

**NRES Committee East Midlands -
Nottingham 2**

Annual Report

01 April 2011 – 31 March 2012

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee East Midlands - Nottingham 2
Type of REC:	Type III
Type of Flag:	CTIMPS, Paediatrics, Phase 1 SSA's
Chair:	Dr Martin Hewitt
Vice-Chair:	Dr Simon Roe
Alternate Vice-Char:	Dr Frances Game
Co-ordinator:	Miss Heather Harrison
PRSC Co-ordinator:	Miss Heather Harrison
Assistant Co-ordinator:	Mr Stephen Briggs
Committee Address:	The Old Chapel Royal Standard Place Nottingham NG1 6FS
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Chair's overview of the past year:

It has been another interesting and stimulating year for the committee and its members. Again valuable members have left the committee to develop their careers and this year Anita Hughes left us. We thank her for her wise words and good humour.

The committee achieved its many goals in reviewing a large number of complex and difficult projects and managing to provide appropriate opinions in an appropriate time scale. Only 5% of projects were rejected. We have endeavoured, where possible, to provide approval with conditions but this is sometimes difficult.

The committee acted as a pilot site to the Proportionate Review process and contributed to the development of a service which is now available nationally. The committee continues to see that it has a role in supporting research teams in steering their way through the complex process of ethics application.

Again we are indebted to the continued support and organisation from our administrative staff.

NRES Committee East Midlands - Nottingham 2 Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Ms Gill Bumphrey	Clinical Trials Pharmacist	Expert	01/12/2011	
Miss Shamim Byrne	Consultant Gynaecologist/Obstetrician	Expert	14/12/2009	
Mrs Adele Eyre	Company Director	Lay Plus	04/03/2010	31/01/2012
Dr Frances Game	Consultant Physician	Expert	27/07/2004	
Dr Martin Hewitt	Consultant Paediatric Oncologist	Expert	23/07/2002	
Mrs Sheila Hodgson	Clinical Trials Pharmacist	Expert	22/10/2002	
Mr Asam Latif	Research Pharmacist	Expert	01/08/2011	
Mrs Linda Reynolds	Occupational Therapist	Expert	25/10/2006	
Dr Simon Roe	Consultant Nephrologist	Expert	23/07/2002	
Dr John Shaw	Lay Member	Lay	01/09/2011	
Miss Catherine Shenton	Lay Member	Lay Plus	09/03/2010	
Mrs Sally Ann Smith	Retired Audit Manager	Lay Plus	16/04/2010	
Mr Glen Swanwick	Lay Member	Lay Plus	20/05/2008	
Miss Alison Thorpe	Research Technician / part time PhD	Lay	03/06/2008	
Ms Margret Vince	Translator	Lay Plus	25/10/2006	
Ms Anita Hughes	Health Services Researcher	Expert	28/07/2004	31/01/2012

Deputy Members

Name	Occupation	Expert or Lay	Meeting date attended
None			

Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended
Ms Elaine Blackshaw	Expert Member	Expert	26/09/2011
Mr Robert Johnson	Expert Member	Expert	18/04/2011

Member Bank

Name	Occupation	Expert or Lay	Meeting date attended
N/A			

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

Name	Declaration of Interest	Date
Dr John Shaw	Volunteer at Haywood House, NUH, City Campus Member of Advisory Group, Biomedical Research Unit, NUH, QMC Campus	15/11/2011
Dr John Shaw	Member of patient advisory group at Biomedical Research Unit, Nottingham Digestive Diseases Centre	19/12/2011
Dr Simon Roe	None	19/12/2011
Ms Gill Bumphrey	Small Shareholding - Astra Zeneca	30/01/2012
Ms Gill Bumphrey	Significant Shareholding - Nova Laboratories Ltd	30/01/2012
Ms Gill Bumphrey	Employed by the University of Nottingham Clinical Trials Unit	30/01/2012
Dr Martin Hewitt	None	19/12/2011
Mrs Sheila Hodgson	None	05/01/2012
Miss Alison Thorpe	Working alongside and partially funded by Oncimmure ltd a University of Nottingham spin-out company	06/01/2012
Mr Asam Latif	Research fellow at University of Nottingham	17/01/2012
Mr Asam Latif	Locum community pharmacist	17/01/2012
Mrs Linda Reynolds	Undertaking PhD	21/01/2012
Miss Shamim Byrne	If involved with research it will be within Sherwood Forest Hospitals NHS Trust	06/01/2012
Miss Shamim Byrne	Member of the Higher Education Academy (HEA)	06/01/2012
Mrs Sally Ann Smith	None	19/12/2011
Miss Catherine Shenton	None	19/12/2011
Ms Margret Vince	None	19/12/2011
Mr Glen Swanwick	Research projects previously involved in:- Project 65+ Pincer trial G.M.C Project	19/12/2011
Dr Fran Game	None	19/12/2011

Meetings for Full Ethical Review 01 April 2011 - 31 March 2012:

Month	Date	Number of Members Present at Meeting
April	18/04/2011	8
May	23/05/2011	8
June	27/06/2011	9
July	25/07/2011	9
September	26/09/2011	7
October	24/10/2011	10
November	28/11/2011	14
December	19/12/2011	11
January	23/01/2012	14
February	27/02/2012	10
March	26/03/2012	11

11 full committee meetings were held during the reporting period.

Proportionate Review Sub Committee Meetings held during 01 April 2011 - 31 March 2012:

Month	Date	Number of Members Present at Meeting
April	18/04/2011	3
May	23/05/2011	3
June	27/06/2011	3
July	25/07/2011	3
September	26/09/2011	3
October	24/10/2011	3
November	28/11/2011	3
December	19/12/2011	3
January	23/01/2012	4
February	27/02/2012	3
March	26/03/2012	3

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

Attendance of Members: 01 April 2011 – 31 March 2012:

Name	Number of Meetings Attended
Miss Catherine Shenton	11
Dr Simon Roe	10
Mrs Sheila Hodgson	10
Ms Margret Vince	10
Mrs Sally Ann Smith	9
Dr Martin Hewitt	9
Dr Frances Game	9
Mrs Linda Reynolds	8
Dr John Shaw	6
Miss Shamim Byrne	6
Miss Alison Thorpe	5
Mrs Adele Eyre	5
Mr Glen Swanwick	5
Mrs Anita Hughes	4
Ms Gill Bumphrey	3
Mr Asam Latif	3

Number of inquorate meetings held:**Attendance of Members at proportionate review sub-committee meetings:
01 April 2011 – 31 March 2012:**

Name	Number of Meetings Attended
Miss Catherine Shenton	11
Ms Margret Vince	9
Dr Martin Hewitt	8
Dr Simon Roe	3
Dr John Shaw	2
Mrs Anita Hughes	1

Training 01 April 2011 – 31 March 2012:

Name of Member	Date	Event(s) attended
Mrs Sally Ann Smith	01/11/2011 - 01/11/2011	Members and Mixed Audience Training - NRES Reviewing CTIMPs, NRES
Dr Martin Hewitt	02/11/2011 - 02/11/2011	'Nuts & Bolts' of running a REC, NRES
Mrs Linda Reynolds	06/10/2011 - 06/10/2011	East Midlands Local Training Event, NRES - East Midlands
Mrs Linda Reynolds	13/09/2011 - 13/09/2011	NRES Update Session, NRES
Miss Catherine Shenton	13/09/2011 - 13/09/2011	NRES Update Session, NRES
Miss Catherine Shenton	06/10/2011 - 06/10/2011	East Midlands Local Training Event, NRES - East Midlands
Ms Margret Vince	13/09/2011 - 13/09/2011	NRES Update Session, NRES
Ms Margret Vince	06/10/2011 - 06/10/2011	East Midlands Local Training Event, NRES
Mrs Sally Ann Smith	13/09/2011 - 13/09/2011	NRES Update Session, NRES
Mrs Adele Eyre	13/09/2011 - 13/09/2011	NRES Update Session, NRES
Miss Alison Thorpe	01/11/2011 - 01/11/2011	NRES Reviewing Clinical Trials of Investigational Medicinal Products (CTIMPs) Training Day, NRES
Miss Catherine Shenton	19/01/2012 - 19/01/2012	NRES Shared Ethical Debate, NRES
Miss Catherine Shenton	27/03/2012 - 27/03/2012	National Members Training Day, NRES
Mrs Sheila Hodgson	27/06/2011 - 27/06/2011	Shared Ethical Debate - Committee meeting, NRES
Ms Margret Vince	27/06/2011 - 27/06/2011	Shared Ethical Debate - 27/06/2011 Committee meeting, NRES
Mrs Linda Reynolds	27/06/2011 - 27/06/2011	Shared Ethical Debate - 27/06/2011 Committee Meeting, NRES
Miss Shamim Byrne	27/06/2011 - 27/06/2011	Shared Ethical Debate 27th June committee meeting, NRES
Miss Catherine Shenton	27/06/2011 - 27/06/2011	Shared ethical debate 27th June committee meeting, NRES
Mrs Adele Eyre	27/06/2011 - 27/06/2011	Shared Ethical Debate 27th June Full Committee, NRES
Mrs Sally Ann Smith	27/06/2011 - 27/06/2011	Shared Ethical Debate 27th June Committee Meeting, NRES
Dr Frances Game	27/06/2011 - 27/06/2011	Shared Ethical Debate 27th June committee meeting, NRES
Dr Simon Roe	27/06/2011 - 27/06/2011	Shared Ethical Debate 27th June Committee meeting, NRES
Mr Glen Swanwick	04/11/2011 - 04/11/2011	Dementia Champions Leading Improvements in Fundamental Care, QMC
Miss Shamim Byrne	28/03/2012 - 28/03/2012	NRES Members National Training

		Day, NRES
Dr Frances Game	28/03/2012 - 28/03/2012	NRES Members National Training Day, NRES
Mrs Sheila Hodgson	28/03/2012 - 28/03/2012	NRES Members National Training Daye, NRES
Dr Simon Roe	28/03/2012 - 28/03/2012	NRES Members National Training Day, NRES
Mrs Sally Ann Smith	28/03/2012 - 28/09/2012	NRES Members National Training Day, NRES
Mr Glen Swanwick	28/03/2012 - 28/03/2012	NRES Members National Training Day, NRES
Ms Margret Vince	28/03/2012 - 28/03/2012	NRES Members National Training Day, NRES
Mrs Sally Ann Smith	27/03/2012 - 27/03/2012	E-learning package on use of Human Tissue in research, Self directed - E-learning
Mrs Sally Ann Smith	27/03/2012 - 27/03/2012	Reviewed NRES guidance on approval of research involving ionising radiation, Self Directed
Mrs Sally Ann Smith	28/03/2012 - 28/03/2012	Reviewed NRES guidance on research involving medical devices, Self Directed
Mrs Sally Ann Smith	28/03/2012 - 28/03/2012	Reviewed NRES guidance on informed consent in CTIMPS, Self Directed
Mr Glen Swanwick	04/11/2011 - 04/11/2011	Dementia champions leading improvements in fundamental care, QMC
Mr Asam Latif	29/03/2012 - 29/03/2012	Induction, NRES
Ms Gill Bumphrey	29/03/2012 - 29/03/2012	Induction, NRES
Dr Martin Hewitt	27/02/2012 - 27/02/2012	Feedback from Shared Ethical Debate workshop
Mrs Sheila Hodgson	27/02/2012 - 27/02/2012	Feedback from Shared Ethical Debate
Mrs Linda Reynolds	27/02/2012 - 27/02/2012	Feedback from Shared Ethical Debate
Dr Simon Roe	27/02/2012 - 27/02/2012	Feedback from Shared Ethical Debate
Dr John Shaw	27/02/2012 - 27/02/2012	Feedback from Shared Ethical Debate
Miss Catherine Shenton	27/02/2012 - 27/02/2012	Feedback from Shared Ethical Debate
Mrs Sally Ann Smith	27/02/2012 - 27/02/2012	Feedback from Shared Ethical Debate
Mr Glen Swanwick	27/02/2012 - 27/02/2012	Feedback from Shared Ethical Debate
Ms Margret Vince	27/02/2012 - 27/02/2012	Feedback from Shared Ethical Debate
Miss Alison Thorpe	27/02/2012 - 27/02/2012	Feedback from Shared Ethical Debate

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	19	31.67
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank	0	0.00
Research Database	0	0.00
Others	41	68.33
Total Applications Reviewed	60	100

Table 2: Other REC activity during the reporting period:

Number of applications made invalid by co-ordinator	3
Number of studies withdrawn prior to the meeting	3
Number of student applications reviewed	18
Number of paediatric applications reviewed	15
Number of device applications reviewed	1
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	0
Number of applications reviewed funded by the US DHHS	0

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	1	1.67
Favourable Opinion with Additional Conditions	11	18.33
Unfavourable Opinion	3	5.00
Provisional Opinion	45	75.00
Invalid	0	0.00
No Opinion Pending Consultation with Referee	0	0.00
Provisional Opinion Pending Consultation with Referee	0	0.00
Not Requiring Review by NHS REC	0	0.00
Total	60	100
Number of studies sent back to full committee meeting for final opinion	5	

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	39	65.00
Further Information Favourable Opinion with Additional Conditions	4	6.67
Further Information Unfavourable Opinion	1	1.67
Favourable Opinion with Standard Conditions	1	1.67
Favourable Opinion with Additional Conditions	11	18.33
Unfavourable Opinion	3	5.00
Provisional Opinion	1	1.67
Provisional Opinion Pending Consultation with Referee	0	0.00
Invalid	0	0.00
No Opinion Pending Consultation with Referee	0	0.00
Further Information response not complete	0	0.00
Not Requiring Review by NHS REC	0	0.00
No decision entered on RED	0	0.00
Number of studies withdrawn after the meeting	0	0.00
Total	60	100

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

Total Applications Reviewed	36
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Table 6: 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	11	30.56
Favourable Opinion with Additional Conditions	15	41.67
No Opinion transfer to full committee for review	2	5.56
Provisional Opinion	7	19.44
Unfavourable Opinion	1	2.78
Total	36	100

Table 7: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	5.45
Number of applications for full ethical review over 60 days	1
Number of applications over 60 days as a % of total	1.67%
Number of days taken to final decision - average	36
Number of days taken to final decision - mode	45
Number of SSAs (non-Phase 1) reviewed	1
Number of applications for SSA review over 25 days	0
Number of applications for SSA review over 25 days as % of all non-Phase 1 (SSAs)	0.0%
Number of SSAs (Phase 1) reviewed	17
Number of applications for SSA review over 14 days	1
Number of applications for SSA review over 14 days as % of all Phase 1 (SSAs)	5.9%
Number of substantial amendments reviewed	140
Number of substantial amendments over 35 days	8
Number of substantial amendments over 35 days as a % of total substantial amendments	5.7%
Number of Section 30 applications reviewed	0
Number of Section 30 applications over 60 days	0
Number of Section 30 applications over 60 days as a % of total Section 30 applications	0%
Number of modified amendments reviewed	2
Number of modified amendments over 14 days	0
Number of modified amendments over 14 days as a % of total modified amendments	0.0%
Number of proportionate review applications for ethical review over 14 days*	8
Number of proportionate review applications over 14 days as a % of total	23.53%

***NB – Proportionate Review Service was in pilot phase until September 2011 and was an aim not a target**

Table 8: Breakdown of current status of all applications reviewed within the reporting period:

Further Information Favourable Opinion with Standard Conditions		
REC Reference	Application Short Title	Number of Days on Clock
11/EM/0104	The impact of CFT training on crisis teams	41
11/EM/0115	NovImmune: Open label study of NI-0801 in Primary Biliary Cirrhosis	58
11/EM/0116	Everolimus alone or with Pasireotide LAR in pancreatic cancer.	35
11/EM/0120	Ethnic Variations in Childhood Health and Body Composition	46
11/EM/0140	MS and hookworm	45
11/EM/0157	H.E.A.L.T.H V1	31
11/EM/0197	Developing a measure of in-patient social functioning	18
11/EM/0203	AV Graft and Fistula Complications in Chronic Kidney Disease (GRAFIC)	27
11/EM/0207	143-Phase 3 Study in Primary Hypercholesteremia or Mixed Dyslipidemia	44
11/EM/0211	Paediatric Kidney Transplant- Valcyte- CMV prophylaxis	33
11/EM/0245	Small and Large Bowel Transit tests using MRI	24
11/EM/0254	Reducing the incidence of Postnatal Depression-A Pilot Study.	21
11/EM/0255	Efficacy and PK/PD Relationship of MORAb-004 in Metastatic Melanoma	30
11/EM/0256	Ustekinumab in Subjects with Primary Biliary Cirrhosis	31
11/EM/0310	IVANOF1 study	61
11/EM/0331	Home NB-UVB for focal or early vitiligo	49
11/EM/0333	Study of Parental Consent in the Neonatal Unit	41
11/EM/0335	Thrombotic and bleeding risk in Antiphospholipid Syndrome	39
11/EM/0381	Decision making processes in the use of technology for Type 1 diabetes	34
11/EM/0383	Home Jejunostomy Feeding following Oesophagectomy/Gastrectomy V1.11	32
11/EM/0384	Relationship between IL-17 and Adenoma Carcinoma	21
11/EM/0385	The journey of having a child diagnosed with autism spectrum disorder	22
11/EM/0396	QoL in parents of children with inhibitors	26
11/EM/0406	Preliminary investigation of CBT stress management in prostate cancer	29
11/EM/0412	Palliative Eox & Omegaven In Oesophago-Gastric Cancer Patients	47
11/EM/0417	NRL001 in patients with faecal incontinence	45
11/EM/0426	BaP	60
11/EM/0440	Mode of Action of Moviprep version 3.0	36
11/EM/0450	Pazopanib in patients with renal cancer (PaZ02)	37
11/EM/0461	Can ultrasound detect early enthesopathy in patients with psoriasis?	42

11/EM/0463	The ADIPOSE study	38
12/EM/0020	Exploring the genetic basis of Hereditary Haemorrhagic Telangiectasia	34
12/EM/0026	Schema Functioning Amongst Female Forensic Mental Health Patients	49
12/EM/0029	SMARTTOUCH Amigo Remote Catheter System AF Ablation Trial	49
12/EM/0039	Adrenal recovery following short and long-term glucocorticoid therapy	42
12/EM/0055	Allergy and Asthma phenotypes	15
12/EM/0068	Predicting long term feeding outcomes in infants born prematurely.	17
12/EM/0076	Parents' and health care professionals' use of information	24
12/EM/0077	The Assessment of Stroke Patients for Telerehabilitation	40
12/EM/0080	Retinal and peripheral microvascular reactivity in Hypertension v1	36
12/EM/0096	Evaluation of foster carers and adopted parents groups	24
12/EM/0099	Post-operative monitoring of DIEP flaps using tissue oxymetry	15
12/EM/0111	Social cognition in ADHD	43
12/EM/0114	Smoking attitudes among patients in a secure mental health service	23
12/EM/0144	CINC Compassion in nursing care study V1.0	10
12/EM/0148	Treatment Pathways associated with Hodgkin and Large Cell Lymphoma	9

Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/EM/0165	B1801031 Etanercept vs placebo in early non radiographic axial SpA	50
11/EM/0237	IVICA: Intravenous iron in colorectal cancer associated anaemia	42
11/EM/0259	Honey dressings	32
11/EM/0455	CAOMECS Transplantation to Patients with LSCD	51

Further Information Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
11/EM/0370	AIN457 to assess safety, tolerability, efficacy & PK in asthma	31

Favourable Opinion with Standard Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/EM/0182	Implementing case management successfully	4
11/EM/0183	Routes to Quit	5
11/EM/0184	Evaluation of a local pay-for-performance scheme for primary care	7
11/EM/0185	Birth environment study: The midwives' perspective (V3 Final)	10

11/EM/0261	Evaluation of Community Pharmacy Weight Management Programme Version 1	13
11/EM/0351	The Paediatric Observation Priority Score (POPS)	6
11/EM/0444	Asking Patients about changing follow up after testicular cancer	7
11/EM/0469	Quality and Safety Concerns in Kidney Allocation Transplant Outcomes	6
11/EM/0472	Pharmacovigilance at Guy's and St Thomas' and ADRs to Warfarin	8
12/EM/0104	Factors affecting self-care behaviours among type 1 diabetes patients	6
12/EM/0113	Assisted tooth brushing in long-stay psychiatric inpatients	27
12/EM/0142	BCAC Tissue Microarray Project	8

Favourable Opinion with Additional Conditions		
REC Reference	Application Short Title	Number of Days on Clock
11/EM/0076	Comparative molecular analysis of Childhood Brain tumours	34
11/EM/0097	Vaginal microbiome in pregnancy	35
11/EM/0109	Auditory Games for Tinnitus Benefit v.1	45
11/EM/0132	ALSS: is the modified extension test a valid screening tool? v2.0	8
11/EM/0138	Method evaluation of aldosterone and renin concentration assays. V4	8
11/EM/0151	Does childbirth preparation increase women's satisfaction? Version 1	22
11/EM/0163	A study of effect of the FertilMate™ Cooling Patch on Male Fertility	19
11/EM/0221	A study of OT hip precautions following THR	20
11/EM/0238	Perinatal Mental Illness Knowledge	7
11/EM/0265	ED nursing staff views and attitudes to conducting research	15
11/EM/0266	Staff and Patient opinions of food and mealtimes in hospital.	8
11/EM/0344	Nottingham Osteoarthritis Biomarker Study 2011	16
11/EM/0354	F1 Workload Study	5
11/EM/0382	Varicose veins Parts 1 and 2 Version 1.0	13
11/EM/0387	Early lung cancer detection in Corby	27
11/EM/0416	Genetic causes of chronic cough and neuropathy	33
11/EM/0446	Performance on the RBMT for people with mild intellectual disabilities	6
11/EM/0447	Do people with dementia want services for people with dementia?	7
11/EM/0456	Connecting for service improvement in healthcare	6
11/EM/0459	MEWS to support ambulance clinicians' decisions to transport	33
11/EM/0470	Exploratory development of a macular perimetric test for clinical use.	8
12/EM/0024	Children's Eating Study - Version 1.0	49
12/EM/0056	A study of vitamin supplementation in Children in Camden PCT	5

12/EM/0058	Mechanisms involved in the pathogenesis of pulmonary fibrosis. V1.2	9
12/EM/0081	Breast Aware	23
12/EM/0140	DIRECT Metformin	11

Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
11/EM/0302	Ultra high field MRI scanning of the brain	57
11/EM/0334	A0081256-Chronic neuropathic low back pain-PINPOINT Study	13
12/EM/0036	Optical coherence tomography (OCT) and ocular development	45
12/EM/0049	Short term clinical outcomes in babies with cord pH \leq 7.10	7

Provisional Opinion

REC Reference	Application Short Title	Number of Days on Clock
12/EM/0101	Brief Alcohol Intervention: Feasibility in Older Adult Mental Health	N/A

Provisional Opinion Pending Consultation with Referee

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

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

REC Reference	Application Short Title	Number of Days on Clock
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Invalid Application

REC Reference	Application Short Title	Number of Days on Clock
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No Opinion Pending Consultation with Referee

REC Reference	Application Short Title	Number of Days on Clock
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Not Requiring Review by NHS REC

REC Reference	Application Short Title	Number of Days on Clock
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Table 9: Items exceeding timelines:

Full applications for ethical review over 60 day timeline		
REC Reference	Application Short Title	Number of Days on Clock
11/EM/0310	IVANOF1 study	61

Proportionate review applications for ethical review over 14 days timeline		
REC Reference	Application Short Title	Number of Days on Clock
11/EM/0221	A study of OT hip precautions following THR	20
11/EM/0265	ED nursing staff views and attitudes to conducting research	15
11/EM/0384	Relationship between IL-17 and Adenoma Carcinoma	21
11/EM/0385	The journey of having a child diagnosed with autism spectrum disorder	22
11/EM/0396	QoL in parents of children with inhibitors	26
12/EM/0055	Allergy and Asthma phenotypes	15
12/EM/0099	Post-operative monitoring of DIEP flaps using tissue oxymetry	15

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

SSAs (Phase 1) over 14 days timeline		
REC Reference	Application Short Title	Number of Days on Clock
11/EM/0448	A Phase 1, First-in-Human Study of an Oral Formulation of Z944	15

Substantial Amendments over 35 day timeline			
Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock
10/H0408/104/AM02	Dapagliflozin in subjects with Type II diabetes and hypertension	Substantial Amendment 2	41
09/H0408/71/AM07	The Effects of Cooling the Dialysate on Systolic Dysfunction	Substantial amendment 7	39
11/EM/0062/AM01	Azithromycin in Asthma	Amendment 1	36
07/Q2404/39/AM13	A6181114-Open label Sunitinib	Sub Amendment 12	36

	Malate (SU011248) continuation protocol		
11/EM/0013/AM02	OPTION Version 1.0	Amendment 1	42
09/H0408/88/AM11	FOLFIRI plus ZD4054 in colorectal cancers refractory to oxaliplatin	Substantial Amendment 10	49
10/H0408/105/AM03	SPARK (Safety Paediatric efficacy pharmacokinetic with Kuvan®)	Amendment 3	46
10/H0408/63/AM18	Phase II study of AZD2423 in posttraumatic neuralgia	Substantial Amendment 15	41

Modified Amendments over 14 day timeline

Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock
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Section 30 application over 60 day timeline

Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock
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