NHS
Health Research Authority

Research Ethics Service

West Midlands - Edgbaston Research Ethics Committee

Annual Report

01 April 2016 - 31 March 2017

Part 1 – Committee Membership and Training

Name of REC:	West Midlands - Edgbaston Research Ethics Committee
Type of REC:	RECs recognised to review CTIMPS in patients - type iii
Type of Flag:	Medical Device Study, Phase 1 Studies in Patients, Research Involving Children
Chair:	Mr Paul Hamilton
Vice-Chair:	Professor John Marriott
Alternate Vice-Chair:	Dr Sarahjane Jones
REC Manager:	Helen Poole
REC Assistant:	Adam Garretty (until end January 2017). Joanne O'Neil (February 2017 onwards).
Committee Address:	The Old Chapel Royal Standard Place Nottingham NG1 6FS
Telephone:	0207 104 8115
Email:	NRESCommittee.WestMidlands-Edgbaston@nhs.net

Chair's overview of the past year:

The committee has worked well over the last twelve months, particularly taking into account the tight time constraints set by our current meeting hosts who require us, after a 1 pm start, to vacate the building by 5 pm without fail. With six studies, quite often the majority of them CTIMPs, the committee has met the challenge this poses and worked conscientiously to get the work done in the time available. This keeps me on my mettle but my colleagues, including excellent support staff, make the committee a pleasure to chair.

Some members have acted as co-opted members of other committees and we all find this a valuable experience providing an opportunity to compare working practices and to develop collegiality.

Particular points to mention are that the PR pilot was very successful and has been rolled across the board. Eric Silove, our greatly respected paediatric expert member, left the Committee at the end May 2016. Adam Garretty left as REC Assistant at the end of January 2017 and Joanne O'Neil joined us.

Our performance data is very encouraging: substantial amendments and full applications were all reviewed within timelines (35 days and 60 days respectively). Average time to completion for full applications 30 days.

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	26/04/2016 Transferred to Solihull
Dr Hora Ejtehadi	Senior Academic Lecturer	Lay	07/05/2015	
Mr Chris Foy	Medical Statistician	Expert	01/05/2010	
Mr Paul Hamilton	Parish Administrator	Lay Plus	01/01/2008	
Dr Adrian Hamlyn	Consultant Physician & Hepatologist	Expert	01/02/2007	
Dr Sarahjane Jones	Senior 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	31/05/2016
Dr Michael Wolffe	Optometrist	Expert	01/04/2008	

West Midlands - Edgbaston Research Ethics Committee: Deputy Members

None

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

Name	Profession	Status	Meeting date attended
Mrs Rita Patel	Contracts and Innovation Manager	Lay	15/03/2017
Dr Ronald Jubb	Retired Consultant Rheumatologist	Expert	15/03/2017

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

Name	Declaration of Interest	Date
Dr Oladipo Babalola	Student involved in research at De Montfort University.	01/12/2016
Dr Hora Ejtehadi	As part of her job at Birmingham City University she is involved with undergraduate/post graduate research that may require applying for funding. Also part of a local ethics committee within the university. Not involved in any peer review bodies.	01/12/2016
Mr Chris Foy	Father (for whom Chris has power of attorney, not yet activated) has a substantial holding of shares in GSK. CF personally holds no shares in any company conducting research. Employed by the NIHR Research Design Service to provide advice to NHS staff and others seeking research grants. Also participates in the Gloucestershire NHS Community's Peer Review Committee.	01/12/2016
Mr Paul Hamilton	Member of the University of Warwick's Research Governance and Ethics Committee and its Biomedical and Scientific Research Ethics Sub-Committee. Now employed part time as a Parish Administrator, whereas before he was a retired local government office. This is relevant for the HRA profile but does not affect his status.	01/12/2016
Dr Adrian Hamlyn	Member of British Medical Association and British Society of Gastroenterology.	01/12/2016
Dr Sarahjane Jones	Volunteers with the charity Endometriosis UK as a support. Works at Birmingham City University as a senior research fellow. Change to classification of role (date of occurrence 01.08.16): now a Senior Research Fellow in Health and Social Care at Birmingham City University. Designs and conducts research, all or which is required to go through the HRA process and a lot of it requires review by a REC.	01/12/2016
Dr Nigel Langford	NICE HTA Appraisal Committee C, CQC Specialist Advisor, Member for the Medical Practitioners Tribunal Service, Medical Protection Society member.	01/12/2016
Professor John Marriott	Member of the British Pharmaceutical Society, Fellow of the Royal Pharmaceutical Society. Member University of Birmingham Clinical Trials Oversight Committee.	01/12/2016
Mrs Alison Parsons	Acts as advisor to a Community Interest Company working with offenders - 'Mentoring West Midlands'. This is not Health and Social Care but a related field.	01/12/2016
Mr Philip Russell	Volunteer at Good Hope Hospital (Heart of England NHS Foundation Trust) in Patient Service (PALS team), one day per week.	01/12/2016
Dr Michael Wolffe	Vice Chair for the Partially Sighted Society. Chair for Look - Federation of Families with Visually Impaired Children. Member of a Research Ethical Committee of Institute of Optometry.	01/12/2016

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

Month	Date	Number of Members Present at Meeting
April	20/04/2016	9
June	15/06/2016	9
July	20/07/2016	9
August	17/08/2016	10
October	19/10/2016	7
November	16/11/2016	10
December	14/12/2016	9
January	18/01/2017	8
February	15/02/2017	9
March	15/03/2017	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	20/04/2016	3
May	18/05/2016	3
June	15/06/2016	3
July	20/07/2016	3
August	17/08/2016	3
October	19/10/2016	3
November	16/11/2016	3
December	07/12/2016	3
January	18/01/2017	3
February	15/02/2017	3
March	15/03/2017	3

11 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	29/04/2016	2
May	09/05/2016	2
May	23/05/2016	2
June	06/06/2016	2
June	24/06/2016	2
July	04/07/2016	2
July	22/07/2016	2
August	01/08/2016	2
August	15/08/2016	2

September	02/09/2016	2
September	16/09/2016	2
October	05/10/2016	2
October	12/10/2016	2
October	24/10/2016	2
November	07/11/2016	2
November	30/11/2016	2
December	05/12/2016	2
December	28/12/2016	2
January	16/01/2017	2
February	09/02/2017	2
February	20/02/2017	2
March	06/03/2017	2
March	13/03/2017	2
March	27/03/2017	2

25 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
Dr Oladipo Babalola	8
Dr Sheila D'Souza (transferred to another REC 26 April 2016)	1
Dr Hora Ejtehadi (joined May 2016)	6
Mr Chris Foy	9
Mr Paul Hamilton	10
Dr Adrian Hamlyn	8
Dr Sarahjane Jones	8
Dr Nigel Langford	3
Professor John Marriott	9
Mrs Alison Parsons	7
Mr Philip Russell	9
Dr Eric Silove	2
Dr Michael Wolffe	7

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

Name	Number of Meetings Attended
Dr Oladipo Babalola	2
Dr Hora Ejtehadi	2
Mr Chris Foy	5
Mr Paul Hamilton	11
Dr Adrian Hamlyn	1
Dr Sarahjane Jones	2
Professor John Marriott	3
Mrs Alison Parsons	2
Mr Philip Russell	2
Dr Michael Wolffe	2
Dr Nigel Langford	2

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

Name	Number of Meetings Attended
Dr Oladipo Babalola	2
Mr Chris Foy	2
Mr Paul Hamilton	22
Dr Adrian Hamlyn	3
Dr Sarahjane Jones	2
Dr Nigel Langford	1

Professor John Marriott	14
Mrs Alison Parsons	1
Mr Philip Russell	1
Dr Michael Wolffe	2

Training 01 April 2016 - 31 March 2017

Name of Member	Date	Event(s) attended
Dr Oladipo Babalola	17/05/2016	Equality, Diversity and Human Rights
Dr Oladipo Babalola	23/09/2016	Regional Members' Training Day
Dr Oladipo Babalola	26/10/2016	Qualitative Research and Ethical Review
Dr Oladipo Babalola	16/02/2017	National Members' Training Day
Dr Hora Ejtehadi	06/04/2016	Training - Quantitative Research Methods and Statistics: A Health Research Authority Workshop
Dr Hora Ejtehadi	23/09/2016	Regional Members' Training Day
Mr Chris Foy	01/12/2016	National Chairs' Training Day
Mr Paul Hamilton	23/09/2016	Regional Members' Training Day
Mr Paul Hamilton	01/12/2016	National Training Day for Committee Chairs
Dr Sarahjane Jones	14/09/2016	Handling Health Related Findings in Research (Joint MRC/HRA)
Professor John Marriott	23/09/2016	Regional Members' Training Day
Mrs Alison Parsons	11/05/2016	Training - Assessing the Consequences (benefits and harms) of Research: a Health Research Authority workshop
Mr Philip Russell	23/09/2016	Regional Members' Training Day
Mr Chris Foy	27/03/2017	Chairs' Review Programme Workshop
Dr Michael Wolffe	29/03/2017	The ICR Ethics and GCP Forum

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	25	48.08
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	1	1.92
Others	26	50.00
Total Applications Reviewed	**52**	**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	14
Number of paediatric applications reviewed	10
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	4

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

Decisions taken at meetings following review of applications	Number	%
Favourable Opinion with Standard Conditions	1	1.92
Favourable Opinion with Additional Conditions	6	11.54
Unfavourable Opinion	0	0.00
Provisional Opinion	45	86.54
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	**52**	**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	43	82.69
Further Information Favourable Opinion with Additional Conditions	1	1.92
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	1	1.92
Favourable Opinion with Additional Conditions	6	11.54
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	1.92
Total	**52**	**100**

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

Total Applications Reviewed	**27**

Table 6: **Breakdown of PRS applications and other activity during reporting period:**

Number of applications made invalid by the REC Manager	0
Number of studies withdrawn prior to the meeting	1
Number of student applications reviewed	11
Number of paediatric applications reviewed	4
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**

Decisions taken at proportionate review sub-committee meetings	**Number**	**%**
Favourable Opinion with Standard Conditions	8	29.63
Favourable Opinion with Additional Conditions	6	22.22
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	13	48.15
Unfavourable Opinion	0	0.00
Total	**27**	**100**

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

Average number of applications reviewed per full meeting	5.20
Number of completed applications for full ethical review	51
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	1
Number of completed applications over 40 days as a % of total	1.92%
Number of days taken to final decision – average (mean)	30

Number of completed proportionate review applications for ethical review	26
Number of completed proportionate review applications for ethical review over 21 days	5
Number of completed proportionate review applications over 14 days as a % of total	18.51%

Number of SSAs (non-Phase 1) reviewed	12
Number of completed applications for SSA review over 25 days	1
Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs	8.33%

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	157
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	2
Number of completed substantial amendments over 28 days as a % of total substantial amendments	1.27%

Number of modified amendments reviewed	3
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	119
Number of substantial amendments received for information	1
Number of substantial amendments received for new sites/PIs	47
Number of annual progress reports received	100

Number of safety reports received	74
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/WM/0162	Effect of peripheral defocus on axial growth in hyperopes	35
16/WM/0170	ISIS 304801-CS7 - The APPROACH Open-Label Extension	33
16/WM/0197	RO5459072 in Primary Sjogren's Syndrome	55
16/WM/0198	Patient reported outcomes in rare diseases	24
16/WM/0255	The Utility of Subcutaneous ICDs in the ACHD Population	26
16/WM/0260	An EQA scheme for TPMT activity and thiopurine metabolites v.2.2.	29
16/WM/0261	RCT Online intervention supporting 12-17 yr olds with skin disease	25
16/WM/0263	Therapists' and clients' experiences of therapeutic endings	34
16/WM/0264	Cognitive difficulty or "brain fog" in newly diagnosed coeliac disease	37
16/WM/0265	The TREADON pilot and feasibility trial (Version I)	34
16/WM/0300	Determining the SPSQ as a symptom validity test.	36
16/WM/0306	Mother's experience of the diagnostic process of ASD	40
16/WM/0313	B-cell Responses to Pneumococcal Vaccination in HIV-infected patients	39
16/WM/0314	Jobe study- Monitoring the brain function after cardiac arrest	30
16/WM/0315	Jobe study- Monitoring the brain function after head injury	30
16/WM/0353	Antimicrobial urinary catheter safety study	28
16/WM/0359	Blinatumomab in Aggressive B-Cell Non Hodgkin Lymphoma	39
16/WM/0363	PASART 2	21
16/WM/0365	A study of a new medicine for the treatment of ulcerative colitis	27
16/WM/0428	How We Understand Hallucinations 2 (HUsH2)	31
16/WM/0436	AGB002 - SAIT101 vs Rituximab in patients with low tumour burden FL	25
16/WM/0437	Ariel 4	38
16/WM/0458	REVERE Breathe : Version 1	25
16/WM/0460	Social climate and aggression v1	23
16/WM/0464	Edoxaban treatment versus VKA in patients with AF undergoing PCI	33
16/WM/0471	Phase 2 - MBX-8025 in Participants with Primary Biliary Cholangitis	30
16/WM/0472	CONFIRM	28
16/WM/0473	CA209-817 - Nivolumab and Ipilimumab in advanced malignancies	32
16/WM/0507	CAIN457F2366 (EXCEED 1) Secukinumab compared with Adalimumab in PsA	23
16/WM/0511	071102 - BAX 111 rVWF in Paediatrics	36
16/WM/0512	AEGIS Kids PK (ST10-01-103)	33
16/WM/0513	Phase 2 study of INCB054828 for FGFR1-rearranged neoplasms	27

17/WM/0010	Patient-reported outcome measures in chronic kidney disease	33
17/WM/0011	Phase II Placebo-Controlled Study of Atacicept in IgA Nephropathy	27
17/WM/0017	MifeMiso	23
17/WM/0021	Phase 2 - GS-9674 in patients with NASH	23
17/WM/0031	FOAMI v1.0	29
17/WM/0049	Magic - Magnetic resonance imaging in paediatric constipation	30
17/WM/0059	Gastric Emptying: in vivo studies to determine normal ranges	26
17/WM/0060	CLR_16_22_Ph2 Safety&Efficacy Tildrakizumab in Pts with AS or nr-axSA	23
17/WM/0101	The experiences of parents whose children have required ECLS	34
17/WM/0105	GSK525762 in combination with fulvestrant in the treatment of ER+BC	37
17/WM/0110	PHITT	35

Further Information Favourable Opinion with Additional Conditions		
REC Reference	**Title**	**Number of Days on Clock**
17/WM/0050	Tommy's Net	22

Further Information Unfavourable Opinion		
REC Reference	**Title**	**Number of Days on Clock**
None		

Favourable Opinion with Standard Conditions		
REC Reference	**Title**	**Number of Days on Clock**
16/WM/0356	Open-label ALN-AS1 in Patients with Acute Intermittent Porphyria	27

Favourable Opinion with Additional Conditions		
REC Reference	**Title**	**Number of Days on Clock**
16/WM/0276	SNIFFLE-4 Study	27
16/WM/0501	WISTERIA: WEE1 inhibitor with Cisplatin and Radiotherapy	29
17/WM/0007	REVERE Move: Version 1	21
17/WM/0057	Early Cardiac Rehabilitation Exercise for Sternotomy Patients.	23
17/WM/0102	V1:Routine evaluation of clinical outcomes in a psychotherapy service	21
17/WM/0106	MRI for early response prediction to anti-TNF therapy	25

Unfavourable Opinion		
REC Reference	**Title**	**Number of Days on Clock**
None		

Provisional Opinion		
REC Reference	**Title**	**Number of Days on Clock**
None		

Provisional Opinion Pending Consultation with Referee		
REC Reference	**Title**	**Number of Days on Clock**
None		

Further information response not complete		
REC Reference	**Title**	**Number of Days on Clock**
None		

Withdrawn after the meeting		
REC Reference	**Title**	**Number of Days on Clock**
17/WM/0061	CLR_16_23Phase2b study of Tildrakizumab for Active Psoriatic Arthritis	21

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/WM/0180	Companion Study	24
16/WM/0269	Understanding patients' perceptions and experiences of DOT: Version 1	17
16/WM/0331	Using games as neuropsychological tests with children with ABI (V1)	13

16/WM/0444	Our Visit	9
16/WM/0445	Patient Reported Outcome Measure In Skin Cancer Reconstruction Study	17
17/WM/0024	Advanced theory of mind assessment in frontotemporal dementia	25
17/WM/0025	Validation of craving automated scale for substance addiction	23
17/WM/0026	Exploring Medication Adherence in Kidney Transplant Recipients	20
17/WM/0027	Goals in Mind	15
17/WM/0063	ABT-foodASIT001	19
17/WM/0064	cardiac anatomy revealed by micro-CT of archived heart samples	12
17/WM/0065	Prevalence of atopy in male genital lichen sclerosus	22

Further Information Favourable Opinion with Additional Conditions		
REC Reference	**Title**	**Number of Days on Clock**
None		

Further Information Unfavourable Opinion		
REC Reference	**Title**	**Number of Days on Clock**
None		

Favourable Opinion with Standard Conditions		
REC Reference	**Title**	**Number of Days on Clock**
16/WM/0188	Biomarker development in prostate cancer: a sub-study of STAMPEDE	16
16/WM/0380	Prognostication in Burns	6
16/WM/0446	Pilot study of patient reported outcomes with Trabectedin	15
16/WM/0474	Computational study for optimization of a patient-specific spinal cage	11
16/WM/0506	Comprehensive assessment of older people with cancer	17
16/WM/0509	Family Resilience Study Phase 2	17
17/WM/0104	Improving Primary Care After Stroke: Testing a new stroke service	11
17/WM/0107	Driving and TIAs	15

Favourable Opinion with Additional Conditions		
REC Reference	**Title**	**Number of Days on Clock**
16/WM/0178	EPROS - Disease Registry Salvage Antiviral Therapy post HSCT	29

16/WM/0230	Use of LiDCOplus in fluid resuscitation decision-making	10
16/WM/0274	REplicating MeAsurements of Total Haemoglobin The 'REMATcH' study	9
16/WM/0468	Neuroimaging predictors of RA fatigue	16
17/WM/0108	InS:PIRE evaluation	14
17/WM/0109	Epidemiological study of influences on Gorlin syndrome outcome	9

Unfavourable Opinion		
REC Reference	**Title**	**Number of Days on Clock**
None		

Provisional Opinion		
REC Reference	**Title**	**Number of Days on Clock**
None		

Further information response not complete		
REC Reference	**Title**	**Number of Days on Clock**
17/WM/0066	S-AVANT observational study follow up	n/a

Withdrawn after the meeting		
REC Reference	**Title**	**Number of Days on Clock**
None		

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**
01/7/026/AM25	An Open Label, Randomised Multicentre Comparative Trial of 5 Years Adjuvant Exemestane Treatment Versus Tamoxifen followed by Exmestane in Postmenopausal Women With Early Breast Canc	AM11	13/05/2016	8
02/7/106/AM17	BSPAR Etanercept Cohort Study	SA07	06/06/2016	15
04/MRE07/35/AM116	Stampede (version 1.0) – PR08	MRC PR08	29/03/2016	13
04/MRE07/35/AM124	Stampede (version 1.0) – PR08	SA08.03.17	09/03/2017	19
05/MRE07/25/AM22	The IMPACT Study, Version 8, February 2005	21	27/06/2016	19
05/MRE07/26/AM21	Dialysis Outcomes and Practice Patterns Study (DOPPS) v.2	DOPPS 6 2016	29/04/2016	28
05/MRE07/62/AM23	BILCAP Phase III Research Trial, version 1.4	Protocol V8	09/09/2016	9
06/MRE07/36/AM19	Mild bleeding disorders caused by platelet defects - v2-1	17	11/04/2016	10
06/MRE07/40/AM12	Cognitive processes underlying disorders of memory	7	14/12/2016	26
09/H1208/31/AM07	Bone health in breast cancer survivors	SubAM01	16/01/2017	25
09/H1208/33/AM30	A3921024 RA long term follow up of CP-690,550	22.04.16	22/04/2016	24
09/H1208/42/AM22	Axi-STS Trial, version 1	AM11	13/04/2016	27
11/WM/0279/AM11	NECTAR-HF Research Study	AE Withdrawal	25/04/2016	20
11/WM/0341/AM21	Efficacy of Lenalidomide/Dexamethasone +/-Elotuzumab in untreated MM	9	18/05/2016	13
11/WM/0341/AM22	Efficacy of Lenalidomide/Dexamethasone +/-Elotuzumab in untreated MM	SA20.12.2016	20/12/2016	12
11/WM/0375/AM08	A Phase 1b/2 Study of MEDI-573, with AI comparator in Breast Cancer	3	03/01/2017	19
12/WM/0077/AM05	Immune cell function and metabolism in rheumatoid arthritis: version1	2	11/08/2016	21
12/WM/0306/AM11	WP4 Exercise Outcome Study	7	23/09/2016	15
12/WM/0341/AM77	AMG 145 and Statin Therapy in patients with Cardiovascular Disease	49	18/07/2016	7
12/WM/0341/AM79	AMG 145 and Statin Therapy in patients with Cardiovascular Disease	53	10/08/2016	15

13/WM/0114/AM15	SHINE MCL3002	10	07/06/2016	8
13/WM/0140/AM05	Stopping nilotinib treatment for CML patients	SA3	09/05/2016	23
13/WM/0232/AM09	Decitabine for Acute Myeloid Leukaemia in Children	03.06.16	03/06/2016	21
13/WM/0277/AM09	The Subjective Experience of Auditory Verbal Hallucinations	13.06.16	07/06/2016	11
13/WM/0304/AM04	SPIRO - CKD	SA4	28/11/2016	22
13/WM/0311/AM18	Effects of Liraglutide in Young adults with Type 2 DIAbetes (LYDIA)	SA7	03/08/2016	11
13/WM/0365/AM07	A 3 yr extension study of Secukinumab in Psoriatic Arthritis patients	6	30/08/2016	18
13/WM/0365/AM09	A 3 yr extension study of Secukinumab in Psoriatic Arthritis patients	6	30/08/2016	15
13/WM/0400/AM07	Steroid tape to treat overgranulating PD exit sites	4	15/06/2016	12
13/WM/0483/AM05	Understanding sex differences in disruptive behaviour version 1	3	11/03/2016	4
14/WM/0013/AM14	Developing a new drug to treat infants hospitalised with RSV infection	9	24/10/2016	24
14/WM/0013/AM15	Developing a new drug to treat infants hospitalised with RSV infection	10	19/12/2016	9
14/WM/0049/AM07	NN7999-3895 Trial Evaluating Safety & Efficacy of N9-GP in Haem B PUPs	SA04	28/02/2017	19
14/WM/0052/AM08	PARTNERS2: collaborative care for people with serious mental illness	AM07	31/05/2016	7
14/WM/0052/AM09	PARTNERS2: collaborative care for people with serious mental illness	AM08	04/08/2016	10
14/WM/0112/AM11	NOVOCART 3D PLUS (N3D) Study	4	23/06/2016	10
14/WM/0122/AM02	Wound healing & adaptation following breast reconstruction	SA1	23/03/2016	15
14/WM/0135/AM15	Daratumumab+Rd vs Rd in Relapsed or Refractory Multiple Myeloma	8	24/06/2016	10
14/WM/0135/AM16	Daratumumab+Rd vs Rd in Relapsed or Refractory Multiple Myeloma	18.08.16	18/08/2016	20
14/WM/0135/AM17	Daratumumab+Rd vs Rd in Relapsed or Refractory Multiple Myeloma	SA10	25/11/2016	10
14/WM/0170/AM10	Phase III study of Momelotinib in Patients with Myelofibrosis	6	29/04/2016	28
14/WM/0170/AM11	Phase III study of Momelotinib in Patients with Myelofibrosis	SA#07	19/09/2016	16
14/WM/1029/AM03	Drug Utilization Study of Stribild in Adults with HIV	1	03/04/2016	8
14/WM/1036/AM07	Child weigHt mANaGement for Ethnically diverse	6	16/06/2016	4

	communities: CHANGE			
14/WM/1055/AM07	Masitinib/Placebo + FOLFIRI in Metastatic Colorectal Cancer V1.0	6	01/04/2016	6
14/WM/1055/AM08	Masitinib/Placebo + FOLFIRI in Metastatic Colorectal Cancer V1.0	7	14/04/2016	11
14/WM/1055/AM09	Masitinib/Placebo + FOLFIRI in Metastatic Colorectal Cancer V1.0	Combined Investigators Brochure	04/01/2017	10
14/WM/1143/AM12	SMT19969/C003	6	01/06/2016	8
14/WM/1146/AM04	CHHIP (Cellular humoral and hormonal control of immunity in pregnancy)	2	31/03/2016	8
14/WM/1146/AM05	CHHIP (Cellular humoral and hormonal control of immunity in pregnancy)	3	24/11/2016	9
14/WM/1170/AM05	CompARE Trial, Version 1.0	5	28/04/2016	24
14/WM/1170/AM07	CompARE Trial, Version 1.0	AM07	22/07/2016	6
14/WM/1170/AM09	CompARE Trial, Version 1.0	AM09	24/11/2016	8
14/WM/1185/AM08	Sofosbuvir/Ribavirin in Adolescents and Children	6	30/03/2016	13
14/WM/1185/AM10	Sofosbuvir/Ribavirin in Adolescents and Children	SA#7	11/11/2016	19
14/WM/1188/AM10	4054 - REAL 1 NNC0195-0092 in adults with growth hormone deficiency	SA04	18/07/2016	20
14/WM/1188/AM13	4054 - REAL 1 NNC0195-0092 in adults with growth hormone deficiency	1.0	12/01/2017	21
14/WM/1200/AM20	AFGEN: Long-term Registry of Atrial Fibrillation patients	3	03/01/2017	17
14/WM/1212/AM01	SUBMIT	24.03.16	24/03/2016	20
14/WM/1213/AM10	ROSCO V1.0, 15th October 2014	8	04/11/2016	23
14/WM/1260/AM05	PHAZAR	3	24/10/2016	25
15/WM/0009/AM09	Daratumumab + VMP vs VMP only in newly diagnosed multiple myeloma	SA5	02/03/2017	14
15/WM/0011/AM04	ADC-1013 First-in-Human Study	03	18/05/2016	14
15/WM/0011/AM05	ADC-1013 First-in-Human Study	UK4	12/08/2016	21
15/WM/0011/AM06	ADC-1013 First-in-Human Study	SA REC UK05	24/10/2016	25
15/WM/0015/AM06	A Dose Finding Study In Pediatric Subjects With Biliary Atresia.	4	03/05/2016	24
15/WM/0057/AM01	The SONIC study	2	26/07/2016	6
15/WM/0070/AM02	Generation of human cell lines from tumour tissue	V3 19/10/2016	19/10/2016	24
15/WM/0071/AM05	Isle of Wight Birth Cohort 26 Year Follow-up	3	12/05/2016	16

15/WM/0092/AM06	LOTUS	AM05	31/05/2016	15
15/WM/0092/AM08	LOTUS	SA06	03/03/2017	8
15/WM/0102/AM05	Randomised Trial To Evaluate 3 Daratumumab Dose Schedules in SMM	SA03	15/11/2016	22
15/WM/0126/AM09	Torch	9	08/07/2016	10
15/WM/0139/AM10	UCB5857 For Participants with Primary Sjogren's Syndrome	6	07/04/2016	5
15/WM/0139/AM12	UCB5857 For Participants with Primary Sjogren's Syndrome	8	12/07/2016	20
15/WM/0139/AM13	UCB5857 For Participants with Primary Sjogren's Syndrome	SA9	03/08/2016	19
15/WM/0148/AM01	Observational study for frailty load on colorectal unit	2	12/05/2016	3
15/WM/0211/AM06	Phase 1b Study in Subjects with Multiple Myeloma ACE-MY-001	SA3	09/08/2016	4
15/WM/0238/AM03	4153: Once Daily Semaglutide in Obese Subjects without DM	Protocol Amendment 3	12/10/2016	9
15/WM/0238/AM05	4153: Once Daily Semaglutide in Obese Subjects without DM	4	07/12/2016	20
15/WM/0242/AM01	PM CT and MRI in Children	01	24/08/2016	8
15/WM/0242/AM02	PM CT and MRI in Children	SA2	09/02/2017	12
15/WM/0245/AM02	Emotion recognition in people with Parkinson's (SPiEs) v1.0	SA1	13/02/2017	28
15/WM/0255/AM03	Biological correlates of dimensional symptoms of psychosis (BioPoP)	2	01/08/2016	15
15/WM/0263/AM02	GS-US-401-1787,Open label Study - Long-term Safety of ONO/GS-4059	IB 6th Edition	11/08/2016	4
15/WM/0263/AM03	GS-US-401-1787,Open label Study - Long-term Safety of ONO/GS-4059	SA3	14/02/2017	27
15/WM/0268/AM05	ENRICH Ibrutinib for untreated mantle cell lymphoma	SA3	20/01/2017	20
15/WM/0275/AM01	Genetic analysis of ovarian granulosa cell tumours	1	23/11/2016	14
15/WM/0312/AM03	Isolation of mucins from patient sputum	1	04/10/2016	14
15/WM/0327/AM05	TReatment Of Pulmonary HYpertension (TROPHY) 1 study, UK version 1	2	16/08/2016	11
15/WM/0339/AM03	Improving outcomes in children exposed to excess steroid hormones	2	22/06/2016	12
15/WM/0363/AM02	COBALT: Study of Obeticholic Acid in Primary Biliary Cirrhosis	02	29/03/2016	20
15/WM/0363/AM03	COBALT: Study of Obeticholic Acid in Primary Biliary Cirrhosis	SA03	02/06/2016	7
15/WM/0363/AM06	COBALT: Study of Obeticholic Acid in Primary Biliary Cirrhosis	SA05	10/11/2016	20
15/WM/0364/AM07	Phase 2 - MBX-8025 in Participants with Primary Biliary Cirrhosis	SA5	05/05/2016	27
15/WM/0377/AM03	Study evaluating MEDI4736 + AZD9150/AZD5069 in solid	2	19/05/2016	12

	tumors & RMSCCHN			
15/WM/0377/AM06	Study evaluating MEDI4736 + AZD9150/AZD5069 in solid tumors & RMSCCHN	SA3	03/10/2016	22
15/WM/0377/AM07	Study evaluating MEDI4736 + AZD9150/AZD5069 in solid tumors & RMSCCHN	SA4	29/11/2016	10
15/WM/0377/AM08	Study evaluating MEDI4736 + AZD9150/AZD5069 in solid tumors & RMSCCHN	SA 5	10/03/2017	18
15/WM/0386/AM02	A qualitative study to explore engagement with cervical screening	1	14/06/2016	10
15/WM/0444/AM07	Lifestyle Health and Wellbeing Survey	7	08/08/2016	10
15/WM/0444/AM09	Lifestyle Health and Wellbeing Survey	9	17/11/2016	21
15/WM/0447/AM01	Cerebral vasomotor regulation in atrial fibrillation (CVR-AF)	01	09/06/2016	15
15/WM/0455/AM01	SAFE-TKR Study	SA1	02/03/2017	8
15/WM/0456/AM02	CGAI - The REGAIN Study (Treatment for Chronic Migraine)	I5Q-MC-CGAI	13/04/2016	27
15/WM/0456/AM04	CGAI - The REGAIN Study (Treatment for Chronic Migraine)	4	30/06/2016	27
15/WM/0456/AM06	CGAI - The REGAIN Study (Treatment for Chronic Migraine)	09/08/2016	09/08/2016	7
15/WM/0456/AM08	CGAI - The REGAIN Study (Treatment for Chronic Migraine)	SA6	17/02/2017	24
15/WM/0457/AM06	54767414MMY3010	SA04	26/04/2016	20
15/WM/0457/AM08	54767414MMY3010	5	26/09/2016	10
15/WM/0457/AM09	54767414MMY3010	SA06	05/12/2016	31
16/WM/0009/AM01	The ‘Can Do Ramadan’ Study	3.0	24/03/2016	13
16/WM/0009/AM02	The ‘Can Do Ramadan’ Study	SA2	04/05/2016	23
16/WM/0009/AM03	The ‘Can Do Ramadan’ Study	3.0	11/11/2016	15
16/WM/0009/AM04	The ‘Can Do Ramadan’ Study	SA4	03/02/2017	18
16/WM/0010/AM01	A phase II trial of pembrolizumab in NSCLC PS2 patients	1	04/04/2016	8
16/WM/0010/AM04	A phase II trial of pembrolizumab in NSCLC PS2 patients	SA03	08/02/2017	13
16/WM/0014/AM01	HOLDS	1	16/08/2016	20
16/WM/0019/AM01	A Phase 1 Study of DCR-PH1 in Patients with PH 1	20.04.16	20/04/2016	9
16/WM/0030/AM03	Outpatient Study - Prophylactic Administration of PrEP-001 Against HRV	SA02	13/06/2016	21
16/WM/0030/AM04	Outpatient Study - Prophylactic Administration of PrEP-001 Against HRV	SA03	18/11/2016	20
16/WM/0055/AM01	The relationship between CTCA and EPC count.	1	19/04/2016	25
16/WM/0096/AM01	Perception, Experience & Relationship with Food & Eating in CF Adults	SA1	20/03/2017	8
16/WM/0108/AM02	CABP	2	17/01/2017	22

16/WM/0108/AM03	CABP	SA03	10/02/2017	11
16/WM/0170/AM02	ISIS 304801-CS7 - The APPROACH Open-Label Extension	21.07.16	17/06/2016	7
16/WM/0170/AM03	ISIS 304801-CS7 - The APPROACH Open-Label Extension	2	16/08/2016	17
16/WM/0170/AM04	ISIS 304801-CS7 - The APPROACH Open-Label Extension	3	24/11/2016	7
16/WM/0170/AM05	ISIS 304801-CS7 - The APPROACH Open-Label Extension	4	04/01/2017	18
16/WM/0170/AM07	ISIS 304801-CS7 - The APPROACH Open-Label Extension	5	14/03/2017	14
16/WM/0178/AM03	EPROS - Disease Registry Salvage Antiviral Therapy post HSCT	UK02	20/09/2016	15
16/WM/0180/AM01	Companion Study	SA01	18/10/2016	4
16/WM/0197/AM01	RO5459072 in Primary Sjogren's Syndrome	SA01	28/07/2016	14
16/WM/0197/AM02	RO5459072 in Primary Sjogren's Syndrome	2	01/09/2016	15
16/WM/0197/AM04	RO5459072 in Primary Sjogren's Syndrome	3	06/12/2016	22
16/WM/0198/AM04	Patient reported outcomes in rare diseases	1	13/10/2016	12
16/WM/0255/AM01	The Utility of Subcutaneous ICDs in the ACHD Population	1	30/08/2016	20
16/WM/0264/AM01	Cognitive difficulty or “brain fog” in newly diagnosed coeliac disease	1	26/10/2016	14
16/WM/0276/AM01	SNIFFLE-4 Study	01	14/08/2016	18
16/WM/0353/AM03	Antimicrobial urinary catheter safety study	SA03	10/02/2017	11
16/WM/0356/AM02	Open-label ALN-AS1 in Patients with Acute Intermittent Porphyria	1.0	08/11/2016	15
16/WM/0356/AM03	Open-label ALN-AS1 in Patients with Acute Intermittent Porphyria	2	09/12/2016	23
16/WM/0356/AM05	Open-label ALN-AS1 in Patients with Acute Intermittent Porphyria	SA3	22/02/2017	19
16/WM/0436/AM01	AGB002 - SAIT101 vs Rituximab in patients with low tumour burden FL	SA1	20/02/2017	17
16/WM/0437/AM02	Ariel 4	1	01/12/2016	7
16/WM/0445/AM01	Patient Reported Outcome Measure In Skin Cancer Reconstruction Study	SA1	14/03/2017	8
16/WM/0464/AM01	Edoxaban treatment versus VKA in patients with AF undergoing PCI	SA1	10/02/2017	11
16/WM/0471/AM01	Phase 2 - MBX-8025 in Participants with Primary Biliary Cholangitis	1	25/01/2017	15
16/WM/0472/AM01	CONFIRM	SA1	13/02/2017	28
16/WM/0473/AM01	CA209-817 - Nivolumab and Ipilimumab in advanced malignancies	1	20/01/2017	10

16/WM/0501/AM01	WISTERIA: WEE1 inhibitor with Cisplatin and Radiotherapy	SA01	10/02/2017	11
16/WM/0512/AM03	AEGIS Kids PK (ST10-01-103)	SA1	10/02/2017	11
16/WM/0513/AM01	Phase 2 study of INCB054828 for FGFR1-rearranged neoplasms	SA1	15/02/2017	17
97/7/001/AM10		9	14/09/2016	1

Unfavourable opinion				
Amendment REC Reference	**Title**	**Version**	**Date**	**Number of Days on Clock**
13/WM/0140/AM06	Stopping nilotinib treatment for CML patients	4	15/11/2016	32
14/WM/0112/AM13	NOVOCART 3D PLUS (N3D) Study	SA05 - Countersigned	04/02/2017	22
16/WM/0359/AM01	Blinatumomab in Aggressive B-Cell Non Hodgkin Lymphoma	1	17/01/2017	15

Table 10.2: **Breakdown of current status of all modified amendments reviewed within the reporting period**

Favourable opinion timeline				
Amendment REC Reference	**Title**	**Version**	**Date**	**Number of Days on Clock**
13/WM/0140/AM06/1	Stopping nilotinib treatment for CML patients	Mod1 of SA4	06/02/2017	8
15/WM/0211/AM05/1	Phase 1b Study in Subjects with Multiple Myeloma ACE-MY-001	2	21/04/2016	7
16/WM/0359/AM01/1	Blinatumomab in Aggressive B-Cell Non Hodgkin Lymphoma	Modified Amendment 1	13/03/2017	4

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

Table 11: **Items exceeding timelines**

Full applications for ethical review over 60 day timeline		
REC Reference	**Title**	**Number of Days on Clock**

Proportionate review applications for ethical review over 21 day timeline		
REC Reference	**Title**	**Number of Days on Clock**
16/WM/0178	EPROS - Disease Registry Salvage Antiviral Therapy post HSCT	29
16/WM/0180	Companion Study	24
17/WM/0024	Advanced theory of mind assessment in frontotemporal dementia	25
17/WM/0025	Validation of craving automated scale for substance addiction	23
17/WM/0065	Prevalence of atopy in male genital lichen sclerosus	22

SSAs (non Phase 1) over 25 day timeline		
REC Reference	**Title**	**Number of Days on Clock**
16/WM/0349	A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events	29

SSAs (Phase 1) over 14 day timeline		
REC Reference	**Title**	**Number of Days on Clock**

Substantial Amendments over 35 day timeline				
Amendment REC Reference	**Title**	**Version**	**Date**	**Number of Days on Clock**

Modified Amendments over 14 day timeline				
Amendment REC Reference	**Title**	**Version**	**Date**	**Number of Days on Clock**