

**West Midlands - Edgbaston Research Ethics  
Committee**

**Annual Report**

**01 April 2015 - 31 March 2016**



## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	West Midlands - Edgbaston Research Ethics Committee
<b>Type of REC:</b>	REC recognised to review CTIMPs in Patients – Type iii REC recognised to review Phase 1 in Patients
<b>Type of Flag:</b>	Medical Device, Paediatric
<b>Chair:</b>	Mr Paul Hamilton
<b>Vice-Chair:</b>	Professor John Marriott
<b>Alternate Vice-Chair:</b>	Dr Sarahjane Jones
<b>REC Manager:</b>	Helen Poole
<b>REC Assistant:</b>	Adam Garretty (August 2015 – April 2016), Rachel Nelson (April 2015 – August 2015)
<b>Committee Address:</b>	The Old Chapel Royal Standard Place Nottingham NG1 6FS
<b>Telephone:</b>	0207 104 8115
<b>Email:</b>	NRESCcommittee.WestMidlands-Edgbaston@nhs.net

### Chair's overview of the past year:

Two new members joined the committee; Oladipo Babalola and Hora Ejtehadhi who have fitted in well and make regular contributions to the review process and, along with an increasing number of other members, contribute to the proportionate review and virtual sub-committee work. We were very sad to see our paediatric expert member, Eric Silove, leave the committee in April 2016.

We have benefitted greatly from the continuity of support by our REC Manager, Helen Poole, who was joined by our new REC Assistant, Adam Garretty, who, too, has fitted in well to the team.

The committee's performance data are, again, this year, impressive: 30 PR studies reviewed; 54 full studies within time period and 145 substantial amendments with zero running over our Key Performance Indicator of 28 days!

Members continue to do their work with great care and good humour. Applicants have commented positively on our conduct and thanked us for our helpful suggestions for improving their studies.

**Paul Hamilton**

## West Midlands - Edgbaston Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Dr Oladipo Babalola	Relief Pharmacy Manager	Expert	05/06/2015	
Dr Sheila D'Souza	Dentist	Expert	09/11/2015	
Dr Hora Ejtehadi	Senior Academic Lecturer	Lay	07/05/2015	
Mr Chris Foy	Medical Statistician	Expert	01/05/2010	
Mr Paul Hamilton	Retired Local Government Officer	Lay Plus	01/01/2008	
Dr Adrian Hamlyn	Consultant Physician & Hepatologist	Expert	01/02/2007	
Dr Sarahjane Jones	Research Fellow	Lay	05/02/2013	
Dr Nigel Langford	Consultant Clinical Pharmacologist & General Physician	Expert	19/11/2008	
Professor John Marriott	Pharmaceutical Chemist/Academic Pharmacist	Expert	01/01/2008	
Mrs Alison Parsons	Retired Senior Manager	Lay Plus	01/01/2013	
Mr Philip Russell	Retired Head Teacher	Lay Plus	05/11/2008	
Dr Eric Silove	Retired Paediatric Cardiologist	Expert	16/01/2006	
Miss Heather Small	Heart Study Co-ordinator	Expert	20/02/2009	04/03/2015
Dr Michael Wolffe	Optometrist	Expert	01/04/2008	

## West Midlands - Edgbaston Research Ethics Committee: Deputy Members

Name	Profession	Status	Meeting date attended
None	None	N/A	N/A

## West Midlands - Edgbaston Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended
Dr Nigel Birch	Retired from Rolls-Royce	Lay Plus	12/05/2014
Ms Gill Bumphrey	Clinical Trials Pharmacist	Expert	01/12/2012
Mrs Jeanne-Anne Charly	Staff Nurse	Expert	08/07/2013

**West Midlands - Edgbaston Research Ethics Committee: Members' Declarations of Interest:**

<b>Name</b>	<b>Declaration of Interest</b>	<b>Date</b>
Dr Oladipo Babalola	None declared	01/12/2015
Dr Sheila D'Souza	None declared.	09/12/2015
Dr Hora Ejtehadi	Staff member at Birmingham City University, involved with educational research as well as staff research. Supervising the PhD and MSc students.	01/12/2015
Mr Chris Foy	Father has a substantial holding of shares in Glaxo Smith Kline, and I have a lasting power of attorney over his financial affairs (not activated yet). Also I am employed by NIHR to advise NHS researchers in SW England on their grant applications.	01/12/2015
Mr Paul Hamilton	At the University of Warwick I am a member of the University Research Governance and Ethics Committee, and the Biomedical and Scientific Research Ethics Sub Committee.	01/12/2015
Dr Adrian Hamlyn	Member of BMA	01/12/2015
Dr Sarahjane Jones	Employed by Birmingham City University as a research fellow. Volunteers for Endometriosis UK as a support group leader. This organisation does seek funding for research and I might be involved in research with them.	01/12/2015
Dr Nigel Langford	NICE _ HTA Committee - Clinical Pharmacology. Performs research for University Hospitals Leicester.	01/12/2015
Professor John Marriott	Head of Pharmacy School, University of Birmingham which is a clinical research group.	01/12/2015
Mrs Alison Parsons	None declared	01/12/2015
Mr Philip Russell	Voluntary work within the Patient Advice and Liaison Service (PALS) at Heart of England NHS Foundation Trust (Good Hope Hospital, Sutton Coldfield). Involvement in PALS - possible concern/complaint from patients involved in research studies.	01/12/2015
Dr Eric Silove	Have participated in a University of Birmingham MSc course on Genomics. Have advised on some ethical issues and might be asked to participate again.	01/12/2015
Dr Michael Wolffe	Vice Chair and Trustee for Partially Sighted Society. Chair and Trustee of 'Look' - Federation of Families of Visually Impaired Children. Member of Research Ethical Committee Institute of Optometry, London. Chair of BSI Committees in Field of Ophthalmic Optics. UK Expert to ISO & CEN Committees related to Ophthalmic Optics.	01/12/2015

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

Month	Date	Number of Members Present at Meeting
April	15/04/2015	10
June	17/06/2015	0
July	15/07/2015	10
August	19/08/2015	9
September	16/09/2015	7
October	14/10/2015	8
November	18/11/2015	12
December	16/12/2015	11
January	20/01/2016	10
February	17/02/2016	10
March	16/03/2016	10

11 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	15/04/2015	3
May	13/05/2015	3
June	17/06/2015	3
July	15/07/2015	3
August	19/08/2015	3
September	18/09/2015	3
October	14/10/2015	3
November	18/11/2015	3
December	16/12/2015	3
January	20/01/2016	3
February	17/02/2016	3
March	16/03/2016	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	08/04/2015	2
April	17/04/2015	2
May	04/05/2015	2
May	18/05/2015	2
June	01/06/2015	2
June	19/06/2015	2
July	03/07/2015	2
July	20/07/2015	2

August	13/08/2015	2
August	24/08/2015	2
September	07/09/2015	2
September	21/09/2015	2
October	05/10/2015	2
October	19/10/2015	2
November	02/11/2015	2
November	02/11/2015	2
November	06/11/2015	2
November	17/11/2015	2
November	30/11/2015	2
December	18/12/2015	2
January	04/01/2016	2
January	18/01/2016	2
February	01/02/2016	2
February	12/02/2016	2
February	15/02/2016	2
February	29/02/2016	2
March	17/03/2016	2
March	29/03/2016	2
March	29/03/2016	2

29 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	None	N/A

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

Name	Number of Meetings Attended
Dr Oladipo Babalola (new member from 5 <sup>th</sup> June 2015)	5
Dr Sheila D'Souza (new member from 9 <sup>th</sup> November 2015. Left April 2016)	3
Dr Hora Ejtehadi	7
Mr Chris Foy	9
Mr Paul Hamilton	9
Dr Adrian Hamlyn	7
Dr Sarahjane Jones	8
Dr Nigel Langford	7
Professor John Marriott	10
Mrs Alison Parsons	6
Mr Philip Russell	8
Dr Eric Silove	7
Dr Michael Wolffe	8

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

Name	Number of Meetings Attended
Mr Chris Foy	5
Mr Paul Hamilton	9
Dr Adrian Hamlyn	4
Dr Sarahjane Jones	3
Dr Nigel Langford	1
Professor John Marriott	6
Mrs Alison Parsons	1
Mr Philip Russell	3
Dr Eric Silove	2
Dr Michael Wolffe	2

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

Name	Number of Meetings Attended
Mr Chris Foy	4
Mr Paul Hamilton	19
Dr Adrian Hamlyn	3
Dr Sarahjane Jones	6
Dr Nigel Langford	1
Professor John Marriott	16
Mrs Alison Parsons	1



Mr Philip Russell	3
Dr Eric Silove	2
Dr Michael Wolffe	3

**Training 01 April 2015 - 31 March 2016**

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Dr Oladipo Babalola	25/09/2015	Members' Regional Training Day
Dr Hora Ejtehad	03/02/2016	Handling Health Related Findings in Research (Joint MRC/HRA)
Dr Hora Ejtehad	10/02/2016	Committee Members Induction
Mr Chris Foy	05/05/2015	Equality and Diversity - ELearning Course
Mr Chris Foy	04/09/2015	Local Training - Joint Oxford Training
Mr Chris Foy	03/12/2015	HRA Workshop - Pragmatic or Point of Care Trials
Mr Chris Foy	09/12/2015	National Training Day for Committee Chairs
Mr Chris Foy	17/12/2015	Workshop for REC Statistician Members
Mr Paul Hamilton	07/05/2015	NREAP Meeting
Mr Paul Hamilton	09/12/2015	National Training Day for Committee Chairs
Dr Adrian Hamlyn	01/01/2016	Acting as a 'Buddy' for new member Sheila D'Souza
Dr Sarahjane Jones	08/07/2015	Acting as 'buddy' for new member - Dr Hora Ejtehad
Dr Sarahjane Jones	06/10/2015	Quantitative Research Methods and Statistics: A Health Research Authority Workshop
Dr Sarahjane Jones	19/11/2015	Personal Data in Research - A Workshop
Dr Nigel Langford	25/09/2015	Members' Regional Training Day
Professor John Marriott	08/07/2015	Acting as 'buddy' for new member - Oladipo Babalola
Professor John Marriott	25/09/2015	Members' Regional Training Day
Mr Philip Russell	25/09/2015	Members' Regional Training Day
Dr Eric Silove	26/05/2015	Reading Materials - Ethical Issues and Consenting Participants
Dr Michael Wolffe	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:**

<b>Applications for full ethical review – Study Type</b>	<b>Number</b>	<b>%</b>
Clinical Trial of Investigational Medicinal Product	28	51.85
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	26	48.15
<b>Total Applications Reviewed</b>	<b>54</b>	<b>100</b>

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

Number of applications made invalid by the REC Manager	1
Number of applications withdrawn prior to the meeting	1
Number of student applications reviewed	12
Number of paediatric applications reviewed	7
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	2

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

<b>Decisions taken at meetings following review of applications</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	3	5.56
Unfavourable Opinion	0	0.00
Provisional Opinion	51	94.44
Provisional Opinion Pending Consultation with Referee	0	0.00
<b>Total</b>	<b>54</b>	<b>100</b>
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	50	92.59
Further Information Favourable Opinion with Additional Conditions	0	0.00
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	3	5.56
Unfavourable Opinion	0	0.00
Provisional Opinion	0	0.00
Provisional Opinion Pending Consultation with Referee	0	0.00
Further Information response not complete	0	0.00
No decision entered on system	0	0.00
Number of studies withdrawn after the meeting	1	1.85
<b>Total</b>	<b>54</b>	<b>100</b>

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

<b>Total Applications Reviewed</b>	<b>30</b>
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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	1
Number of student applications reviewed	16
Number of paediatric applications reviewed	3
Number of device applications reviewed	0
Number of qualitative applications reviewed	5

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

<b>Decisions taken at proportionate review sub-committee meetings</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	7	23.33
Favourable Opinion with Additional Conditions	6	20.00
No Opinion transfer to full committee for review	3	10.00
Provisional Opinion	13	43.33
Unfavourable Opinion	1	3.33
<b>Total</b>	<b>30</b>	<b>100</b>

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

<b>Average number of applications reviewed per full meeting</b>	4.91
<b>Number of completed applications for full ethical review</b>	53
<b>Number of completed applications for full ethical review over 60 days</b>	0
<b>Number of completed applications over 60 days as a % of total</b>	0.00%
<b>Number of completed applications for full ethical review over 40 days</b>	2
<b>Number of completed applications over 40 days as a % of total</b>	3.20%
<b>Number of days taken to final decision – average (mean)</b>	31

<b>Number of completed proportionate review applications for ethical review</b>	26
<b>Number of completed proportionate review applications for ethical review over 14 days</b>	2* (0)
<b>Number of completed proportionate review applications over 14 days as a % of total</b>	7.69%* (0.00%)

*\*Please note that these studies were part of the Proportionate Review Pilot which has been set up to test whether allowing REC staff increased time to work with applicants to ensure that the study documentation is clear, accurate and complete, as well as allowing a minimum number of days for REC members to undertake the ethical review is preferable against set evaluation criteria. One of the objectives of the pilot is to assess the impact of extending the length of review to 21 calendar days rather than 14 calendar days. The numbers in red are the figures excluding any applications which were part of the Proportionate Review pilot.*

<b>Number of SSAs (non-Phase 1) reviewed</b>	7
<b>Number of completed applications for SSA review over 25 days</b>	0
<b>Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs</b>	0.00%

<b>Number of SSAs (Phase 1) reviewed</b>	0
<b>Number of completed applications for SSA review over 14 days</b>	0
<b>Number of completed applications for SSA review over 14 days as % of all Phase 1 SSAs</b>	0.00%

<b>Number of substantial amendments reviewed</b>	145
<b>Number of completed substantial amendments over 35 days</b>	0
<b>Number of completed substantial amendments over 35 days as a % of total substantial amendments</b>	0.00%
<b>Number of completed substantial amendments over 28 days</b>	0
<b>Number of completed substantial amendments over 28 days as a % of total substantial amendments</b>	0.00%

<b>Number of modified amendments reviewed</b>	10
<b>Number of completed modified amendments over 14 days</b>	0
<b>Number of completed modified amendments over 14 days as</b>	0.00%

<b>a % of total modified amendments</b>	
<b>Number of minor amendments received</b>	142
<b>Number of substantial amendments received for information</b>	1
<b>Number of substantial amendments received for new sites/PIs</b>	53
<b>Number of annual progress reports received</b>	116
<b>Number of safety reports received</b>	57
<b>Number of Serious Adverse Events received</b>	2
<b>Number of final reports received</b>	23

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

<b>Further Information Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
15/WM/0090	Christian women, anorexia and theological responses (1)	28
15/WM/0126	Torch	26
15/WM/0139	UCB5857 For Participants with Primary Sjogren's Syndrome	24
15/WM/0140	Family CBT intervention for children with ASD and anger difficulties	23
15/WM/0141	Lesbian Cancer Voices	26
15/WM/0211	Phase 1b Study in Subjects with Multiple Myeloma ACE-MY-001	29
15/WM/0221	Alginate formulations for enhancing colonic health	28
15/WM/0238	4153: Once Daily Semaglutide in Obese Subjects without DM	29
15/WM/0242	PM CT and MRI in Children	31
15/WM/0245	Emotion recognition in people with Parkinson's (SPiEs) v1.0	32
15/WM/0255	Biological correlates of dimensional symptoms of psychosis (BioPoP)	29
15/WM/0256	SNIFFLE-3 Study	26
15/WM/0263	GS-US-401-1787, Open label Study - Long-term Safety of ONO/GS-4059	29
15/WM/0268	ENRICH Ibrutinib for untreated mantle cell lymphoma	27
15/WM/0275	Genetic analysis of ovarian granulosa cell tumours	34
15/WM/0284	Research into Pregnancy Complications	33
15/WM/0304	Grandmothers on the neonatal intensive care unit- ethnographic study.	30
15/WM/0323	Evaluation of the Senspoint Lactate Meter	30
15/WM/0327	Treatment Of Pulmonary Hypertension (TROPHY) 1 study, UK version 1	34
15/WM/0339	Improving outcomes in children exposed to excess steroid hormones	26
15/WM/0363	COBALT: Study of Obeticholic Acid in Primary Biliary Cirrhosis	24
15/WM/0364	Phase 2 - MBX-8025 in Participants with Primary Biliary Cirrhosis	23
15/WM/0365	Phase III study with finerenone in Chronic Heart Failure	24
15/WM/0366	RAVINE	38
15/WM/0377	Study evaluating MEDI4736 + AZD9150/AZD5069 in solid tumors & RMSCCHN	39
15/WM/0407	ORL-EXG-1917	29
15/WM/0410	LEO 43204 field treatment of AK on balding scalp	40
15/WM/0411	LEO 43204 Field treatment of AK on the Face or Chest	40
15/WM/0440	Generation of Human Monoclonal Antibodies (Version 1; 01-Dec-2012)	22
15/WM/0447	Cerebral vasomotor regulation in atrial fibrillation (CVR-AF)	24
15/WM/0453	AZD9496 Vs Fulvestrant in Primary Breast Cancer	27
15/WM/0455	SAFE-TKR Study	36



15/WM/0456	CGAI - The REGAIN Study (Treatment for Chronic Migraine)	30
16/WM/0008	HYDRA-P	28
16/WM/0009	The 'Can Do Ramadan' Study	30
16/WM/0011	Influence of sedentary time on skeletal muscle protein metabolism	33
16/WM/0014	HOLDS	33
16/WM/0019	A Phase 1 Study of DCR-PH1 in Patients with PH 1	30
16/WM/0030	Outpatient Study - Prophylactic Administration of PrEP-001 Against HRV	50
16/WM/0036	GBS2	25
16/WM/0044	Microchip electrolyte sensor validation study	28
16/WM/0055	The relationship between CTCA and EPC count.	24
16/WM/0060	Cognitive Biases in Treatment Choices in Multiple Sclerosis	23
16/WM/0072	Effect on EPCs by statin loading in 'all comers' with ACS	24
16/WM/0088	SYNSEQ, version 1.0	34
16/WM/0108	CABP	42
16/WM/0128	A Phase 3 Study with Etanercept & Methotrexate in Psoriatic Arthritis	35
16/WM/0129	Effects of body fat composition on perception of slopes	32
16/WM/0131	CAMHS patients' experiences of preparing to move on to adult services	33
16/WM/0133	Phase 1b Safety and Tolerability Study of GemRIS in NMIBC, V1.1	34

#### Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
None	None	N/A

#### Further Information Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
None	None	N/A

#### Favourable Opinion with Standard Conditions

REC Reference	Title	Number of Days on Clock
None	None	N/A

#### Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/WM/0235	Treatments for FAI and their effects on osteoarthritis	27
15/WM/0457	54767414MMY3010	22
16/WM/0010	A phase II trial of pembrolizumab in NSCLC PS2 patients	28

#### Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
None	None	N/A

#### Provisional Opinion

REC Reference	Title	Number of Days on Clock
None	None	N/A

#### Provisional Opinion Pending Consultation with Referee

REC Reference	Title	Number of Days on Clock
None	None	N/A

#### Further information response not complete

REC Reference	Title	Number of Days on Clock
None	None	N/A

#### Withdrawn after the meeting

REC Reference	Title	Number of Days on Clock
15/WM/0262	LTX-109 in the Treatment of Mildly Infected Diabetic Foot Ulcers	66

**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/WM/0148	Observational study for frailty load on colorectal unit	7
15/WM/0178	Development of a model to predict security incidents in care.	8
15/WM/0225	testing a simple patient commitment to taking medication as prescribed	10
15/WM/0249	Developing a biomarker for children with spinal lipoma	14
15/WM/0250	Polysomnography patient experience an IPA study.	11
15/WM/0310	SO-LIFE	9
15/WM/0312	Isolation of mucins from patient sputum	12
15/WM/0386	A qualitative study to explore engagement with cervical screening	14
15/WM/0434	The prevalence of vitamin D deficiency in psychiatric inpatients	13
15/WM/0444	Lifestyle Health and Wellbeing Survey	12
16/WM/0056	Parents' Information Needs When Managing Children's Postop Pain	11
16/WM/0138	HECTOR 2 - follow-up study (PR Pilot – allows 21 days)	21

#### Further Information Favourable Opinion with Additional Conditions

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

REC Reference	Title	Number of Days on Clock
16/WM/0053	Macroprolactinaemia: epidemiology, pathophysiology, clinical relevance	12

#### Favourable Opinion with Standard Conditions

REC Reference	Title	Number of Days on Clock
15/WM/0188	Does brain injury affect perception of emotional faces	3
15/WM/0226	International CTEPH Registry	9
15/WM/0253	Unexpected Out of hospital births in the UK: What is the problem?	9
15/WM/0436	Development and validation of the VISA-A (Sedentary) questionnaire	12
15/WM/0481	Is modern cardiac rehabilitation still effective?	6
16/WM/0054	Deep Learning for Automatic Screening of Diabetic Retinopathy	10
16/WM/0140	Safe staffing in mental health (PR Pilot – allows 21 days)	15

#### Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/WM/0145	Hypodontia app – are patients better informed? V1	7
15/WM/0252	Older Adults who Frequently Attend the ED	6
15/WM/0349	Upper airway host defences - ENT volunteers	8
15/WM/0433	Patient activation and diabetes outpatient non-attendance	13
16/WM/0096	Perception, Experience & Relationship with Food & Eating in CF Adults	10
16/WM/0098	a scale to measure return to work self-efficacy	9

#### Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
15/WM/0351	Perineal trauma in women having vaginal delivery after previous OASIS	8

#### Provisional Opinion

REC Reference	Title	Number of Days on Clock
None	None	N/A

#### Further information response not complete

REC Reference	Title	Number of Days on Clock
None	None	N/A

#### Withdrawn after the meeting

REC Reference	Title	Number of Days on Clock
None	None	N/A

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

<b>Favourable opinion</b>				
<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>
00/7/061/AM07	Tuberous Sclerosis 2000 Study	14	04/12/2015	17
00/7/061/AM08	Tuberous Sclerosis 2000 Study	15.0	04/01/2016	22
04/MRE07/35/AM109	Stampede (version 1.0) – PR08	18.06.2015	18/06/2015	17
04/MRE07/35/AM112	Stampede (version 1.0) – PR08	30/10/2015	30/10/2015	16
05/MRE07/25/AM21	The IMPACT Study, Version 8, February 2005	20	17/06/2015	19
05/MRE07/26/AM18	Dialysis Outcomes and Practice Patterns Study (DOPPS) v.2	13.05.2015	13/05/2015	19
06/MRE07/40/AM08	Cognitive processes underlying disorders of memory	5	01/10/2015	15
06/MRE07/40/AM10	Cognitive processes underlying disorders of memory	6	11/02/2016	18
09/H1208/33/AM27	A3921024 RA long term follow up of CP-690,550	29.07.2015	29/07/2015	16
10/H1208/41/AM02	Rehabilitation for Operated lung cancer, Version 1	2	06/08/2015	13
10/H1208/41/AM03	Rehabilitation for Operated lung cancer, Version 1	3	23/12/2015	27
11/WM/0050/AM14	EMBODY 4	12	07/08/2015	18
11/WM/0279/AM10	NECTAR-HF Research Study	AE	19/10/2015	27
11/WM/0341/AM17	Efficacy of Lenalidomide/Dexamethasone +/-Elotuzumab in untreated MM	6	20/10/2015	21
11/WM/0341/AM20	Efficacy of Lenalidomide/Dexamethasone +/-Elotuzumab in untreated MM	PIS V10 09 March 2016	21/03/2016	15
12/WM/0039/AM22	Inovate-HF	03.11.15	03/11/2015	1
12/WM/0087/AM08	RAvVA	8	25/05/2015	13
12/WM/0268/AM08	Phase II/III in fingolimod vs placebo in patients with CIDP	11.05.15	11/05/2015	9
12/WM/0268/AM09	Phase II/III in fingolimod vs placebo in patients with CIDP	02.06.15	02/06/2015	21
12/WM/0306/AM08	WP4 Exercise Outcome Study	5	10/11/2015	10
12/WM/0306/AM09	WP4 Exercise Outcome Study	SA#6	11/01/2016	21
12/WM/0341/AM51	AMG 145 and Statin Therapy in patients with Cardiovascular Disease	28	18/03/2015	21
12/WM/0341/AM54	AMG 145 and Statin Therapy in patients with Cardiovascular Disease	31	27/08/2015	13

12/WM/0341/AM57	AMG 145 and Statin Therapy in patients with Cardiovascular Disease	32	29/10/2015	14
12/WM/0341/AM58	AMG 145 and Statin Therapy in patients with Cardiovascular Disease	33	25/11/2015	6
12/WM/0341/AM59	AMG 145 and Statin Therapy in patients with Cardiovascular Disease	34	27/11/2015	4
12/WM/0341/AM63	AMG 145 and Statin Therapy in patients with Cardiovascular Disease	37	20/01/2016	16
12/WM/0341/AM64	AMG 145 and Statin Therapy in patients with Cardiovascular Disease	38	26/01/2016	10
12/WM/0341/AM66	AMG 145 and Statin Therapy in patients with Cardiovascular Disease	41	23/02/2016	6
12/WM/0341/AM72	AMG 145 and Statin Therapy in patients with Cardiovascular Disease	44	24/03/2016	18
12/WM/0408/AM12	REVISE-Diabetes	7	02/09/2015	22
12/WM/0408/AM14	REVISE-Diabetes	08	15/10/2015	21
13/WM/0114/AM13	SHINE MCL3002	SA8	19/11/2015	18
13/WM/0114/AM14	SHINE MCL3002	9	04/01/2016	15
13/WM/0232/AM08	Decitabine for Acute Myeloid Leukaemia in Children	INT2	05/11/2015	15
13/WM/0277/AM07	The Subjective Experience of Auditory Verbal Hallucinations	SA5 - V1.6 15.10.15	22/10/2015	14
13/WM/0304/AM02	SPIRO - CKD	2	23/04/2015	9
13/WM/0304/AM03	SPIRO - CKD	11.08.15	11/08/2015	8
13/WM/0355/AM03	Role of Vascular Biomarkers in Heart Failure patients undergoing CRT	3	19/05/2015	5
13/WM/0364/AM04	Targeted retreatment of COPD exacerbations	3	29/01/2015	15
13/WM/0365/AM06	A 3 yr extension study of Secukinumab in Psoriatic Arthritis patients	5	30/10/2015	13
13/WM/0400/AM03	Steroid tape to treat overgranulating PD exit sites	25.06.2015	30/06/2015	7
13/WM/0438/AM06	Providing newborn screening information antenatally	5	22/07/2015	23
13/WM/0438/AM07	Providing newborn screening information antenatally	Substantial Amendment 02.10.15	02/10/2015	10
14/WM/0007/AM01	Observational Study to Determine Prognostic Factors in Skin Lymphoma	1	20/05/2015	7
14/WM/0013/AM13	Developing a new drug to treat infants hospitalised with RSV	08	02/03/2016	15

	infection			
14/WM/0049/AM02	NN7999-3895 Trial Evaluating Safety & Efficacy of N9-GP in Haem B PUPs	1	20/04/2015	15
14/WM/0049/AM04	NN7999-3895 Trial Evaluating Safety & Efficacy of N9-GP in Haem B PUPs	2	11/05/2015	21
14/WM/0049/AM05	NN7999-3895 Trial Evaluating Safety & Efficacy of N9-GP in Haem B PUPs	02	12/08/2015	13
14/WM/0052/AM04	PARTNERS2: collaborative care for people with serious mental illness	4	04/09/2015	8
14/WM/0052/AM06	PARTNERS2: collaborative care for people with serious mental illness	5	17/11/2015	7
14/WM/0052/AM07	PARTNERS2: collaborative care for people with serious mental illness	6	08/01/2016	13
14/WM/0112/AM03	NOVOCART 3D PLUS (N3D) Study	1	07/05/2015	13
14/WM/0112/AM07	NOVOCART 3D PLUS (N3D) Study	02	23/12/2015	13
14/WM/0124/AM04	UK FASHIoN	2	20/11/2015	8
14/WM/0124/AM05	UK FASHIoN	3	17/02/2016	13
14/WM/0135/AM13	Daratumumab+Rd vs Rd in Relapsed or Refractory Multiple Myeloma	19.08.15	19/08/2015	21
14/WM/0135/AM14	Daratumumab+Rd vs Rd in Relapsed or Refractory Multiple Myeloma	SA07	30/11/2015	22
14/WM/0146/AM02	OPAL study	2	31/03/2015	17
14/WM/0170/AM09	Phase III study of Momelotinib in Patients with Myelofibrosis	5	06/10/2015	12
14/WM/0177/AM01	Mechanisms underlying inflammation associated muscle loss	1	08/11/2015	11
14/WM/1036/AM04	Child weigHt mANaGement for Ethnically diverse communities: CHANGE	4	06/07/2015	14
14/WM/1036/AM05	Child weigHt mANaGement for Ethnically diverse communities: CHANGE	5	17/11/2015	8
14/WM/1056/AM05	Efficacy and Safety of SOF/GS-5816 FDC for 12 weeks in Chronic HCV	2	12/06/2015	27
14/WM/1062/AM03	Recovering Quality of Life (ReQoL)	14	02/04/2015	6
14/WM/1062/AM06	Recovering Quality of Life (ReQoL)	4	03/07/2015	18
14/WM/1062/AM08	Recovering Quality of Life (ReQoL)	5	12/11/2015	4
14/WM/1062/AM09	Recovering Quality of Life (ReQoL)	6	09/12/2015	12
14/WM/1097/AM01	Impulse control behaviour in Parkinson's	1	16/03/2015	23
14/WM/1097/AM03	Impulse control behaviour in Parkinson's	2	27/04/2015	6

14/WM/1097/AM06	Impulse control behaviour in Parkinson's	3	12/06/2015	21
14/WM/1097/AM08	Impulse control behaviour in Parkinson's	4	22/10/2015	17
14/WM/1099/AM02	The REACT study	2	24/11/2015	7
14/WM/1112/AM01	Vimpat	1	30/06/2015	21
14/WM/1143/AM11	SMT19969/C003	5	04/03/2016	18
14/WM/1146/AM03	CHHIP (Cellular humoral and hormonal control of immunity in pregnancy)	1	27/10/2015	20
14/WM/1161/AM01	Cognitive Training for Brain Injury	1	27/08/2015	12
14/WM/1170/AM02	CompARE Trial, Version 1.0	AM02	17/09/2015	25
14/WM/1185/AM04	Sofosbuvir/Ribavirin in Adolescents and Children	17.06.15	17/06/2015	19
14/WM/1185/AM07	Sofosbuvir/Ribavirin in Adolescents and Children	5	12/01/2016	22
14/WM/1188/AM02	4054 - REAL 1 NNC0195-0092 in adults with growth hormone deficiency	10.06.15	10/06/2015	12
14/WM/1188/AM06	4054 - REAL 1 NNC0195-0092 in adults with growth hormone deficiency	2	17/08/2015	22
14/WM/1188/AM07	4054 - REAL 1 NNC0195-0092 in adults with growth hormone deficiency	SA03	08/10/2015	11
14/WM/1200/AM01	AFGEN: Long-term Registry of Atrial Fibrillation patients	1	10/06/2015	21
14/WM/1218/AM03	4043 - REAL 2 NNC0195-0092 in adults with growth hormone deficiency	3	01/04/2015	18
14/WM/1231/AM02	ABT493 and ABT530 with and without Ribavirin in HCV patients	01.06.15	01/06/2015	22
14/WM/1231/AM03	ABT493 and ABT530 with and without Ribavirin in HCV patients	11.08.15	11/08/2015	11
14/WM/1231/AM04	ABT493 and ABT530 with and without Ribavirin in HCV patients	7	13/11/2015	7
14/WM/1231/AM05	ABT493 and ABT530 with and without Ribavirin in HCV patients	8	17/02/2016	13
14/WM/1260/AM02	PHAZAR	2	09/07/2015	8
14/WM/1262/AM04	Open Label Efficacy and Safety of SOF/GS-5816 FDC for 12 weeks in HCV	4	29/04/2015	14
14/WM/1262/AM05	Open Label Efficacy and Safety of SOF/GS-5816 FDC for 12 weeks in HCV	5	12/06/2015	24
14/WM/1264/AM01	Studying finger-thumb grip in patients with carpal tunnel syndrome V1	1	06/05/2015	13
15/WM/0009/AM03	Daratumumab + VMP vs VMP only in newly diagnosed multiple	3	01/04/2015	19



	myeloma			
15/WM/0009/AM06	Daratumumab + VMP vs VMP only in newly diagnosed multiple myeloma	12.01.16	12/01/2016	10
15/WM/0011/AM01	ADC-1013 First-in-Human Study	SA UK01-B	07/07/2015	14
15/WM/0011/AM03	ADC-1013 First-in-Human Study	SA REC UK02	23/02/2016	8
15/WM/0015/AM01	A Dose Finding Study In Pediatric Subjects With Biliary Atresia.	1	12/05/2015	22
15/WM/0015/AM03	A Dose Finding Study In Pediatric Subjects With Biliary Atresia.	2	02/07/2015	18
15/WM/0015/AM05	A Dose Finding Study In Pediatric Subjects With Biliary Atresia.	3	16/10/2015	26
15/WM/0017/AM02	Bile Acid Effects on Fetal Arrhythmia after UDCA Therapy Study (BEATS)	1	06/07/2015	15
15/WM/0050/AM01	Ingenol Mebutate vs. Diclofenac in subjects with AK on face or scalp	1	27/03/2015	12
15/WM/0056/AM01	NICU MR Scanner - Version 1	13.01.16	08/01/2016	9
15/WM/0071/AM02	Isle of Wight Birth Cohort 26 Year Follow-up	13.04.2015	13/04/2015	15
15/WM/0073/AM01	Salivary cortisol awakening response for assessment of hypoadrenalism	1	28/04/2015	19
15/WM/0073/AM02	Salivary cortisol awakening response for assessment of hypoadrenalism	2	12/02/2016	14
15/WM/0092/AM02	LOTUS	AM02 SUB	15/10/2015	5
15/WM/0101/AM01	dCELLA® ACL Scaffold	12.01.16	06/01/2016	10
15/WM/0102/AM03	Randomised Trial To Evaluate 3 Daratumumab Dose Schedules in SMM	SA01	02/10/2015	18
15/WM/0102/AM04	Randomised Trial To Evaluate 3 Daratumumab Dose Schedules in SMM	SA02	30/11/2015	18
15/WM/0111/AM04	Mobilisation of endothelial progenitor cells and statin therapy PILOT	02.06.15	02/06/2015	21
15/WM/0111/AM06	Mobilisation of endothelial progenitor cells and statin therapy PILOT	2	12/10/2015	7
15/WM/0126/AM01	Torch	1	10/06/2015	13
15/WM/0139/AM01	UCB5857 For Participants with Primary Sjogren's Syndrome	1	22/05/2015	10
15/WM/0139/AM05	UCB5857 For Participants with Primary Sjogren's Syndrome	sa3	02/07/2015	19
15/WM/0139/AM06	UCB5857 For Participants with Primary Sjogren's Syndrome	SA4	26/08/2015	14
15/WM/0139/AM09	UCB5857 For Participants with Primary Sjogren's Syndrome	5	04/03/2016	18

15/WM/0238/AM02	4153: Once Daily Semaglutide in Obese Subjects without DM	01	20/10/2015	22
15/WM/0255/AM01	Biological correlates of dimensional symptoms of psychosis (BioPoP)	27112015	27/11/2015	23
15/WM/0263/AM01	GS-US-401-1787, Open label Study - Long-term Safety of ONO/GS-4059	1	15/10/2015	5
15/WM/0268/AM03	ENRICH Ibrutinib for untreated mantle cell lymphoma	SA02	14/01/2016	22
15/WM/0304/AM01	Grandmothers on the neonatal intensive care unit- ethnographic study.	1	15/02/2016	6
15/WM/0327/AM01	Treatment Of Pulmonary Hypertension (TROPHY) 1 study, UK version 1	1	23/12/2015	7
15/WM/0363/AM01	COBALT: Study of Obeticholic Acid in Primary Biliary Cirrhosis	SA01	18/11/2015	13
15/WM/0364/AM03	Phase 2 - MBX-8025 in Participants with Primary Biliary Cirrhosis	SA02	17/11/2015	14
15/WM/0366/AM01	RAVINE	1	05/02/2016	25
15/WM/0377/AM01	Study evaluating MEDI4736 + AZD9150/AZD5069 in solid tumors & RMSCCHN	1	20/01/2016	11
15/WM/0407/AM02	ORL-EXG-1917	10.02.16	10/02/2016	2
15/WM/0410/AM01	LEO 43204 field treatment of AK on balding scalp	2	11/03/2016	12
15/WM/0411/AM01	LEO 43204 Field treatment of AK on the Face or Chest	2	11/03/2016	9
15/WM/0444/AM02	Lifestyle Health and Wellbeing Survey	2	12/02/2016	18
15/WM/0456/AM01	CGAI - The REGAIN Study (Treatment for Chronic Migraine)	12.02.16	05/02/2016	21
15/WM/0457/AM04	54767414MMY3010	SA02	06/02/2016	22
16/WM/0030/AM02	Outpatient Study - Prophylactic Administration of PrEP-001 Against HRV	22.03.16	22/03/2016	7
97/7/001/AM09		8	16/10/2015	16

#### Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
12/WM/0039/AM23	Inovate-HF	12	14/12/2015	19
12/WM/0236/AM04	Investigation of the effect of acute trauma/disease on stem cells	4	20/10/2015	23
12/WM/0413/AM07	Fungal Airway Colonisation and Sensitisation Study (FAST Study)	5	25/06/2015	28
13/WM/0114/AM11	SHINE MCL3002	8	28/09/2015	11
13/WM/0451/AM06	AMG 337 with MET Amplified Gastric, Esophageal or other	14.04.15	14/04/2015	24

	solid tumours			
14/WM/0013/AM12	Developing a new drug to treat infants hospitalised with RSV infection	7	16/09/2015	25
14/WM/1143/AM07	SMT19969/C003	10.07.15	10/07/2015	27
15/WM/0071/AM04	Isle of Wight Birth Cohort 26 Year Follow-up	2	11/12/2015	22
15/WM/0090/AM01	Christian women, anorexia and theological responses (1)	1	22/09/2015	9
15/WM/0211/AM05	Phase 1b Study in Subjects with Multiple Myeloma ACE-MY-001	2	16/03/2016	28

**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
09/H1208/33/AM26/1	A3921024 RA long term follow up of CP-690,550	01.04.15	01/04/2015	1
12/WM/0039/AM15/1	Inovate-HF	31.03.15	31/03/2015	6
12/WM/0039/AM23/1	Inovate-HF	12	12/01/2016	2
12/WM/0413/AM07/1	Fungal Airway Colonisation and Sensitisation Study (FAST Study)	04.01.16	05/11/2015	4
13/WM/0451/AM06/1	AMG 337 with MET Amplified Gastric, Esophageal or other solid tumours	3	19/05/2015	10
14/WM/0013/AM12/1	Developing a new drug to treat infants hospitalised with RSV infection	7	23/10/2015	4
14/WM/0024/AM03/1	Peer support system for young people with type 1 diabetes	07.04.15	07/04/2015	2
14/WM/1143/AM07/1	SMT19969/C003	25.08.15	25/08/2015	2
15/WM/0071/AM04/1	Isle of Wight Birth Cohort 26 Year Follow-up	2.1	07/01/2016	4
	Christian women, anorexia and theological responses (1)	2	23/10/2015	1

15/WM/0090/AM01/1				
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Unfavourable opinion timeline				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
None	None	None	N/A	N/A

**Table 11: Items exceeding timelines****Full applications for ethical review over 60 day timeline**

REC Reference	Title	Number of Days on Clock
None	None	N/A

**Proportionate review applications for ethical review over 14 day timeline**

REC Reference	Title	Number of Days on Clock
16/WM/0138	HECTOR 2 - follow-up study	21
16/WM/0140	Safe staffing in mental health	15

**SSAs (non Phase 1) over 25 day timeline**

REC Reference	Title	Number of Days on Clock
None	None	N/A

**SSAs (Phase 1) over 14 day timeline**

REC Reference	Title	Number of Days on Clock
None	None	N/A

**Substantial Amendments over 35 day timeline**

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

**Modified Amendments over 14 day timeline**

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