

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

Annual Report

01 April 2016 - 31 March 2017



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:	Miss Caroyln Halliwell (April 2016 – Feb 2017) Miss Georgia Copeland (February 2017 – Ongoing)
REC Assistant:	Mrs Jo O'Neil (April 2016 – Feb 2017) Miss Lindsey Wallace (February 2017 – Ongoing)
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 less stable year than the last in terms of committee membership although we have maintained the stability of the Chair, Vice Chair and alternate Vice Chair positions. This year we have lost 4 members; Dr Asam Latif(Expert- pharmacist) Mrs Amanda Bremmer (Lay plus), Miss Catherine Shenton (Lay), and Mrs Sally Ann Smith (Lay), and welcomed just one new member; Miss Desislava Bocheva(Lay plus). The shrinking committee size (9 by March 2017) has meant that we have had to co-opt 3 times in the reporting period April 2016-March 2017

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 4 applications taking longer than 40 days, the average days to final decision being only 28 days. This is despite an average of over 4.60 full applications being reviewed per meeting. Similarly none of the applications for proportionate review took more than 14 days to complete or 21 days once this timeline was imposed (33 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.

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
Miss Desislava Bocheva	Student	Lay Plus	03/01/2017	
Miss Shamim Byrne	Gynaecologist/Obstetrician	Expert	14/12/2009	
Dr 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	28/11/2016
Mr Jon Merrills	Barrister/Pharmacist	Expert	10/09/2014	
Mrs Bernadette Roberts	Retired Finance Manager	Lay Plus	21/04/2015	
Dr Ian Ross	Retired Consultant Physician	Expert	01/07/2014	
Dr John Shaw	Retired Patent Licensing Manager	Lay	01/09/2011	
Miss Catherine Shenton	Retired Nurse	Lay Plus	09/03/2010	25/07/2016
Mrs Sally Ann Smith	Retired Audit Manager	Lay Plus	16/04/2010	13/09/2016
Ms Margret Vince	Translator	Lay Plus	25/10/2006	

East Midlands - Nottingham 2 Research Ethics Committee: Deputy Members

None

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

Name	Profession	Status	Meeting date attended
Dr Brian Hands	Retired General Practitioner	Expert	27/03/2017 26/09/2017
Mrs Anne Walker	Voluntary worker in Health Care	Lay Plus	27/03/2017
Mr Michael Andrews	Retired Company Secretary	Lay Plus	26/09/2017

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

Name	Declaration of Interest	Date
Miss Shamim Byrne	Auditory Verbal UKC.I.C.S	28/11/2016
Mr Simon Deery	None declared	10/10/2016
Mr Simon Deery	Public Health Registrar - involved in flu vaccine research at University of Nottingham	28/11/2016
Professor Frances Game	Clinical Director R&D Derby Teaching Hospitals NHS Foundation Trust	28/11/2016
Mr Jon Merrills	None declared	28/11/2016
Mrs Bernadette Roberts	None declared	28/11/2016
Dr Ian Ross	None declared	28/11/2016
Dr John Shaw	PPI member Nottingham Digestive Diseases Centre BRU, QMC	17/01/2017
Dr John Shaw	Member of PPI group at NUH NDDC BRU	26/09/2016
Ms Margret Vince	None declared	28/11/2016
Miss Desislava Bochev	None declared	27/02/2017

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

Month	Date	Number of Members Present at Meeting
April	25/04/2016	8
May	23/05/2016	10
June	27/06/2016	8
July	25/07/2016	7
September	26/09/2016	7
October	24/10/2016	7
November	28/11/2016	8
January	23/01/2017	8
February	27/02/2017	9
March	27/03/2017	8

10 full committee meetings were held during the reporting period.

Proportionate Review Sub-Committee Meetings held during 01 April 2016 - 31 March 2017:

Month	Date	Number of Members Present at Meeting
April	25/04/2016	3
May	23/05/2016	3
June	27/06/2016	3
July	25/07/2016	3
August	22/08/2016	3
September	26/09/2016	3
October	24/10/2016	3
December	19/12/2016	3
January	23/01/2017	3
February	27/02/2017	3

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

Sub-Committee Meetings held during 01 April 2016 - 31 March 2017:

Month	Date	Number of Members Present at Meeting
April	11/04/2016	2
April	25/04/2016	2
May	09/05/2016	2
May	23/05/2016	2
June	10/06/2016	2
June	27/06/2016	2
July	11/07/2016	2
July	25/07/2016	2
August	01/08/2016	2
August	08/08/2016	2
August	22/08/2016	2

September	09/09/2016	2
September	26/09/2016	2
October	10/10/2016	2
October	24/10/2016	2
November	11/11/2016	2
November	28/11/2016	2
December	09/12/2016	2
December	19/12/2016	2
January	09/01/2017	2
January	23/01/2017	2
February	06/02/2017	2
February	27/02/2017	2
March	13/03/2017	3
March	16/03/2017	2
March	27/03/2017	2

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

Details of inquorate meeting held: 01 April 2016 - 31 March 2017

None

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

Name	Number of Meetings Attended
Miss Desislava Bocheva	2
Miss Shamim Byrne	8
Mr Simon Deery	6
Professor Frances Game	9
Mrs Jane Hennebury	3
Dr Asam Latif	3
Mr Jon Merrills	8
Mrs Bernadette Roberts	8
Dr Ian Ross	9
Dr John Shaw	8
Miss Catherine Shenton	4
Ms Margret Vince	8

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

Name	Number of Meetings Attended
Miss Shamim Byrne	5
Mr Simon Deery	2
Professor Frances Game	5
Mrs Jane Hennebury	1
Dr Asam Latif	1
Mr Jon Merrills	3
Mrs Bernadette Roberts	3
Dr Ian Ross	4
Dr John Shaw	3
Miss Catherine Shenton	1
Ms Margret Vince	2

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

Name	Number of Meetings Attended
Miss Shamim Byrne	4
Mr Simon Deery	4
Professor Frances Game	10
Dr Asam Latif	2
Mr Jon Merrills	6
Mrs Bernadette Roberts	3
Dr Ian Ross	17

Dr John Shaw	3
Ms Margret Vince	4

Training 01 April 2016 - 31 March 2017

Name of Member	Date	Event(s) attended
Miss Shamim Byrne	11/05/2016	Assessing the Consequences of Research - A HRA Workshop
Miss Shamim Byrne	14/10/2016	Genetic and Genomic Research
Mr Simon Deery	23/09/2016	Local Training Day - Regional
Professor Frances Game	02/06/2016	Equality and Diversity training
Mrs Jane Hennebury	30/08/2016	Equality Diversity and Human Rights
Mr Jon Merrills	01/04/2016	Reading up on Access to Health Records
Mr Jon Merrills	01/04/2016	Read HRA Guidance for applicants attending REC meeting
Mr Jon Merrills	01/07/2016	Read various medical/pharmacy articles on grapefruit juice/drug interactions
Mr Jon Merrills	01/07/2016	Read articles on Brexit and CE marking
Mr Jon Merrills	10/10/2016	Equality Diversity and Human Rights
Mrs Bernadette Roberts	23/09/2016	Local Training Day - Regional
Mrs Bernadette Roberts	11/10/2016	Equality Diversity and Human Rights
Dr Ian Ross	01/12/2016	National Training Day for Committee Chairs
Dr Ian Ross	22/03/2017	Training - National Members Training Day
Dr John Shaw	31/08/2016	HRA approval training for non-commercial studies
Dr John Shaw	31/08/2016	HRA approval training for commercial studies
Dr John Shaw	31/08/2016	Reviewing the research design of clinical trials
Dr John Shaw	31/08/2016	Sense and readability : PIS for research studies
Dr John Shaw	31/08/2016	When should placebo surgery as a control in clinical trials be carried out?
Ms Margret Vince	14/10/2016	Genetic and Genomic Research
Ms Margret Vince	22/03/2017	Training - National Members 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	36.96
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	29	63.04
Total Applications Reviewed	46	100

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

Number of applications made invalid by the REC Manager	2
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	17
Number of paediatric applications reviewed	13
Number of device applications reviewed	3
Number of prisoner applications reviewed	2
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	5

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

Decisions taken at meetings following review of applications	Number	%
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	9	19.57
Unfavourable Opinion	1	2.17
Provisional Opinion	34	73.91
Provisional Opinion Pending Consultation with Referee	2	4.35
Total	46	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	26	56.52
Further Information Favourable Opinion with Additional Conditions	6	13.04
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	9	19.57
Unfavourable Opinion	1	2.17
Provisional Opinion	2	4.35
Provisional Opinion Pending Consultation with Referee	0	0.00
Further Information response not complete	1	2.17
No decision entered on system	0	0.00
Number of studies withdrawn after the meeting	1	2.17
Total	46	100

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

Total Applications Reviewed	35
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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	7
Number of studies withdrawn prior to the meeting	0
Number of student applications reviewed	12
Number of paediatric applications reviewed	10
Number of device applications reviewed	0
Number of qualitative applications reviewed	4

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	17.14
Favourable Opinion with Additional Conditions	11	31.43
No Opinion transfer to full committee for review	2	5.71
Provisional Opinion	14	40.00
Unfavourable Opinion	2	5.71
Total	35	100

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

Average number of applications reviewed per full meeting	4.60
Number of completed applications for full ethical review	45
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	4
Number of completed applications over 40 days as a % of total	8.70%
Number of days taken to final decision – average (mean)	28
Number of completed proportionate review applications for ethical review	33
Number of completed proportionate review applications for ethical review over 14 days <u>(Please note, the timeline for the review of PR applications was extended from 14 to 21 calendar days in December 2016)</u>	7
<u>Number of complete proportionate review applications for ethical review over 21 days</u>	0
Number of completed proportionate review applications over 14 days as a % of total	21.21%
Number of SSAs (non-Phase 1) reviewed	2
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	137
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	5
Number of completed substantial amendments over 28 days as a % of total substantial amendments	3.65%
Number of modified amendments reviewed	7
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	112
Number of substantial amendments received for information	1
Number of substantial amendments received for new sites/PIs	31
Number of annual progress reports received	88
Number of safety reports received	57
Number of Serious Adverse Events received	0
Number of final reports received	20

Table 9.1: Breakdown of current status of all full applications reviewed within the reporting period

Further Information Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
16/EM/0141	Brain-in-Hand (BiH) Technology For Acquired Brain Injury (ABI)	24
16/EM/0174	LBM & lung function in adolescents with CF	24
16/EM/0214	Timing ability in Alzheimer's disease FINAL 1.0	30
16/EM/0240	Ibrutinib in paediatrics and young adults with non-Hodgkin Lymphoma	25
16/EM/0241	Open Label Extension of BMN 111 in children with achondroplasia	26
16/EM/0258	EDS in Ataxia Telangiectasia Patients - IEDAT-02 (ATTeST)	22
16/EM/0311	Understanding the dynamic stability of lower limb amputees during gait	27
16/EM/0314	Tulip - Long Term Extension	26
16/EM/0316	How level of amputation affects bone health.	25
16/EM/0318	HippityHop	28
16/EM/0408	Phase 2 open-label study with GS-5745 in subjects with gastric cancer	25
16/EM/0415	ALX-0171 in the treatment of children's respiratory (airway) disease	26
16/EM/0422	Study of mepolizumab in patients with HES who receive standard therapy	23
16/EM/0449	Development of a model to predict security incidents.	22
16/EM/0465	INCYTE, Efficacy and Safety of INCB054828 in Urothelial Cancer	30
16/EM/0477	Compassion for Female Breast Cancer and Gynaecological Cancer Patients	46
16/EM/0482	PACE-KD	30
17/EM/0012	The Natural History of Ataxia-Telangiectasia	38
17/EM/0014	PRO-100-0145 - TissuGlu Mastectomy	30
17/EM/0035	Diagnostic criteria for psoriasis in children	20
17/EM/0037	VERDIS-AHP	26
17/EM/0060	An extension study of Ixekizumab in Ankylosing Spondylitis (RHBY).	36
17/EM/0078	Educational provision for young offenders	48
17/EM/0121	Comparative study of non-invasive respiratory support CCD-01534CA1-01	29
17/EM/0122	ALXN1210 IN CHILDREN AND ADOLESCENTS WITH aHUS.	30
17/EM/0123	COPD Quality of Life Study	42

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
16/EM/0173	PM01183 in Selected Advanced Solid Tumors	32
17/EM/0034	Exploration of the lived experiences of an Enabling Environment	21

17/EM/0036	How Are Hallucinations And Delusions Shaped By Experiences Of Deafness	25
17/EM/0077	LACI-2	55
17/EM/0085	Characterising Phenotypes and Genotypes in a UK Population Cohort	36
17/EM/0120	TRITON3: A Multicenter, Randomised,Phase 3 Study of Rucaparib in mCRPC	30

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
16/EM/0222	Contralateral muscle rehabilitation post ACL reconstruction	21
16/EM/0223	SKIP (Supporting Kids with Diabetes in Physical Activity) v1.0	23
16/EM/0255	Feasibility of an SMS service to support wellbeing and attachment	21
16/EM/0271	Studying Tailored Home-Based Exercise Prescriptions in Breast Cancer	19
16/EM/0289	Clinical and cost effectiveness of Alpha-Stim AID CES	23
16/EM/0299	Ankle Fractures treated with Teriparatide	23
16/EM/0391	Clinical Study of Solo Tympanostomy Tube Device v1.0	21
17/EM/0079	MRI & US of Muscle Pathology II	26
17/EM/0109	Phenotyping of COPD and other destructive lung diseases	11

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
16/EM/0164	How consent is constructed and negotiated by men who have sex with men	25

Provisional Opinion

REC Reference	Title	Number of Days on Clock
16/EM/0445	Computer aided therapy to promote motor development in autistic users	n/a
17/EM/0119	VIGOR-ALS	n/a

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
16/EM/0176	The Role of Tea in a modern British Hospice	n/a

Withdrawn after the meeting		
REC Reference	Title	Number of Days on Clock
16/EM/0211	A placebo control study for patients with non-hodgkin lymphoma	40

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

Further Information Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
16/EM/0169	Recovery after Aortic Aneurysm Surgery Study	20
16/EM/0293	Survivorship Concerns following treatment for High Grade Glioma	14
16/EM/0329	Urgent care: Sense-making and help-seeking	13
16/EM/0424	The immunology and metabolomics of endometrial receptivity	7
16/EM/0427	Non-invasive ventilator modems: a qualitative study	7
16/EM/0453	Heel Neutral, Lateral Push Test Intra/Inter Observer Reliability	9
16/EM/0454	A Multicentre, Seroprevalence Study of Subjects With Haemophilia B	8
17/EM/0010	Parents of adults with MS: How does their role change over time?	9
17/EM/0040	Generation of Dental Pulp-like tissue	15
17/EM/0084	UK Paediatric NAFLD Cohort Study (UK-PNAFLD)	21
17/EM/0088	Parent-child interaction and children's language development V1	15

Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/EM/0177	An ethnographic study of clinical encounters	19
16/EM/0425	Stratification of patients with patellofemoral pain	11
17/EM/0090	Haemostatic function and cell signalling in multiple myeloma	17

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
16/EM/0168	Autofluorescence spectroscopy of ocular tissues	18
16/EM/0228	Study of cow's milk casein in type-1 diabetes	6
16/EM/0330	Host derived markers of Lyme disease	5
16/EM/0373	The molecular pathology of bony lesions of the jaws	8
16/EM/0521	Impact of bedtime routines on dental health and child development	8
16/EM/0522	A study on female sexual function during and after pregnancy.	8

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/EM/0227	ThermRheum Version 1	10
16/EM/0236	Periodontal Treatment and Oral Health Related Quality of Life	6
16/EM/0281	ALIVE UK 1.0	14
16/EM/0328	Which infants in a NNU are at most risk of feeding difficulties?	12
16/EM/0378	Imaging to define progression in ADPKD	8
16/EM/0379	Adaptive immune response in neonates	11
16/EM/0451	Medial Column Instability and Spring Ligament Failure	5
16/EM/0452	Comparing Ultrasound vs. Magnetic Resonance Imaging and Examination	5
17/EM/0039	CAPRA	10
17/EM/0042	Training balance	5
17/EM/0045	Intraocular pressure after lower lid lateral tarsal strip v3.3	7

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
16/EM/0283	HippityHop	13
16/EM/0331	VOICE	11

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
09/H0408/47/AM22	Lapatinib versus Trastuzumab in ErbB2Positive Metastatic Breast Cancer	SA05.12.2016	05/12/2016	4
10/H0408/115/AM21	Imaging to Understand Pain in Osteoarthritis	SA10	18/01/2017	7
11/EM/0074/AM13	192024-054: LUMIGAN® 0.1 mg/mL compared with LUMIGAN® 0.3 mg/mL	SA05.09.2016	31/08/2016	11
11/EM/0450/AM14	Pazopanib in patients with renal cancer (PaZ02)	SA12	09/12/2016	21
11/EM/0450/AM16	Pazopanib in patients with renal cancer (PaZ02)	9	06/01/2017	12
11/EM/0470/AM03	Exploratory development of a macular perimetric test for clinical use.	SA03	25/10/2016	20
12/EM/0167/AM06	Alisertib vs pralatrexate or gemcitabine Phase III open label study	SA5	13/07/2016	14
12/EM/0283/AM16	Pre-term Cord Clamping Trial	SA10	13/09/2016	14
12/EM/0369/AM25	Tranexamic acid for IntraCerebral Haemorrhage TICH-2	SA03/16	26/05/2016	19
12/EM/0400/AM08	A Paediatric Renal Transplant Study	Substantial Amendment SA8	16/03/2016	29
12/EM/0400/AM09	A Paediatric Renal Transplant Study	SA9	01/09/2016	15
13/EM/0030/AM21	SIFT	10	22/02/2017	12
13/EM/0072/AM02	Quantitative Detection of Circulating Tumour DNA in Cancer Patients	SA2	04/04/2016	24
13/EM/0102/AM05	BRown fat Activation In Diabetic & Thyroid disorders in children	SA2	10/05/2016	14
13/EM/0173/AM02	Biomarker development in myotonic dystrophy type 1	SA2	01/11/2016	34
13/EM/0188/AM01	IntReALL SR 2010	SA1	01/09/2016	13
13/EM/0189/AM17	NALA-Drug Comparator study in HER2+ Metastatic Breast Cancer patients	SA9	06/04/2016	19
13/EM/0189/AM18	NALA-Drug Comparator study in HER2+ Metastatic Breast Cancer patients	SA10	10/06/2016	18
13/EM/0189/AM19	NALA-Drug Comparator study in HER2+ Metastatic Breast Cancer patients	SA11	31/08/2016	15
13/EM/0189/AM20	NALA-Drug Comparator study in HER2+ Metastatic Breast Cancer patients	SA12	30/11/2016	9
13/EM/0239/AM15	RESPITE	Substantial	08/03/2016	29

		Amendment 11		
13/EM/0239/AM16	RESPITE	SA12	05/08/2016	26
13/EM/0268/AM08	VX11-770-109 Roll-Over Study Paediatric CF CFTR gating mutation	SA6	22/07/2015	7
13/EM/0434/AM21	UK HARP-III Study	SA11	25/05/2016	19
13/EM/0458/AM13	BMN 111 in Children with Achondroplasia	SA6	21/04/2016	18
13/EM/0458/AM14	BMN 111 in Children with Achondroplasia	SA7	25/11/2016	14
13/EM/0458/AM15	BMN 111 in Children with Achondroplasia	10	09/02/2017	19
14/EM/0073/AM10	MK-8835/PF-04971729 vs. Placebo in T2DM Subjects with Stage 3 Chronic	Substantial Amendment 8	11/03/2016	27
14/EM/0084/AM06	The EVARREST ₂ Paediatric Mild/Moderate Bleeding Study	SA05	22/06/2016	21
14/EM/0084/AM07	The EVARREST ₂ Paediatric Mild/Moderate Bleeding Study	SA06	19/09/2016	11
14/EM/0121/AM10	RITUXILUP, Version 1.1	SA6	08/08/2016	23
14/EM/0121/AM11	RITUXILUP, Version 1.1	SA7	22/09/2016	19
14/EM/0130/AM10	A Phase 3 Open-Label Randomized Study of Quizartinib (AC220)	SA5.0	21/06/2016	8
14/EM/0130/AM11	A Phase 3 Open-Label Randomized Study of Quizartinib (AC220)	SA7.0	10/11/2016	18
14/EM/0143/AM08	An Extension Study to MEA115661 in Severe Asthma	SA6	06/09/2016	21
14/EM/0172/AM10	Baby-OSCAR Trial	7	26/04/2016	4
14/EM/0189/AM06	Imaging Pain Relief in Osteoarthritis version 1.5	SA5	16/12/2016	8
14/EM/0192/AM04	Reduced Appetite in Crohn's disease	SA5	09/06/2016	18
14/EM/0192/AM05	Reduced Appetite in Crohn's disease	SA6	05/12/2016	15
14/EM/1199/AM02	Evaluation of the High Frequency Digit Triplet test in Cystic Fibrosis	2	13/06/2016	26
14/EM/1202/AM04	Evaluation of interventions for parents of excessively crying infants	SA4	20/05/2016	21
14/EM/1213/AM04	Early motion and directed exercise (EMADE) in ankle fracture fixation	SA3	02/12/2016	4
14/EM/1222/AM02	OMACS	SA1	27/10/2016	15
14/EM/1223/AM03	Predicting postoperative morbidity using perioperative immune sampling	3	08/02/2017	22
14/EM/1264/AM06	Biopsychosocial Intervention for Stroke Carers	SA6	04/11/2016	4
14/EM/1307/AM05	ML29659 - ESTHER - Disease Registry Study	SA4	20/09/2016	7
14/EM/1308/AM06	Ext Study AT1001-042- Effects of AT1001 in Patients with Fabry Disease	5	17/11/2016	13

15/EM/0037/AM02	Bone density and structural adaptations across a season in athletes	SA2	09/06/2016	35
15/EM/0055/AM06	Rapid Intervention with GTN in Hypertensive Stroke Trial - RIGHT-2	SA04	07/04/2016	6
15/EM/0095/AM13	ACELARATE	SA09	27/03/2016	26
15/EM/0095/AM15	ACELARATE	SA12	21/11/2016	10
15/EM/0096/AM04	Phase III study of BTX-A-HAC NG in treatment of Glabellar Lines	SA1	10/08/2016	21
15/EM/0097/AM02	LUMINIST : Non-Interventional	SA1	06/05/2016	18
15/EM/0145/AM01	Angiogenesis Assay Validation (version 1)	SA1	09/06/2016	16
15/EM/0173/AM01	Gestational age Assessment Tool	SA1	09/06/2016	25
15/EM/0179/AM08	UNTOUCHED	SA1	24/05/2016	20
15/EM/0179/AM10	UNTOUCHED	SA2	03/02/2017	22
15/EM/0200/AM01	Eating behaviours and well-being in a Cystic Fibrosis sample	substantial amendment of	01/03/2016	22
15/EM/0208/AM03	PEARL	SA2	27/06/2016	11
15/EM/0225/AM03	Tamoxifen in oesophageal cancer (Version 1)	SA2	29/04/2016	15
15/EM/0239/AM01	Medicines related hospital admissions and medication reviews v.1	SA1	15/12/2016	25
15/EM/0243/AM03	The Role of Myocardial Fibrosis in Degenerative Mitral Regurgitation	Substantial Amendment 1	16/06/2016	27
15/EM/0243/AM05	The Role of Myocardial Fibrosis in Degenerative Mitral Regurgitation	SA2	09/08/2016	20
15/EM/0254/AM04	The Health Survey for England 2016 to 2019	SA3	04/07/2016	8
15/EM/0254/AM06	The Health Survey for England 2016 to 2019	SA5	10/11/2016	18
15/EM/0277/AM03	PROPS - Preventative Role Of a fixed dose combination Pill in Stroke	SA5	05/05/2016	19
15/EM/0287/AM01	Optimism & pessimism effect on recovery from elective cardiac surgery	SA1	30/09/2016	22
15/EM/0287/AM02	Optimism & pessimism effect on recovery from elective cardiac surgery	2	15/03/2017	12
15/EM/0290/AM01	PAVS_V1	SA1	31/03/2016	21
15/EM/0306/AM05	BAROQUE	SA3	28/04/2016	15
15/EM/0309/AM03	Efficacy and Safety of Budesonide delivered by VR475 Inhalation System	SA1	06/05/2016	18
15/EM/0309/AM04	Efficacy and Safety of Budesonide delivered by VR475	SA2	26/08/2016	19

	Inhalation System			
15/EM/0309/AM05	Efficacy and Safety of Budesonide delivered by VR475 Inhalation System	SA3	15/12/2016	26
15/EM/0315/AM01	Axillary plexus block - Dealing with the tourniquet	SA1	02/08/2016	21
15/EM/0316/AM01	The Sons of Gout Study	Substantial Amendment 1	14/03/2016	26
15/EM/0316/AM02	The Sons of Gout Study	SA2	24/04/2016	25
15/EM/0316/AM03	The Sons of Gout Study	3	02/02/2017	19
15/EM/0351/AM03	Evaluation of sputum MMP9 in COPD subject, version1	SA2	17/03/2016	14
15/EM/0353/AM01	Learning from Medication Incidents in Children	SA1	18/11/2016	10
15/EM/0422/AM05	Baxalta- 391401 Part 2 BAX69 - Metastatic colorectal cancer	SA5	11/08/2016	27
15/EM/0422/AM08	Baxalta- 391401 Part 2 BAX69 - Metastatic colorectal cancer	Early Termination	08/02/2017	20
15/EM/0440/AM03	AZTEC	3	01/12/2016	21
15/EM/0469/AM01	Cardiovascular changes in High Risk pregnancy	SA1	16/06/2016	7
15/EM/0470/AM01	Evaluating the safety, tolerability and efficacy of Tirasemtiv in ALS	Substantial Amendment 1	15/02/2016	28
15/EM/0473/AM04	Phase II anetumab ravtansine as 2nd line treatment for MPM	SA3	15/05/2016	7
15/EM/0473/AM06	Phase II anetumab ravtansine as 2nd line treatment for MPM	SA4	09/09/2016	19
15/EM/0473/AM07	Phase II anetumab ravtansine as 2nd line treatment for MPM	5	06/10/2016	11
15/EM/0473/AM08	Phase II anetumab ravtansine as 2nd line treatment for MPM	SA6	27/01/2017	10
15/EM/0474/AM01	Interstitial laser thermotherapy (imILT) treatment of breast cancer	SA1	10/01/2017	16
15/EM/0486/AM01	Extravascular lung water in reperfusion lung injury	SA1	11/07/2016	14
15/EM/0490/AM02	OPTIMUM-BP (version 1.0)	SA1	12/09/2016	15
15/EM/0490/AM03	OPTIMUM-BP (version 1.0)	SA2	08/12/2016	12
15/EM/0519/AM01	Reference range study for FGF-21 and hepcidin	SA1	04/07/2016	13
15/EM/0521/AM02	IM power010: Phase 3 study of Atezolizumab in non-small lung cancer	SA1	10/03/2016	19
15/EM/0521/AM04	IM power010: Phase 3 study of Atezolizumab in non-small lung cancer	SA2	26/10/2016	16
15/EM/0534/AM01	Partnership in Prostate Cancer Care: (ICARE-P)	SA1	22/03/2016	20
16/EM/0001/AM01	Strategies for management of corneal neovascularisation	1	22/06/2016	20
16/EM/0002/AM01	Strategies for management of recurrent pterygium	SA1	22/06/2016	26
16/EM/0002/AM02	Strategies for management of recurrent pterygium	SA2	13/01/2017	12
16/EM/0030/AM02	A Phase 2 study of NGM282 in Patients with PSC	2	27/06/2016	16
16/EM/0032/AM01	INC280 in NSCLC patients with cMET activated pathway	SA1	14/09/2016	13

16/EM/0032/AM03	INC280 in NSCLC patients with cMET activated pathway	SA3	05/01/2017	22
16/EM/0037/AM01	Ixekizumab in Ankylosing Spondylitis	Substantial Amendment 2.1 2016	28/01/2016	32
16/EM/0037/AM02	Ixekizumab in Ankylosing Spondylitis	Substantial Amendment 26.04.16	26/04/2016	17
16/EM/0037/AM03	Ixekizumab in Ankylosing Spondylitis	SA3	13/05/2016	11
16/EM/0037/AM05	Ixekizumab in Ankylosing Spondylitis	SA4	26/09/2016	15
16/EM/0037/AM07	Ixekizumab in Ankylosing Spondylitis	6	15/02/2017	21
16/EM/0128/AM01	M13-596 2nd gen HCV treatment in transplant subjects	SA1	19/07/2016	10
16/EM/0128/AM05	M13-596 2nd gen HCV treatment in transplant subjects	SA2	14/12/2016	6
16/EM/0133/AM02	A potential new treatment for nonradiographic axial spondyloarthritis	SA2	22/08/2016	23
16/EM/0133/AM06	A potential new treatment for nonradiographic axial spondyloarthritis	SA4	05/01/2017	14
16/EM/0141/AM03	Brain-in-Hand (BiH) Technology For Acquired Brain Injury (ABI)	SA2	16/11/2016	10
16/EM/0173/AM01	PM01183 in Selected Advanced Solid Tumors	Amendment 4	14/09/2016	12
16/EM/0214/AM02	Timing ability in Alzheimer's disease FINAL 1.0	SA1	04/11/2016	4
16/EM/0223/AM03	SKIP (Supporting Kids with Diabetes in Physical Activity) v1.0	1.2	20/01/2017	6
16/EM/0240/AM01	Ibrutinib in paediatrics and young adults with non-Hodgkin Lymphoma	SA1	04/10/2016	7
16/EM/0241/AM01	Open Label Extension of BMN 111 in children with achondroplasia	SA1	04/10/2016	7
16/EM/0241/AM02	Open Label Extension of BMN 111 in children with achondroplasia	SA2	29/11/2016	10
16/EM/0241/AM03	Open Label Extension of BMN 111 in children with achondroplasia	3	10/02/2017	18
16/EM/0258/AM01	EDS in Ataxia Telangiectasia Patients - IEDAT-02 (ATTeST)	SA1	22/12/2016	18
16/EM/0258/AM02	EDS in Ataxia Telangiectasia Patients - IEDAT-02 (ATTeST)	2	22/02/2017	27
16/EM/0289/AM01	Clinical and cost effectiveness of Alpha-Stim AID CES	SA1	17/08/2016	27
16/EM/0289/AM02	Clinical and cost effectiveness of Alpha-Stim AID CES	SA2	15/09/2016	12
16/EM/0289/AM03	Clinical and cost effectiveness of Alpha-Stim AID CES	SA3	30/11/2016	4
16/EM/0289/AM04	Clinical and cost effectiveness of Alpha-Stim AID CES	4	06/03/2017	15
16/EM/0311/AM01	Understanding the dynamic stability of lower limb amputees	1	20/02/2017	28

	during gait			
16/EM/0316/AM01	How level of amputation affects bone health.	1	20/02/2017	7
16/EM/0379/AM02	Adaptive immune response in neonates	1	15/02/2017	21
16/EM/0415/AM02	ALX-0171 in the treatment of children's respiratory (airway) disease	SA2	30/11/2016	9
16/EM/0521/AM01	Impact of bedtime routines on dental health and child development	1	22/02/2017	24
GM129901/AM14		SA24.01.2017	19/01/2017	14

Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
10/H0408/115/AM20	Imaging to Understand Pain in Osteoarthritis	SA9	07/06/2016	24
12/EM/0261/AM03	OCT (Optical Coherence Tomography) and Ocular Development	SA3	25/07/2016	27
14/EM/1307/AM04	ML29659 - ESTHER - Disease Registry Study	SA3	14/07/2016	13
15/EM/0254/AM05	The Health Survey for England 2016 to 2019	SA4	10/10/2016	11
16/EM/0141/AM01	Brain-in-Hand (BiH) Technology For Acquired Brain Injury (ABI)	SA1	20/07/2016	20
16/EM/0174/AM01	LBM & lung function in adolescents with CF	SA1	05/09/2016	10

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
10/H0408/115/AM20/1	Imaging to Understand Pain in Osteoarthritis	Mod1 of SA9	22/09/2016	11
12/EM/0261/AM03/1	OCT (Optical Coherence Tomography) and Ocular Development	Mod1 of SA3	08/09/2016	4
13/EM/0030/AM17/2	SIFT	SA9	14/12/2016	6
14/EM/1264/AM04/1	Biopsychosocial Intervention for Stroke Carers	SA4	21/07/2016	6

14/EM/1307/AM04/1	ML29659 - ESTHER - Disease Registry Study	SA3 MA1	27/07/2016	5
15/EM/0254/AM05/1	The Health Survey for England 2016 to 2019	Mod1 to SA4	28/11/2016	10
16/EM/0141/AM01/1	Brain-in-Hand (BiH) Technology For Acquired Brain Injury (ABI)	Mod1 of SA1	01/11/2016	9

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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None

Proportionate review applications for ethical review over 14 day timeline

REC Reference	Title	Number of Days on Clock
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16/EM/0168 Autofluorescence spectroscopy of ocular tissues

18

16/EM/0169 Recovery after Aortic Aneurysm Surgery Study

20

16/EM/0177 An ethnographic study of clinical encounters

19

Proportionate review applications for ethical review over 21 day timeline

REC Reference	Title	Number of Days on Clock
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None

SSAs (non Phase 1) over 25 day timeline

REC Reference	Title	Number of Days on Clock
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None

SSAs (Phase 1) over 14 day timeline

REC Reference	Title	Number of Days on Clock
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None

Substantial Amendments over 35 day timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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None

Modified Amendments over 14 day timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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None