontinence	SA1	01/03/2017	27
16/EM/0142/AM14	aTTom-Extended Version 1.0, 15th March 2016	SA2	03/05/2017	11
16/EM/0142/AM28	aTTom-Extended Version 1.0, 15th March 2016	3	28/11/2017	5
16/EM/0198/AM05	GO30081 Atezolizumab in patients with untreated extensive-stage SCLC	5	21/06/2017	22
16/EM/0198/AM06	GO30081 Atezolizumab in patients with untreated extensive-stage SCLC	SA6	16/11/2017	20
16/EM/0198/AM07	GO30081 Atezolizumab in patients with untreated extensive-stage SCLC	7	12/12/2017	7
16/EM/0252/AM08	An observational, Quality of Life study in Lemtrada MS patients	SA3	06/10/2017	18

16/EM/0252/AM10	An observational, Quality of Life study in Lemtrada MS patients	4	15/03/2018	8
16/EM/0269/AM02	REVEAL-Vasc	SA1	28/04/2017	24
16/EM/0278/AM04	DIUR-006	SA1	25/09/2017	17
16/EM/0308/AM01	Placental MRI (PiP-Ox)_ Version 1	SA1	28/03/2017	15
16/EM/0337/AM01	Preventing progressive pacemaker-induced remodelling	SA1	17/10/2017	20
16/EM/0382/AM07	PERSPECTIVE	SA4	26/06/2017	30
16/EM/0382/AM10	PERSPECTIVE	SA 6 2017/12/11	11/12/2017	17
16/EM/0384/AM06	Phase 3b AUGUSTUS study	4	14/07/2017	14
16/EM/0439/AM06	NOVELTY	SA2	03/01/2018	12
16/EM/0457/AM02	Long term outcome after accidental dural puncture in obstetric population	SA1	19/04/2017	13
16/EM/0459/AM02	A Phase 2b study for adults with Respiratory Syncytial Virus.	SA03	20/06/2017	23
16/EM/0459/AM03	A Phase 2b study for adults with Respiratory Syncytial Virus.	SA04	17/07/2017	23
16/EM/0459/AM04	A Phase 2b study for adults with Respiratory Syncytial Virus.	SA05	18/09/2017	23
16/EM/0468/AM01	Exploring Endotypes in Chronic Rhinosinusitis (ExpRess)	SA1	24/04/2017	25
17/EM/0006/AM01	ALD403 for Chronic Migraine Prevention	SA1	10/04/2017	15
17/EM/0006/AM03	ALD403 for Chronic Migraine Prevention	SA2	18/09/2017	23
17/EM/0011/AM01	SOLVE	AM1	17/10/2017	17
17/EM/0013/AM03	HVC study to qualify molecular biomarkers associated with flu	SA1	30/05/2017	21
17/EM/0013/AM06	HVC study to qualify molecular biomarkers associated with flu	SA2	12/10/2017	20
17/EM/0020/AM01	The Jockey Study	SA1	11/05/2017	12
17/EM/0028/AM01	CADBIO	SA1	28/04/2017	25
17/EM/0028/AM02	CADBIO	SA2	09/10/2017	16
17/EM/0029/AM02	Promoting engagement in physical activity in rheumatoid arthritis	SA 1 15/12/2017	15/12/2017	17
17/EM/0054/AM01	Coping styles, resilience and self-blame following a traumatic event.	1	18/08/2017	12
17/EM/0058/AM01	1245.110 EMPEROR-Preserved Study	SA1	26/04/2017	8
17/EM/0058/AM03	1245.110 EMPEROR-Preserved Study	26.05.17	26/05/2017	10
17/EM/0058/AM05	1245.110 EMPEROR-Preserved Study	SA4	19/07/2017	21
17/EM/0058/AM08	1245.110 EMPEROR-Preserved Study	SA 6 2017/12/21	21/12/2017	15
17/EM/0058/AM10	1245.110 EMPEROR-Preserved Study	8	08/03/2018	15
17/EM/0059/AM01	1245.121 EMPEROR-Reduced Study	1	26/04/2017	13
17/EM/0059/AM03	1245.121 EMPEROR-Reduced Study	26.05.17	26/05/2017	10
17/EM/0059/AM05	1245.121 EMPEROR-Reduced Study	4_IB to V16	19/07/2017	21
17/EM/0059/AM08	1245.121 EMPEROR-Reduced Study	SA 6 2017/12/21	21/12/2017	15

17/EM/0059/AM10	1245.121 EMPEROR-Reduced Study	8	08/03/2018	15
17/EM/0083/AM01	3rd Generation Study - Six Year Follow-Up	SA1	06/09/2017	22
17/EM/0092/AM01	Questionnaire to measure levels of self-conscious emotions in COPD	SA1	21/06/2017	22
17/EM/0092/AM02	Questionnaire to measure levels of self-conscious emotions in COPD	SA2	08/09/2017	13
17/EM/0126/AM01	Human IBD Enteroid Study(MINIGUT)	01	06/11/2017	15
17/EM/0139/AM01	JN1017C - mCRPC - UK	SA1	30/06/2017	27
17/EM/0155/AM03	POINT	SA3	25/09/2017	16
17/EM/0155/AM04	POINT	SA4	18/10/2017	19
17/EM/0155/AM05	POINT	SA5	22/11/2017	14
17/EM/0155/AM08	POINT	6	12/02/2018	18
17/EM/0175/AM01	Mi-PART	AM01	07/08/2017	7
17/EM/0175/AM03	Mi-PART	2	02/03/2018	16
17/EM/0176/AM01	Mapping Sound Propagation through the Human Lung for Better Diagnosis	SA1	04/10/2017	23
17/EM/0176/AM03	Mapping Sound Propagation through the Human Lung for Better Diagnosis	2	13/12/2017	9
17/EM/0181/AM01	A mixed methods evaluation of online provision of oral contraceptives	SA1	18/07/2017	22
17/EM/0293/AM01	D3250C00045, Benralizumab in Patients with Severe Asthma (ANDHI)	1	10/01/2018	8
17/EM/0303/AM01	Future Thinking and Medicine Use in Chronically Ill Young People	SA1	06/10/2017	19
17/EM/0313/AM01	Lysin CF-301 for Treatment of Staphylococcus aureus bacteremia	SA1, Protocol Amendment 2	15/01/2018	20
17/EM/0324/AM01	Phase III with Octreotide capsules/Placebo in acromegaly patients	1	28/12/2017	17
17/EM/0338/AM01	ABL001 versus Bositunib in Chronic Myeloid Leukaemia	1	22/12/2017	24
17/EM/0343/AM01	Development of an objective measure of cochlear implant outcome	1	12/12/2017	24
17/EM/0343/AM02	Development of an objective measure of cochlear implant outcome	2	27/02/2018	24
17/EM/0344/AM01	Parental Opinions of Appendicitis	SA1	16/11/2017	15
17/EM/0422/AM01	IDEAS - (Identification of DEterminants of Altered circadian rhythms)	SA 1 30/11/2017	30/11/2017	21

6819/AM10	An Investigation into Candidate Genes & Protein Profiling for AAA	15	13/11/2017	14
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Unfavourable opinion

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

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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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 21 day timeline

REC Reference	Title	Number of Days on Clock
17/EM/0128	Validation of a shortened Patient Measure of Safety (PMOS-10)	26
17/EM/0314	The role of community pharmacy in diabetes prevention	23
17/EM/0343	Development of an objective measure of cochlear implant outcome	27
17/EM/0345	Posterior Ligament Complex Assessment in Thoracolumbar Fractures	23
17/EM/0349	Malaria antigen presentation in blood dendritic cells	29
18/EM/0084	A critical evaluation of community based integrated care policy v1	26

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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