

**East Midlands - Nottingham 2 Research Ethics
Committee**

Annual Report

01 April 2015 - 31 March 2016



Part 1 – Committee Membership and Training

Name of REC:	East Midlands - Nottingham 2 Research Ethics Committee
Type of REC:	RECs Recognised to review CTIMPS in patients - type iii
Type of Flag:	Research Involving Children
Chair:	Professor Frances Game
Vice-Chair:	Dr Ian Ross
Alternate Vice-Chair:	Mr Jon Merrills
REC Manager:	Mrs Carolyn Halliwell
REC Assistant:	Miss Joanne Unsworth
Committee Address:	The Old Chapel Royal Standard Place Nottingham NG1 6FS
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Chair's overview of the past year:

This has been a more stable year than the last in terms of committee membership with stability in the Chair, Vice Chair and alternate Vice Chair positions. This year we have lost 4 members; Dr Rosemina Ahmed (Expert) Ms Gill Bumphrey (Expert – pharmacist), Dr Alison Thorpe (Expert), and Ms Veronica Lyon (Lay), and welcomed 2 new members; Mrs Amanada Brammer (Lay plus) and Mrs Bernadette Roberts (Lay) .

The committee continues to succeed in working to excellent timelines with no applications to the full committee taking longer than 60 days to final decision and only 3 (5%) longer than 40 days, the average days to final decision being only 26 days. This is despite an average of over 5 full applications being reviewed per meeting. Similarly none of the applications for proportionate review took more than 14 days to complete (38 in total). The advance rota to share the workload of these and the applications for substantial amendments continues to work well with even distribution of work-load.

Attendance at full meetings is good and we have only had to co-opt members on 2 occasions during the years.

We remain extremely grateful for the support from the REC centre staff; their advice and guidance is, as always invaluable.

East Midlands - Nottingham 2 Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Dr Rosemina Ahmad	Radiology Consultant	Expert	12/05/2014	11/01/2016
Mrs Amanda Brammer	Student/Derby University	Lay Plus	06/05/2015	
Ms Gill Bumphrey	Clinical Trials Pharmacist	Expert	01/12/2012	26/10/2015
Miss Shamim Byrne	Gynaecologist/Obstetrician	Expert	14/12/2009	
Mr Simon Deery	Public Health Registrar	Expert	03/12/2013	
Professor Frances Game	Consultant Physician	Expert	27/07/2004	
Mrs Jane Hennebury	Lawyer	Lay Plus	03/02/2014	
Dr Asam Latif	Research Pharmacist	Expert	17/01/2012	
Mrs Veronica Lyon	Smoking Cessation Advisor	Lay Plus	22/01/2013	26/10/2015
Mr Jon Merrills	Barrister/Pharmacist	Expert	10/09/2014	
Mrs Bernadette Roberts	Retired Finance Manager	Lay	21/04/2015	
Dr Ian Ross	Retired Consultant Physician	Expert	01/07/2014	
Dr John Shaw	Retired Patent Licencing Manager	Lay	01/09/2011	
Miss Catherine Shenton	Librarian	Lay Plus	09/03/2010	
Mrs Sally Ann Smith	Retired Audit Manager	Lay Plus	16/04/2010	
Dr Alison Thorpe	Research and Governance Facilitator	Expert	01/09/2011	26/08/2015
Ms Margret Vince	Translator	Lay Plus	25/10/2006	

East Midlands - Nottingham 2 Research Ethics Committee: Deputy Members

Name	Profession	Status	Meeting date attended
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None

East Midlands - Nottingham 2 Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended
Dr Margaret Stone	Senior Research Fellow (Retired)	Lay	25/01/2016
Mr Paul Hamilton	Retired Local Government Officer	Lay Plus	25/01/2016

East Midlands - Nottingham 2 Research Ethics Committee: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Ms Gill Bumphrey	Shareholdings in organisations involved in or possibly seeking to be involved in the conduct of research: Nova Laboratories Ltd AstraZeneca - small number of shares	21/03/2016
Miss Shamim Byrne	None declared	
Dr Simon Deery	Junior doctor in NHS. To become public health trainee in August 2016.	21/03/2016
Professor Frances Game	Director of R&D at Derby Teaching Hospitals NHS Foundation Trust.	21/03/2016
Mrs Jane Hennebury	None declared	01/02/2016
Dr Asam Latif	None declared	21/03/2016
Mr Jon Merrills	None declared	21/03/2016
Mrs Bernadette Roberts	None declared	25/01/2016
Dr Ian Ross	None declared	21/03/2015
Ms Margret Vince	None declared	14/07/2015
Dr John Shaw	PPI member NDDC/BRU at NUH	21/03/2016
Miss Catherine Shenton	None declared	21/03/2016
Ms Margret Vince	None declared	21/03/2016

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

Month	Date	Number of Members Present at Meeting
April	27/04/2015	9
May	18/05/2015	11
June	22/06/2015	13
July	27/07/2015	11
September	28/09/2015	9
October	26/10/2015	10
November	23/11/2015	8
January	25/01/2016	7
February	22/02/2016	9
March	21/03/2016	9

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	27/04/2015	3
May	18/05/2015	3
June	22/06/2015	3
July	27/07/2015	3
August	24/08/2015	3
September	28/09/2015	3
October	26/10/2015	3
November	23/11/2015	3
December	14/12/2015	3
January	25/01/2016	3
February	22/02/2016	3
March	21/03/2016	3

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

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

Month	Date	Number of Members Present at Meeting
April	10/04/2015	2
April	27/04/2015	2
May	11/05/2015	2
May	18/05/2015	2
June	03/06/2015	2
June	22/06/2015	2
July	06/07/2015	2
July	17/07/2015	2
July	27/07/2015	2

August	10/08/2015	2
August	24/08/2015	2
September	07/09/2015	2
September	21/09/2015	2
September	28/09/2015	2
October	12/10/2015	2
October	26/10/2015	2
November	09/11/2015	2
November	23/11/2015	2
December	07/12/2015	2
December	14/12/2015	2
December	29/12/2015	2
January	11/01/2016	2
January	25/01/2016	2
February	08/02/2016	2
February	22/02/2016	2
March	07/03/2016	2
March	21/03/2016	2
March	21/03/2016	2

28 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
Dr Rosemina Ahmad	3
Mrs Amanda Brammer	5
Ms Gill Bumphrey	5
Miss Shamim Byrne	5
Mr Simon Deery	7
Professor Frances Game	7
Mrs Jane Hennebury	2
Dr Asam Latif	6
Mrs Veronica Lyon	3
Mr Jon Merrills	9
Mrs Bernadette Roberts	3
Dr Ian Ross	9
Dr John Shaw	9
Miss Catherine Shenton	9
Mrs Sally Ann Smith	4
Dr Alison Thorpe	2
Ms Margret Vince	6

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

Name	Number of Meetings Attended
Dr Rosemina Ahmad	2
Ms Gill Bumphrey	1
Miss Shamim Byrne	1
Mr Simon Deery	1
Professor Frances Game	8
Dr Asam Latif	1
Mrs Veronica Lyon	1
Dr Ian Ross	6
Dr John Shaw	4
Miss Catherine Shenton	1
Mrs Sally Ann Smith	1
Dr Alison Thorpe	1
Ms Margret Vince	4

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

Name	Number of Meetings Attended
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Dr Rosemina Ahmad	3
Mrs Amanda Brammer	1
Ms Gill Bumphrey	2
Miss Shamim Byrne	3
Professor Frances Game	15
Dr Asam Latif	1
Mrs Veronica Lyon	1
Mr Jon Merrills	3
Dr Ian Ross	15
Dr John Shaw	3
Miss Catherine Shenton	3
Dr Alison Thorpe	2
Ms Margret Vince	5

Training 01 April 2015 - 31 March 2016

Name of Member	Date	Event(s) attended
Dr Rosemina Ahmad	25/09/2015	Members Regional Training Day
Mrs Amanda Brammer	15/06/2015	Training - Committee Members Induction
Miss Shamim Byrne	28/05/2015	Training - Research Involving Adults Who Lack Capacity (including research in emergency situations)
Mr Simon Deery	27/04/2015	Shred Ethical Debate
Mr Simon Deery	06/05/2015	'Responsible conduct of research' Shamoo, Adil 3rd edn, Oxford University Press
Mr Simon Deery	06/05/2015	Medical Professionalism seminar
Mr Simon Deery	28/05/2015	Training - Research Involving Adults Who Lack Capacity (including research in emergency situations)
Mr Simon Deery	25/09/2015	Members Regional Training Day
Dr Asam Latif	06/10/2015	Quantitative Research Methods and Statistics - A HRA Workshop
Mr Jon Merrills	15/05/2015	NREAP Meeting
Mrs Bernadette Roberts	20/05/2015	CTIMPS Training
Mrs Bernadette Roberts	15/06/2015	Committee members induction
Mrs Bernadette Roberts	30/06/2015	HTA
Mrs Bernadette Roberts	25/09/2015	Members Regional Training Day
Dr Ian Ross	25/09/2015	Members Regional Training Day
Dr Ian Ross	19/10/2015	The Ethical Issues of Research Involving Children
Dr Ian Ross	27/11/2015	CTIMP Training Day
Miss Catherine Shenton	25/09/2015	Members Regional Training Day
Ms Margret Vince	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	17	32.08
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	36	67.92
Total Applications Reviewed	53	100

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

Number of applications made invalid by the REC Manager	3
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	16
Number of paediatric applications reviewed	9
Number of device applications reviewed	5
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	3

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	5.66
Favourable Opinion with Additional Conditions	9	16.98
Unfavourable Opinion	3	5.66
Provisional Opinion	38	71.70
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	53	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	29	54.72
Further Information Favourable Opinion with Additional Conditions	8	15.09
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	3	5.66
Favourable Opinion with Additional Conditions	9	16.98
Unfavourable Opinion	3	5.66
Provisional Opinion	1	1.89
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	53	100

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

Total Applications Reviewed	42
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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	3
Number of studies withdrawn prior to the meeting	0
Number of student applications reviewed	17
Number of paediatric applications reviewed	5
Number of device applications reviewed	0
Number of qualitative applications reviewed	6

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

Decisions taken at proportionate review sub-committee meetings	Number	%
Favourable Opinion with Standard Conditions	9	21.43
Favourable Opinion with Additional Conditions	9	21.43
No Opinion transfer to full committee for review	3	7.14
Provisional Opinion	19	45.24
Unfavourable Opinion	2	4.76
Total	42	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	5.30
Number of completed applications for full ethical review	53
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	5.66%
Number of days taken to final decision – average (mean)	26
Number of completed proportionate review applications for ethical review	38
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	3
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	127
Number of completed substantial amendments over 35 days	0
Number of completed substantial amendments over 35 days as a % of total substantial amendments	0.00%
Number of completed substantial amendments over 28 days	6
Number of completed substantial amendments over 28 days as a % of total substantial amendments	4.72%
Number of modified amendments reviewed	4
Number of completed modified amendments over 14 days	0
Number of completed modified amendments over 14 days as a % of total modified amendments	0.00%
Number of minor amendments received	108
Number of substantial amendments received for information	0
Number of substantial amendments received for new sites/PIs	37
Number of annual progress reports received	96

Number of safety reports received	53
Number of Serious Adverse Events received	0
Number of final reports received	30

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/0172	Qualitative study of mental health during cross-sex hormone treatment	35
15/EM/0173	Gestational age Assessment Tool	36
15/EM/0179	UNTOUCHED	29
15/EM/0225	Tamoxifen in oesophageal cancer (Version 1)	19
15/EM/0226	Health visitors work with families receiving additional support V1.0	22
15/EM/0227	Realist Evaluation of Best Beginnings Interventions	20
15/EM/0272	Psychosocial predictors of the persistence of paranoia in adolescents	25
15/EM/0277	PROPS - Preventative Role Of a fixed dose combination Pill in Stroke	22
15/EM/0302	E-CABG registry (version 1.0)	17
15/EM/0306	BAROQUE	20
15/EM/0309	Efficacy and Safety of Budesonide delivered by VR475 Inhalation System	30
15/EM/0316	The Sons of Gout Study	34
15/EM/0411	Understanding the Nature & Frequency of Avoidable Harm In Primary Care	24
15/EM/0419	TROLLEY	24
15/EM/0422	Baxalta- 391401 Part 2 BAX69 - Metastatic colorectal cancer	23
15/EM/0431	Developing a betrayal scale for people with personality disorders	34
15/EM/0440	AZTEC	28
15/EM/0468	Carbohydrate Reduction and Impact on Gastrointestinal System V1.0	21
15/EM/0521	IM power010: Phase 3 study of Atezolizumab in non-small lung cancer	42
15/EM/0522	Evolocumab vs LDL Apheresis in participants with Hypercholesterolemia	26
16/EM/0001	Strategies for management of corneal neovascularisation	31
16/EM/0002	Strategies for management of recurrent pterygium	31
16/EM/0016	Patient experience with surgical anaesthesia v2	42
16/EM/0017	PEACE III (EORTC 1333)	35
16/EM/0030	A Phase 2 study of NGM282 in Patients with PSC	36
16/EM/0032	INC280 in NSCLC patients with cMET activated pathway	34
16/EM/0037	Ixekizumab in Ankylosing Spondylitis	31
16/EM/0128	M13-596 2nd gen HCV treatment in transplant subjects	30
16/EM/0133	A potential new treatment for nonradiographic axial spondyloarthritis	17

Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/EM/0175	SARCOFALLS study v 1.0	29
15/EM/0315	Axillary plexus block - Dealing with the tourniquet	24
15/EM/0469	Cardiovascular changes in High Risk pregnancy	35
15/EM/0470	Evaluating the safety, tolerability and efficacy of Tirasemtiv in ALS	22
15/EM/0473	Phase II anetumab ravtansine as 2nd line treatment for MPM	28
15/EM/0474	Interstitial laser thermotherapy (imLT) treatment of breast cancer	34
15/EM/0519	Reference interval study on fibroblast growth factor-21	45
16/EM/0059	Why people in mental health distress repeatedly attend ED	34

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
15/EM/0182	Mechanisms of learning and memory in the human brain v1	37
15/EM/0208	PEArL	18
15/EM/0297	Physiotherapy in Conservatively Managed Distal Radius Fractures	17

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/EM/0192	Effects of Peripheral Vestibular Stimulation on Balance Post Stroke	18
15/EM/0254	The Health Survey for England 2016 to 2019	17
15/EM/0274	Renal MRI Feasibility Study in Patients with CKD and AKI	17
15/EM/0447	Adiposity in Infants of Mothers with Diabetes	23
15/EM/0471	PEPS Data Linkage Study	22
15/EM/0518	Transtibial amputee balance training: A randomised controlled trial	22
16/EM/0018	Hand osteoarthritis classification study	21
16/EM/0042	Mechanisms Affecting Gut of Preterm Infants (MAGPIE)	21
16/EM/0088	Hospital to Home: Smokers Support Study	16

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
15/EM/0276	Patient experience with surgical anaesthesia v1	17
15/EM/0427	Psychodynamics of the occupational medicine consultation	21
16/EM/0058	Traumatic brain injury follow up study	21

Provisional Opinion

REC Reference	Title	Number of Days on Clock
16/EM/0059	Why people in mental health distress repeatedly attend ED	n/a
16/EM/0068	Section 136 Patient Follow Up: Version 1	n/a
16/EM/0128	M13-596 2nd gen HCV treatment in transplant subjects	n/a

Provisional Opinion Pending Consultation with Referee

REC Reference	Title	Number of Days on Clock
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None

Further information response not complete

REC Reference	Title	Number of Days on Clock
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None

Withdrawn after the meeting

REC Reference	Title	Number of Days on Clock
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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
15/EM/0199	Qualitative Eating behaviours and well-being in a CF sample	11
15/EM/0239	Medicines related hospital admissions and medication reviews v.1	10
15/EM/0243	The Role of Myocardial Fibrosis in Degenerative Mitral Regurgitation	9
15/EM/0286	Median Nerve Elastography Version 1	14
15/EM/0290	PAVS_V1	9

15/EM/0355	Development of iPSCs for studying the molecular pathology of MNGIE	9
15/EM/0356	Balance and Cognitive-Motor Dual-Tasking in Multiple Sclerosis - V1	10
15/EM/0404	Exploring aspects of self-care amongst the homeless	9
15/EM/0405	A case study of a Maternity Service Development Programme	9
15/EM/0490	OPTIMUM-BP (version 1.0)	8
15/EM/0492	Study to describe the use of buccal midazolam maleate (Epistatus®)	6
16/EM/0053	Going Smoke Free in Mental Health Trusts: CLAHRC Service User Survey	7
16/EM/0056	Does neonatal airway epithelial cell function predict childhood asthma?	14

Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/EM/0241	An investigation of psychological burden of PET scanning procedures	10
15/EM/0287	Optimism & pessimism effect on recovery from elective cardiac surgery	14
15/EM/0351	Evaluation of sputum MMP9 in COPD subject, version1	9
16/EM/0092	Effect of socioeconomic status on compliance with management v1	14

Further Information Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
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None

Favourable Opinion with Standard Conditions

REC Reference	Title	Number of Days on Clock
15/EM/0285	Ex-vivo perfusion of livers for transplantation	8
15/EM/0353	Learning from Medication Incidents in Children	6
15/EM/0409	To identify a suitable method of decalcification for mandible bone	4
15/EM/0449	Biomedical Informatics for post-transplant recurrent GMN	7
15/EM/0534	Partnership in Prostate Cancer Care: (ICARE-P)	10
15/EM/0535	Relocating patients from homelessness practice to mainstream practices	10
15/EM/0572	Simple Renal Cysts in Children v1.0	9
15/EM/0573	Human peripheral blood lymphocytes for therapeutic antibody screening	13
16/EM/0090	Building Advanced Materials for Vision Loss	9

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/EM/0200	Eating behaviours and well-being in a Cystic Fibrosis sample	9
15/EM/0202	Rome IV Diagnostic Criteria	9
15/EM/0242	Sonic versus ultrasonic activation of sodium hypochlorite	7
15/EM/0451	Urinary micronutrient profile as AKI biomarker after cardiac surgery	7
15/EM/0486	Extravascular lung water in reperfusion lung injury	5
15/EM/0489	Role of Skin Capillary Density in Epithelial ovarian cancer	6
15/EM/0574	FLXIBILITY	9
15/EM/0575	Medically unexplained symptoms severity and adverse life events	8
16/EM/0091	Patient experience in community / district nursing (Version 1.2 Feb16)	6

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
16/EM/0051	What are important therapy outcomes for children who stammer?	5
16/EM/0093	Medicate	8

Provisional Opinion

REC Reference	Title	Number of Days on Clock
16/EM/0139	Cognitive predictors of recovery after brain injury: version 1.1	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
16/EM/0136	Periprostatic Fat and Prostate Cancer Aggressiveness	8

Table 10.1: Breakdown of current status of all substantial amendments reviewed within the reporting period

Favourable opinion				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
04/Q2404/130/AM02	Candidate genes in Alzheimer's Disease - version 1	SA#01	18/05/2015	24
05/Q2404/45/AM03	Changes in Theta rythym due to meditation in Schizophrenia	Substantial Amendment 1	03/06/2015	20
09/H0408/47/AM21	Lapatinib versus Trastuzumab in ErbB2Positive Metastatic Breast Cancer	Substantial Amendment 07.08.15	07/08/2015	18
10/H0408/105/AM11	SPARK (Safety Paediatric efficacy phaRmacokinetic with Kuvan®)	7.0	13/01/2016	11
10/H0408/115/AM19	Imaging to Understand Pain in Osteoarthritis	SA8	23/09/2015	4
11/EM/0416/AM01	Genetic causes of chronic cough and neuropathy	1.0	13/07/2015	26
12/EM/0204/AM10	Safety and tolerability of ONO-4059 in patients with NHL & CLL	Protocol Amendment 7	02/04/2015	28
12/EM/0204/AM11	Safety and tolerability of ONO-4059 in patients with NHL & CLL	Substantial Amendment 20.08.15	10/08/2015	15
12/EM/0204/AM12	Safety and tolerability of ONO-4059 in patients with NHL & CLL	SA11	08/01/2016	14
12/EM/0245/AM03	Longitudinal study of nasogastric feeding tubes on NICUs	Substantial Amendment 2	21/04/2015	20
12/EM/0257/AM04	PremiTranS Study	Substantial Amendment 2	22/07/2015	7
12/EM/0261/AM02	OCT (Optical Coherence Tomography) and Ocular Development	Substantial Amendment 2	01/04/2015	17
12/EM/0283/AM13	Pre-term Cord Clamping Trial	Substantial Amendment 8	22/04/2015	14
12/EM/0283/AM15	Pre-term Cord Clamping Trial	SA9	03/12/2015	11
12/EM/0301/AM02	Drebrin and Melanoma	Substantial Amendment 2	16/04/2015	10
12/EM/0393/AM10	WA28029 - Decreasing TCZ dosing frequency in patients with sJIA	substantial amendment 5	10/03/2015	35
12/EM/0428/AM03	Adipose tissue in Children	amendment 2	05/02/2016	14
13/EM/0012/AM08	A184-178 Ipilimumab in children(aged 12- less than 18)with	Substantial	14/04/2015	15

	malignant m	Amendment 31.03.15		
13/EM/0030/AM14	SIFT	SA#06	11/05/2015	28
13/EM/0030/AM15	SIFT	Substantial Amendment 7	06/08/2015	5
13/EM/0103/AM02	Cognitive and oculomotor function - version1	Substantial Amendment 1	30/06/2015	15
13/EM/0118/AM10	ELFIN	Substantial Amendment 9	27/08/2015	8
13/EM/0118/AM11	ELFIN	11	27/11/2015	21
13/EM/0118/AM13	ELFIN	13	28/01/2016	13
13/EM/0143/AM01	Computational modelling of aortic dissection	Substantial Amendment 1	11/09/2015	12
13/EM/0175/AM01	The use of primary cells for oncology drug discovery.	SA1	06/12/2015	7
13/EM/0189/AM13	NALA-Drug Comparator study in HER2+ Metastatic Breast Cancer patients	Substantial amendment 3	29/04/2015	15
13/EM/0239/AM13	RESPITE	9.0	09/10/2015	11
13/EM/0239/AM14	RESPITE	SA10	21/10/2015	5
13/EM/0251/AM15	Serelaxin when added to standard therapy in acute heart failure	SA#09	22/04/2015	23
13/EM/0251/AM16	Serelaxin when added to standard therapy in acute heart failure	Substantial Amendment 10	20/11/2015	28
13/EM/0284/AM06	LDK378 vs Chemo in ALK+ NSCLC in patients who failed crizotinib	Substantial Amendment 4	17/06/2015	6
13/EM/0284/AM07	LDK378 vs Chemo in ALK+ NSCLC in patients who failed crizotinib	04	11/12/2015	17
13/EM/0351/AM06	Grass Pollen Allergen Immunotherapy Tablet (AIT) Time Course Study	Substantial Amendment 4	07/10/2015	13
13/EM/0357/AM02	Secukinumab - efficacy and safety in Ankylosing Spondylitis extension	Substantial Amendment 2	28/04/2015	18
13/EM/0357/AM03	Secukinumab - efficacy and safety in Ankylosing Spondylitis extension	SA3	23/10/2015	26
13/EM/0357/AM04	Secukinumab - efficacy and safety in Ankylosing Spondylitis extension	SA4	30/10/2015	15
13/EM/0406/AM02	Use of discarded surgical tissue and synovial fluid	Substantial Amendment 1	07/09/2015	8

13/EM/0408/AM01	Vascular changes during colorectal surgery	SA1	04/06/2015	13
13/EM/0434/AM14	UK HARP-III Study	Substantial Amendment 7	04/06/2015	19
13/EM/0434/AM17	UK HARP-III Study	8	20/07/2015	27
13/EM/0434/AM19	UK HARP-III Study	Substantial Amendment 9	04/02/2016	18
13/EM/0458/AM09	BMN 111 in Children with Achondroplasia	Substantial amendment 04.09.15	04/09/2015	26
13/EM/0458/AM11	BMN 111 in Children with Achondroplasia	SA22.10.2015	22/10/2015	27
13/EM/0458/AM12	BMN 111 in Children with Achondroplasia	Substantial Amendment #5	04/03/2016	18
13/EM/0459/AM02	POSNOC	Substantial Amendment 2	18/03/2015	16
14/EM/0064/AM01	Imaging Markers of Brain Network Dysfunction in Multiple Sclerosis	Substantial Amendment 1	10/09/2015	5
14/EM/0073/AM04	MK-8835/PF-04971729 vs. Placebo in T2DM Subjects with Stage 3 Chronic	Substantial amendment to IB	27/04/2015	15
14/EM/0073/AM06	MK-8835/PF-04971729 vs. Placebo in T2DM Subjects with Stage 3 Chronic	Substantial Amendment 4	17/08/2015	8
14/EM/0073/AM09	MK-8835/PF-04971729 vs. Placebo in T2DM Subjects with Stage 3 Chronic	SA7	21/10/2015	5
14/EM/0077/AM18	CQVA149A3401 Open Label Study of NVA237 or QVA149 in moderate COPD	SA 14	26/06/2015	10
14/EM/0077/AM19	CQVA149A3401 Open Label Study of NVA237 or QVA149 in moderate COPD	Substantial Amendment 15	01/09/2015	9
14/EM/0115/AM02	Knee Pain and Related Health in the Community Study	Substantial Amendment 2	09/07/2015	11
14/EM/0121/AM08	RITUXILUP, Version 1.1	substantial amendment 5	07/03/2016	7
14/EM/0130/AM07	A Phase 3 Open-Label Randomized Study of Quizartinib (AC220)	Substantial Amendment 3	30/07/2015	9
14/EM/0130/AM08	A Phase 3 Open-Label Randomized Study of Quizartinib (AC220)	SA#04	04/02/2016	5
14/EM/0143/AM04	An Extension Study to MEA115661 in Severe Asthma	Substantial Amendment 4	16/07/2015	11

14/EM/0172/AM04	Baby-OSCAR Trial	Substantial Amendment 3	21/04/2015	9
14/EM/0172/AM07	Baby-OSCAR Trial	SA5	21/10/2015	21
14/EM/0189/AM03	Imaging Pain Relief in Osteoarthritis version 1.5	Substantial Amendment 2	26/05/2015	17
14/EM/0189/AM04	Imaging Pain Relief in Osteoarthritis version 1.5	Substantial Amendment 3	29/07/2015	16
14/EM/0189/AM05	Imaging Pain Relief in Osteoarthritis version 1.5	4.0	12/02/2016	30
14/EM/0192/AM01	Reduced Appetite in Crohn's disease	Substantial Amendment 1	09/04/2015	27
14/EM/0192/AM02	Reduced Appetite in Crohn's disease	Substantial Amendment 11.11.15	11/11/2015	10
14/EM/0192/AM03	Reduced Appetite in Crohn's disease	4.0	15/01/2016	7
14/EM/0222/AM03	The relationship between depressive symptoms and allocentric memory	third amendment	13/02/2016	19
14/EM/1043/AM01	Use of mobile phones to diagnose and assess Raynaud's Phenomenon.	Substantial Amendment 1	23/03/2015	30
14/EM/1082/AM04	Pfizer B2081011 - Phase 2a PF-05212377 safety& efficacy in Alzheimer's	Substantial Amendment 1	18/05/2015	24
14/EM/1162/AM05	Group facilitation for people who present to hospital with self-harm	Substantial Amendment 1	20/04/2015	10
14/EM/1162/AM06	Group facilitation for people who present to hospital with self-harm	Substantial Amendment 2	26/08/2015	14
14/EM/1199/AM01	Evaluation of the High Frequency Digit Triplet test in Cystic Fibrosis	SA#01	29/01/2016	20
14/EM/1200/AM02	A Study of Mepolizumab as add on therapy in severe asthma	Substantial Amendment 2	31/03/2015	13
14/EM/1200/AM03	A Study of Mepolizumab as add on therapy in severe asthma	Substantial Amendment 3	05/05/2015	13
14/EM/1202/AM01	Evaluation of interventions for parents of excessively crying infants	SA1	13/09/2015	11
14/EM/1202/AM02	Evaluation of interventions for parents of excessively crying infants	SA2	24/09/2015	27
14/EM/1202/AM03	Evaluation of interventions for parents of excessively crying infants	3	15/01/2016	14

14/EM/1213/AM01	Early motion and directed exercise (EMADE) in ankle fracture fixation	Substantial Amendment 1	24/03/2015	19
14/EM/1213/AM03	Early motion and directed exercise (EMADE) in ankle fracture fixation	Substantial Amendment 2	15/07/2015	21
14/EM/1223/AM02	Predicting postoperative morbidity using perioperative immune sampling	Amendment 2	06/11/2015	14
14/EM/1249/AM03	TOPAZ I- study in ABT-450/Ritonavir/ABT-267 and ABT-333 in chronic HCV	Substantial Amendment 2	12/06/2015	11
14/EM/1249/AM04	TOPAZ I- study in ABT-450/Ritonavir/ABT-267 and ABT-333 in chronic HCV	Substantial Amendment 3	31/07/2015	25
14/EM/1249/AM05	TOPAZ I- study in ABT-450/Ritonavir/ABT-267 and ABT-333 in chronic HCV	SA#04	01/02/2016	8
14/EM/1264/AM02	Behavioural Intervention For Stroke Carers	Substantial Amendment 1	24/06/2015	23
14/EM/1264/AM03	Behavioural Intervention For Stroke Carers	Substantial Amendment 2	17/08/2015	16
14/EM/1298/AM01	Screening of compounds for ADME, toxicity and efficacy parameters	1	15/02/2016	12
14/EM/1307/AM02	ML29659 - ESTHER - Disease Registry Study	Substantial Amendment 2	19/03/2015	22
14/EM/1308/AM02	Ext Study AT1001-042- Effects of AT1001 in Patients with Fabry Disease	SA2	15/10/2015	12
14/EM/1308/AM03	Ext Study AT1001-042- Effects of AT1001 in Patients with Fabry Disease	SA3	07/12/2015	16
14/EM/1308/AM04	Ext Study AT1001-042- Effects of AT1001 in Patients with Fabry Disease	4.0	20/01/2016	5
14/EM/1315/AM01	GlobALL	February 2016	03/02/2016	33
15/EM/0037/AM01	Bone density and structural adaptations across a season in athletes	SA1	08/09/2015	17
15/EM/0055/AM02	Rapid Intervention with GTN in Hypertensive Stroke Trial - RIGHT-2	SA2	27/10/2015	29
15/EM/0095/AM01	ACELARATE	SA#02	15/05/2015	27
15/EM/0095/AM11	ACELARATE	4.0	02/07/2015	5
15/EM/0098/AM02	Alcohol Use in People Aged 50 and Over - Version 1	Amendment 2	01/07/2015	16
15/EM/0103/AM01	SIOP Ependymoma II	SA02	27/10/2015	24
15/EM/0103/AM04	SIOP Ependymoma II	SA3	11/11/2015	25

15/EM/0132/AM01	Atrium Chest-drain Evaluation Trial - 1	SA1	07/05/2015	12
15/EM/0132/AM02	Atrium Chest-drain Evaluation Trial - 1	SA2	09/12/2015	18
15/EM/0142/AM01	Eating behaviour in Crohn's disease	SA1	15/06/2015	8
15/EM/0142/AM02	Eating behaviour in Crohn's disease	SA2	26/08/2015	14
15/EM/0192/AM01	Effects of Peripheral Vestibular Stimulation on Balance Post Stroke	Substantial Amendment [1.1]	09/09/2015	14
15/EM/0192/AM02	Effects of Peripheral Vestibular Stimulation on Balance Post Stroke	SA2	16/11/2015	30
15/EM/0199/AM01	Qualitative Eating behaviours and well-being in a CF sample	SA1	19/10/2015	26
15/EM/0208/AM01	PEARL	SA1	26/02/2016	9
15/EM/0225/AM01	Tamoxifen in oesophageal cancer (Version 1)	SA1	09/12/2015	7
15/EM/0227/AM01	Realist Evaluation of Best Beginnings Interventions	substantial amendment 1	29/02/2016	13
15/EM/0254/AM01	The Health Survey for England 2016 to 2019	SA1	04/11/2015	14
15/EM/0254/AM03	The Health Survey for England 2016 to 2019	2	15/02/2016	20
15/EM/0274/AM01	Renal MRI Feasibility Study in Patients with CKD and AKI	substantial amendment 2	22/02/2016	14
15/EM/0277/AM02	PROPS - Preventative Role Of a fixed dose combination Pill in Stroke	SA2	24/08/2015	21
15/EM/0306/AM01	BAROQUE	SA1	16/10/2015	11
15/EM/0306/AM02	BAROQUE	SA2	13/11/2015	14
15/EM/0351/AM01	Evaluation of sputum MMP9 in COPD subject, version1	SA1	01/09/2015	22
15/EM/0422/AM01	Baxalta- 391401 Part 2 BAX69 - Metastatic colorectal cancer	SA1	02/10/2015	34
15/EM/0422/AM02	Baxalta- 391401 Part 2 BAX69 - Metastatic colorectal cancer	2.0	19/11/2015	6
15/EM/0422/AM04	Baxalta- 391401 Part 2 BAX69 - Metastatic colorectal cancer	SA3	11/01/2016	14
15/EM/0473/AM02	Phase II anetumab ravtansine as 2nd line treatment for MPM	SA1	21/12/2015	14
15/EM/0473/AM03	Phase II anetumab ravtansine as 2nd line treatment for MPM	2	17/02/2016	21
15/EM/0522/AM01	Evolocumab vs LDL Apheresis in participants with Hypercholesterolemia	SA1	12/01/2016	14
OG010101/AM03	Laboratory studies of structure & function of the placenta after birth	SA03	05/10/2015	10

Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
13/EM/0030/AM17	SIFT	Substantial	19/02/2016	7

		Amendment 8		
13/EM/0452/AM01	CATH-B Chinese community Access to Treatment for Hepatitis B	Substantial Amendment 1	22/06/2015	21
13/EM/0458/AM08	BMN 111 in Children with Achondroplasia	SA 30.07.15	29/07/2015	12
14/EM/0172/AM08	Baby-OSCAR Trial	6	15/12/2015	8
14/EM/1220/AM02	The impact of neurocardiogenic syncope on young people.	SA2	26/03/2015	13
15/EM/0063/AM01	Visual disability in dry AMD	1.0	19/01/2016	6
GM010201/AM06	The genetic factors associated with non-alcoholic steatohepatitis	5	26/11/2015	22

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
13/EM/0030/AM17/1	SIFT	Substantial Amendment 8	14/03/2016	9
13/EM/0458/AM08/1	BMN 111 in Children with Achondroplasia	SA 30.07.15	17/08/2015	2
15/EM/0063/AM01/1	Visual disability in dry AMD	mod 1 of SA1	15/02/2016	12

Unfavourable opinion timeline				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
14/EM/0172/AM08/1	Baby-OSCAR Trial	Modified Amendment 06	15/12/2015	6

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 14 day timeline

REC Reference	Title	Number of Days on Clock
None		

SSAs (non Phase 1) over 25 day timeline

REC Reference	Title	Number of Days on Clock
None		

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				