

**West Midlands - Coventry & Warwickshire
Research Ethics Committee**

Annual Report

01 April 2017 - 31 March 2018



Part 1 – Committee Membership and Training

Name of REC:	West Midlands - Coventry & Warwickshire Research Ethics Committee
Type of REC:	RECs recognised to review CTIMPS in patients - type iii
Type of Flag:	Phase 1 Studies in Patients, Qualitative Research, Research Involving Adults Lacking Capacity, Research Involving Children, Social Care Research
Chair:	Dr Helen Brittain
Vice-Chair:	Dr Ronald Jubb
Alternate Vice-Chair:	Professor Jane Appleton
REC Manager:	Ms Rachel Nelson (until May 2017) Mr Tad Jones (from July 2017)
REC Assistant:	Mr Adam Garretty
Committee Address:	The Old Chapel Royal Standard Place Nottingham NG1 6FS
Telephone:	02071048105
Email:	NRESCcommittee.WestMidlands-CoventryandWarwick@nhs.net

Chair's overview of the past year:

The Committee has continued to provide a really committed service but special thanks are due to Tad and Adam who work so hard to meet all the time pressures and the ever changing parameters of their task.

This year we have noticed an increase in the number of applicants who do not attend, and find this especially surprising and difficult when considering CTIMPs.

Perhaps better remote methods of contact, other than via a mobile phone, would enhance our ability to deal with this.

We have again enjoyed our Christmas meal in February thanks.

West Midlands - Coventry & Warwickshire Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Professor Jane Appleton	Nurse	Expert	01/04/2010	
Dr Josephine Ashcroft	Retired Research Nurse	Lay	26/06/2017	
Mr Roger Balcombe	Retired Chartered Engineer	Lay Plus	01/04/2010	
Dr Helen Brittain	Clinical Psychologist Retired	Lay	01/04/2010	
Ms Yasumati Damodar	Pharmacist	Expert	22/09/2015	
Mrs Louise Harmer	Undergraduate Medical Education Manager, Technology Enhanced Learning and Clinical Skills and Resuscitation Tutor	Expert	01/04/2010	
Dr Siew Wan Hee	Medical Statistician	Expert	07/02/2017	
Dr Ronald Jubb	Retired Consultant Rheumatologist	Expert	24/09/2014	
Dr Rebecca Keyte	Lecturer in Psychology	Lay Plus	29/03/2017	
Dr Aisha Malik	Part-time Tutor Medical ethics; Part-time and distance learning Tutor for Oxford University Department for continuing education (OUDCE).	Expert	03/11/2016	
Dr Karen Schofield	Retired Consultant Haematologist	Expert	14/08/2014	
Mrs Laura Strumidlo	Principal Lecturer Nursing	Expert	01/12/2016	
Mr Jonathan Ward	Retired Self-employed IT consultant	Lay Plus	27/02/2017	

West Midlands - Coventry & Warwickshire Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended
Mr Chris Foy	Medical Statistician	Expert	26/07/2017
Mrs Bernadette Roberts	Retired Finance Manager	Lay Plus	25/10/2017

West Midlands - Coventry & Warwickshire Research Ethics Committee: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Professor Jane Appleton	Trustee of the charity The British Association for the Study and Prevention of Child Abuse and Neglect (BASPCAN). External advisor to NICE. Reviewer for CLRN funding and NIHR funding applications.	09/01/2018
Dr Josephine Ashcroft	Reviewer of publications for the registered charity Breast Cancer Care (voluntary).	08/09/2017
Mr Roger Balcombe	None declared	06/01/2018
Dr Helen Brittain	Member of the Psychosocial team of British Red Cross. Trustee Warwickshire wildlife trust - assessing work with Mental Health Service users.	10/01/2018
Ms Yasumati Damodar	None declared.	24/01/2018
Mrs Louise Harmer	Registered General Nurse. Registered General Nurse. Undergraduate Medical Education & Technology Enhanced Learning Manager, George Eliot Hospital NHS Trust. Honorary Associate Clinical Professor, The University of Warwick Medical School. Executive Member, Nuneaton Gymnastics Club.	09/01/2018
Dr Siew Wan Hee	Senior Research Fellow with the Warwick Hub Research Design Service West Midlands and an active researcher in Warwick Medical School. Potentially a co-applicant on a number of research projects requiring REC review. Member of a Data Monitoring Committee on Rational MCC (a trial for Merkel Cell Carcinoma) and MERLIN, both sponsored by University of Birmingham.	09/01/2018
Dr Ronald Jubb	None declared	28/02/2018
Dr Rebecca Keyte	Lecturer in Health Psychology at Birmingham City University	28/02/2018
Dr Aisha Malik	IREC member and Co-Chair at the Medical School, University of Birmingham.	24/01/2018
Dr Karen Schofield	None declared.	08/01/2018
Mrs Laura Strumidlo	Principal Lecturer for Nursing at Coventry University	31/03/2018
Mr Jonathan Ward	None declared	05/01/2018

Meetings for Full Ethical Review 01 April 2017 - 31 March 2018:

Month	Date	Number of Members Present at Meeting
April	26/04/2017	8
May	24/05/2017	11
June	28/06/2017	9
July	26/07/2017	8
August	23/08/2017	8
September	27/09/2017	10
October	25/10/2017	7
November	22/11/2017	11
January	24/01/2018	10
February	28/02/2018	10

10 full committee meetings were held during the reporting period.

Proportionate Review Sub-Committee Meetings held during 01 April 2017 - 31 March 2018:

Month	Date	Number of Members Present at Meeting
April	26/04/2017	3
May	24/05/2017	3
June	29/06/2017	3
July	27/07/2017	3
August	22/08/2017	3
September	28/09/2017	3
October	26/10/2017	3
November	23/11/2017	3
January	08/01/2018	3
February	06/02/2018	3
March	12/03/2018	3

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

Sub-Committee Meetings held during 01 April 2017 - 31 March 2018:

Month	Date	Number of Members Present at Meeting
April	05/04/2017	2
April	20/04/2017	2
May	08/05/2017	2
May	08/05/2017	2
May	11/05/2017	2
May	25/05/2017	2
June	08/06/2017	3
June	22/06/2017	2
July	06/07/2017	2
July	20/07/2017	2

August	17/08/2017	2
August	31/08/2017	2
September	28/09/2017	2
October	12/10/2017	2
November	03/11/2017	2
November	23/11/2017	2
December	07/12/2017	2
January	04/01/2018	2
February	01/02/2018	2
March	01/03/2018	2
March	15/03/2018	2
March	29/03/2018	2

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

Details of inquorate meeting held: 01 April 2017 - 31 March 2018

None.

Attendance of Members at full committee meetings:01 April 2017 - 31 March 2018

Name	Number of Meetings Attended
Professor Jane Appleton	5
Dr Josephine Ashcroft	6
Mr Roger Balcombe	7
Dr Helen Brittain	10
Ms Yasumati Damodar	8
Mrs Louise Harmer	9
Dr Siew Wan Hee	4
Dr Ronald Jubb	9
Dr Rebecca Keyte	5
Dr Aisha Malik	5
Dr Karen Schofield	7
Mrs Laura Strumidlo	7
Mr Jonathan Ward	8

Attendance of Members at proportionate review sub-committee meetings: 01 April 2017 - 31 March 2018

Name	Number of Meetings Attended
Professor Jane Appleton	3
Mr Roger Balcombe	1
Dr Helen Brittain	9
Ms Yasumati Damodar	4
Mrs Louise Harmer	4
Dr Siew Wan Hee	1
Dr Ronald Jubb	4
Dr Rebecca Keyte	1
Dr Aisha Malik	3
Dr Karen Schofield	3

Attendance of Members at sub-committee meetings: 01 April 2017 - 31 March 2018

Name	Number of Meetings Attended
Professor Jane Appleton	3
Dr Josephine Ashcroft	1
Dr Helen Brittain	13
Ms Yasumati Damodar	5
Mrs Louise Harmer	5
Dr Siew Wan Hee	1
Dr Ronald Jubb	9

Dr Rebecca Keyte	1
Dr Aisha Malik	3
Dr Karen Schofield	3
Mrs Laura Strumidlo	1

Training 01 April 2017 - 31 March 2018

Name of Member	Date	Event(s) attended
Professor Jane Appleton	16/01/2018	Training for New REC Chairs
Dr Josephine Ashcroft	19/08/2017	Induction for new RES Committee members
Dr Josephine Ashcroft	29/09/2017	Regional Training day
Dr Josephine Ashcroft	23/10/2017	Equality, Diversity and Human Rights
Dr Josephine Ashcroft	04/11/2017	MCA Training
Dr Josephine Ashcroft	11/01/2018	Committee members induction
Dr Josephine Ashcroft	24/01/2018	Read journal articles on vulnerability and pregnant participants
Dr Helen Brittain	04/05/2017	Buddy / Mentor to Rebecca Keyte
Dr Helen Brittain	31/01/2018	Complex cases
Dr Helen Brittain	12/05/2017	Chairs Meeting West Midlands
Dr Helen Brittain	02/11/2017	Chairs Meeting East/West Midlands
Ms Yasumati Damodar	12/06/2017	Safeguarding children and vulnerable adults: level 2
Ms Yasumati Damodar	14/11/2017	Read articles on vulnerability, placebo, stratified trials and multiarm, multistage trials
Mrs Louise Harmer	29/09/2017	Regional Training Day
Dr Siew Wan Hee	06/04/2017	Induction for new Research Ethics Service Committee members
Dr Siew Wan Hee	07/04/2017	Diversity in the Workplace Training
Dr Siew Wan Hee	02/05/2017	Member's Induction
Dr Siew Wan Hee	12/12/2017	Training - National Members Training Day
Dr Ronald Jubb	16/10/2017	Medical Devices
Dr Ronald Jubb	02/11/2017	Chairs Meeting East/West Midlands
Dr Rebecca Keyte	27/04/2017	Online Induction
Dr Rebecca Keyte	31/07/2017	Equality, Diversity and Human Rights
Dr Rebecca Keyte	07/08/2017	Getting results faster briefing
Dr Rebecca Keyte	08/08/2017	Reading - When should placebo surgery as a control in clinical trials be carried out
Dr Rebecca Keyte	10/08/2017	Reading - Consider drug efficacy before first in human trials
Dr Rebecca Keyte	11/08/2017	Reading -Should research ethics committees police reporting bias
Dr Rebecca Keyte	14/08/2017	Reading - The impossibility of informed consent
Dr Rebecca Keyte	21/09/2017	Committee members induction

Dr Aisha Malik	02/05/2017	REC Members Induction
Dr Aisha Malik	13/11/2017	Read 'The concept of vulnerability in research ethics'
Dr Aisha Malik	12/12/2017	Read research governance framework & research using anonymised data
Dr Aisha Malik	01/01/2018	E-modules on Human tissue research and confidentiality & Information governance considerations in research
Dr Aisha Malik	05/01/2018	Lectured on Transplantation and organ donation with ref to HTA 2004
Dr Aisha Malik	06/03/2018	Facilitated training "assessing the risk and consequences of research"
Dr Karen Schofield	26/09/2017	MCA Training
Dr Karen Schofield	07/10/2017	Reflection on MCA studies
Dr Karen Schofield	08/11/2017	The Ethical Issues of Research Involving Children
Mrs Laura Strumidlo	02/05/2017	Member's Induction
Mrs Laura Strumidlo	21/06/2017	Research data management
Mrs Laura Strumidlo	01/09/2017	Co-Chair of Heart of England NHS Foundation Trust Clinical Ethics Committee
Mrs Laura Strumidlo	01/09/2017	Chair of CU Health and Life Science Faculty Ethics and Governance Committee
Mrs Laura Strumidlo	01/09/2017	Presented Health and Social Care research training
Mrs Laura Strumidlo	01/09/2017	Induction for new Research Ethics Service Committee members
Mrs Laura Strumidlo	01/09/2017	Equality Diversity and Human Rights
Mrs Laura Strumidlo	29/09/2017	Regional Training Day
Mr Jonathan Ward	25/07/2017	New members induction
Mr Jonathan Ward	31/07/2017	Equality Diversity and Human Rights

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	6	12.00
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	1	2.00
Others	43	86.00
Total Applications Reviewed	50	100

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

Number of applications made invalid by the REC Manager	0
Number of applications withdrawn prior to the meeting	1
Number of student applications reviewed	21
Number of paediatric applications reviewed	8
Number of device applications reviewed	1
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	14
Number of applications reviewed that are funded by the US DHHS	0
Number of qualitative applications reviewed	17

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	2.00
Favourable Opinion with Additional Conditions	6	12.00
Unfavourable Opinion	2	4.00
Provisional Opinion	41	82.00
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	50	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	34	68.00
Further Information Favourable Opinion with Additional Conditions	6	12.00
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	1	2.00
Favourable Opinion with Additional Conditions	6	12.00
Unfavourable Opinion	2	4.00
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	2.00
Total	50	100

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

Total Applications Reviewed	30
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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	0
Number of studies withdrawn prior to the meeting	0
Number of student applications reviewed	11
Number of paediatric applications reviewed	4
Number of device applications reviewed	1
Number of qualitative applications reviewed	1

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	26.67
Favourable Opinion with Additional Conditions	5	16.67
No Opinion transfer to full committee for review	1	3.33
Provisional Opinion	15	50.00
Unfavourable Opinion	1	3.33
Total	30	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	5.00
Number of completed applications for full ethical review	49
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 days taken to final decision – average (mean)	35
Number of completed proportionate review applications for ethical review	29
Number of completed proportionate review applications for ethical review over 21 days	7
Number of completed proportionate review applications over 21 days as a % of total	24.14%
Number of SSAs (non-Phase 1) reviewed	3
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	33.33%
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	128
Number of completed substantial amendments over 35 days	2
Number of completed substantial amendments over 35 days as a % of total substantial amendments	1.56%
Number of modified amendments reviewed	1
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	138
Number of substantial amendments received for information	2
Number of substantial amendments received for new sites/PIs	33
Number of annual progress reports received	67
Number of safety reports received	47
Number of Serious Adverse Events received	2
Number of final reports received	14

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
17/WM/0121	Understanding People's Experiences of the Enroll-HD Study	37
17/WM/0134	ReSPECT evaluation	33
17/WM/0162	Parental coping during a child's life changing hospital admission	34
17/WM/0209	Validation and Reliability testing of a Nurse Dysphagia Assessment	60
17/WM/0210	Dose-escalating study evaluating safety, PK & PD in psoriasis patients	34
17/WM/0231	Pre-Conception Genetic Screening Study	44
17/WM/0232	Care home staffing and quality of care	49
17/WM/0236	Perspectives on care and support for young adults with a stoma v1.0	26
17/WM/0240	Pre-conception genetic screening - Musketeer's Memorandum study	44
17/WM/0252	Wide Awake Club study	36
17/WM/0268	Parents Experiences of Parenting Preterm Multiples	39
17/WM/0275	Co-design of an ehealth SMS programme for people with MCI	41
17/WM/0279	CHIPS+	37
17/WM/0281	PRO/GLY/004 12 May 2017 V2.0	34
17/WM/0282	Pfizer Paediatric VTE Treatment study	29
17/WM/0294	Circadian Lighting Study	37
17/WM/0308	ALPINE 2: AZLI for children with CF and PA lung infection	53
17/WM/0310	The UnPiCK study version 1	40
17/WM/0311	ASPIRE-SSI	41
17/WM/0313	The communication of benign biopsy results in NHS Breast Screening V.1	29
17/WM/0315	The impact of endometriosis on pregnancy	36
17/WM/0341	Language Processing After Trauma (LPAT)	28
17/WM/0364	Nutrient Intervention Pilot Study	32
17/WM/0370	Assist-HHD	31
17/WM/0373	Care homes' safety culture and sense making	43
17/WM/0409	Needs and Experiences of Women with FGM in the Post-partum Period	44
17/WM/0424	Stars Together Rare Disease Registry	23
17/WM/0425	A clinical trial involving research of the house dust mite SLIT-tablet	31
18/WM/0001	Moral Distress in Moderate to Advanced Dementia Care - MDIG001	35
18/WM/0023	Patients perceptions of the secure inpatient hospital experience	34
18/WM/0025	START:REACTS	28
18/WM/0053	UPSTREAM (EORTC 1559-HNCG)	37

18/WM/0057	Motor neurone disease patients' views about genetic testing for MND	37
18/WM/0058	Service User and Professional Views on Relapse Prevention Plans	43

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
17/WM/0137	Med reviews in Wolverhampton-based care homes - Qual evaluation v1	30
17/WM/0170	Discharge Communication PhD	33
17/WM/0211	FRAIL TOOLS - Validation of frailty scales	38
17/WM/0344	Mini-Fluid bolus	25
17/WM/0390	Seated Physical Activity in Ageing (SPAA)	48
17/WM/0400	The effect of environment on the care of older people with confusion	27

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

Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
17/WM/0089	DePPaRT	26

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
17/WM/0184	Lemkids	26
17/WM/0230	Does sperm DNA integrity affect embryo cleavage patterns?	26
17/WM/0345	Personal Social Services Adult Social Care Survey, England, 2017-18	22
17/WM/0354	Patient and Carer experience of post-stroke motor apraxia	36
17/WM/0380	Ethical and Spiritual Care in Residential Care for Older People	35
18/WM/0030	Brain Imaging of Anaesthesia, version 1.0	23

Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock
17/WM/0274	Improving choices for care	22

18/WM/0046	Safeguarding and Self-Neglect Post Care Act (2014)	25
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Provisional Opinion

REC Reference	Title	Number of Days on Clock
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Provisional Opinion Pending Consultation with Referee

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

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

REC Reference	Title	Number of Days on Clock
17/WM/0375	Do coatings aid swallowability?	41

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
17/WM/0166	Questionnaire to elicit views on complications after cardiac surgery	20
17/WM/0214	Midline approach in Sacrococcygeal teratoma excision	15
17/WM/0330	Xolaris	21
17/WM/0332	Investigating gut bacteria and Bregs in SLE	15
17/WM/0366	iView Expert: explicating medical practitioner's expertise.	18
17/WM/0367	Investigating outcomes in adults with early-treated phenylketonuria	12
17/WM/0368	Practicing taking steps for balance recovery for stroke survivors	18
17/WM/0394	Baltic Art Therapy Group 2018	20
17/WM/0395	Psychiatric Nursing Observations at night: a qualitative study	19
17/WM/0396	International validation of the EORTC QLQ-ANL27	22

17/WM/0434	Glutamate in glioma related seizures	14
17/WM/0435	Assessment of accommodation in anisometropia with dynamic retinoscopy	22
18/WM/0009	SoMoR – UK (Study of Management of RAASi in UK)	26
18/WM/0011	Study of blood pressure: What matters in Later Life? The SWaLLow Study	30
18/WM/0068	Oral biofilm study_Ansbro	34

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
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Favourable Opinion with Standard Conditions

REC Reference	Title	Number of Days on Clock
17/WM/0165	Impact of media systems on embryo development and outcomes	17
17/WM/0167	Using vital sign data in the development of cardiac surgery outcomes	17
17/WM/0295	Differential topological accumulation of gastric somatic mutations	18
17/WM/0296	MYCO WELL D-ONE	19
17/WM/0331	Nystagmus duration after caloric irrigations	11
17/WM/0333	Characterisation of HIV-1 infection of immune cells	14
18/WM/0012	Developing a Dynamic Progress Feedback System v1	25
18/WM/0045	Advanced MRI in low grade gliomas	12

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
17/WM/0264	SUPPORT Study	14
17/WM/0298	Does cryotherapy of the far peripheral retina affect visual function?	18
17/WM/0432	5 and 10 year follow up of the WRAP trial (WRAP Up)	18
18/WM/0008	Co-construction of illness narratives in medical encounters	26
18/WM/0044	PIN study (IRAS 172458) laboratory collaboration - Netherlands	12

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
17/WM/0168	UFE for Fibroids: Comparison of Gel-Bead to Common Embolic Agents	20

Provisional Opinion

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

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

REC Reference	Title	Number of Days on Clock
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Table 10.1: Breakdown of current status of all substantial amendments reviewed within the reporting period

Favourable opinion				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
04/Q2802/26/AM10	Indicators of oocyte and embryo development - version 1	11	28/03/2017	9
05/Q2802/26/AM04	arterial calcification, version 4	AM03/01	30/03/2017	15
05/Q2802/26/AM05	arterial calcification, version 4	04/01	22/10/2017	23
07/H1211/96/AM05	SECONDARY SCREENING IN FAMILIAL PANCREATIC CANCER (v.1)	5	23/10/2017	31
09/H1211/38/AM22	FaMIsHED study	11	01/12/2017	17
10/H1210/1/AM15	Understanding Behaviour in Neurodevelopmental Disorders_V1	7	27/07/2017	28
10/H1210/1/AM16	Understanding Behaviour in Neurodevelopmental Disorders_V1	8	06/02/2018	20
11/WM/0367/AM08	IMMUNOTACE	6	13/09/2017	22
11/WM/0367/AM09	IMMUNOTACE	7	03/11/2017	21
12/WM/0001/AM21	WOLLF - Wound Management of Open Lower Limb Fractures	11	27/03/2017	22
12/WM/0149/AM18	3659 Liraglutide in children & adolescents with Type 2 diabetes	Global Protocol Amendment 13	20/04/2017	26
12/WM/0215/AM08	Apremilast(CC-10004) in the Treatment of Active Ankylosing Spondylitis	IB v18	01/06/2017	32
12/WM/0215/AM09	Apremilast(CC-10004) in the Treatment of Active Ankylosing Spondylitis	IB 19 & ICF V9.0	04/10/2017	33
12/WM/0340/AM22	UK Fixation of Distal Tibia Fractures(UK FixDT) V1.0	11	07/04/2017	10
13/WM/0466/AM05	Molecular Genetic Analysis and Clinical Studies (MGAC)	4	12/09/2017	7
13/WM/0466/AM06	Molecular Genetic Analysis and Clinical Studies (MGAC)	5	23/11/2017	16
14/WM/0019/AM14	PRONIA	7	10/05/2017	13
14/WM/0093/AM11	FOAM Trial, Version 1.0	AM08	28/03/2017	21
14/WM/0101/AM10	CA209-026 Nivolumab in advanced NSCLC	10	26/04/2017	27
14/WM/0101/AM11	CA209-026 Nivolumab in advanced NSCLC	11	05/09/2017	21
14/WM/0101/AM12	CA209-026 Nivolumab in advanced NSCLC	12	22/01/2018	15
14/WM/0156/AM10	Phase 2 Study of Enzalutamide with Trastuzumab in Breast Cancer	7	06/06/2017	23
14/WM/0182/AM05	CFZ533 in patients with primary Sjögren's syndrome	Updated Protocol 06	21/03/2017	16

14/WM/0182/AM06	CFZ533 in patients with primary Sjögren's syndrome	updated IB edition 6	28/04/2017	25
14/WM/0182/AM07	CFZ533 in patients with primary Sjögren's syndrome	Substantial Amendment 7.0 2017	19/06/2017	17
14/WM/1069/AM04	Multidetector Cardiac CT to guide CRT implantation	4	10/04/2017	11
14/WM/1072/AM02	LUCID	3	15/03/2017	10
14/WM/1103/AM12	1227 - Phase 2b double-blind study of hospitalised adults with RSV	IB 9.0	19/10/2016	23
14/WM/1145/AM11	PRISM Study: Study of I10E in Patients with CIDP	9	27/06/2017	16
14/WM/1209/AM10	CENTAUR - CVC	2017/06/13	13/06/2017	26
14/WM/1209/AM13	CENTAUR - CVC	Updated IB Edition 4.0	04/08/2017	19
14/WM/1211/AM12	IMPRESS-AF trial, version 1.0	7	17/07/2017	14
14/WM/1235/AM03	PRISM 2 - Study of I10E in Patients with CIDP	2	28/06/2017	15
15/WM/0036/AM28	Gabapentin for Pelvic Pain (GaPP 2)	20	02/02/2018	32
15/WM/0076/AM02	Understanding the Genomic Basis of Human Disease	1	12/07/2017	21
15/WM/0150/AM19	A Better Start Evaluation	7	05/04/2017	35
15/WM/0156/AM12	Study of the Progression of Choroideremia, V1, 23Mar2015	5	19/12/2017	35
15/WM/0207/AM06	A.R.R.O.W. Study	4	16/03/2017	21
15/WM/0207/AM07	A.R.R.O.W. Study	5	29/01/2018	9
15/WM/0222/AM08	DIASTOLIC	5	07/07/2017	20
15/WM/0232/AM01	Exploring patients' perceptions of root canal treatment	Protocol version 2	11/05/2017	14
15/WM/0261/AM16	ALIFE 2	12	06/06/2017	10
15/WM/0261/AM17	ALIFE 2	13	01/09/2017	28
15/WM/0261/AM25	ALIFE 2	18	24/11/2017	23
15/WM/0261/AM26	ALIFE 2	17	14/11/2017	22
15/WM/0261/AM27	ALIFE 2	19	19/12/2017	20
15/WM/0288/AM04	Supporting the emotional needs of renal patients v.1.	Protocol v14	30/03/2017	21
15/WM/0315/AM05	Lipodystrophy and Body Image: A Qualitative Analysis Version 1	2	05/07/2017	15
15/WM/0392/AM02	SARON	1	04/09/2017	14
15/WM/0392/AM03	SARON	2	09/11/2017	12
16/WM/0001/AM07	WHiTE Four	8	16/06/2017	21
16/WM/0004/AM02	Profiling anxiety in adolescents and adults with Williams Syndrome	2	03/04/2017	9

16/WM/0006/AM11	WHIST - Wound Healing In Surgery for Trauma	11	28/06/2017	15
16/WM/0034/AM03	EXTOD Education	1	25/04/2017	26
16/WM/0034/AM04	EXTOD Education	2	19/12/2017	23
16/WM/0076/AM06	Parenting of mothers with borderline personality disorder V1	5	08/05/2017	25
16/WM/0164/AM08	SMARTChip study	6	16/03/2017	21
16/WM/0164/AM09	SMARTChip study	7	07/06/2017	27
16/WM/0164/AM10	SMARTChip study	8	28/07/2017	23
16/WM/0164/AM11	SMARTChip study	9	27/10/2017	26
16/WM/0207/AM03	Childhood Hypertrophic Cardiomyopathy: A new risk stratification tool	Substantial Amendment 3	17/06/2017	21
16/WM/0215/AM07	Comparison of Humacyte's Human Acellular Vessel with ePTFE grafts V1.2	Administrative letters #1,2	22/03/2017	14
16/WM/0217/AM02	SIFTI-2	2	07/02/2017	33
16/WM/0285/AM03	Evolocumab (AMG 145) in HIV & Hyperlipidemia and/or Mixed Dyslipidemia	3	27/07/2017	26
16/WM/0285/AM04	Evolocumab (AMG 145) in HIV & Hyperlipidemia and/or Mixed Dyslipidemia	4	12/10/2017	32
16/WM/0299/AM05	COMPRESS-RCT	1	29/01/2018	31
16/WM/0299/AM06	COMPRESS-RCT	2	22/02/2018	18
16/WM/0317/AM05	Efficacy / safety of oral S44819 after recent ischemic cerebral event	4	24/05/2017	15
16/WM/0366/AM02	Long term follow up of NI-0501 in HLH patients	1	15/02/2018	20
16/WM/0369/AM03	Comparison of X-396 to Crizotinib in ALK Positive NSCLC Patients	2	17/08/2017	20
16/WM/0369/AM05	Comparison of X-396 to Crizotinib in ALK Positive NSCLC Patients	4	27/02/2018	15
16/WM/0391/AM02	Impacts of skill, uncertainties and delays on prosthesis functionality	2	22/05/2017	31
16/WM/0395/AM07	200807 Anaemia of CKD (dialysis): daprodustat vs erythropoietin	Amendment 2	27/03/2017	10
16/WM/0395/AM11	200807 Anaemia of CKD (dialysis): daprodustat vs erythropoietin	8	09/06/2017	21
16/WM/0395/AM14	200807 Anaemia of CKD (dialysis): daprodustat vs erythropoietin	3	25/01/2018	13
16/WM/0396/AM06	200808 Anaemia of CKD (non-dialysis): daprodustat vs darbepoetin alfa	Amendment 2	27/03/2017	10

16/WM/0396/AM09	200808 Anaemia of CKD (non-dialysis): daprodustat vs darbepoetin alfa	7	09/06/2017	21
16/WM/0396/AM11	200808 Anaemia of CKD (non-dialysis): daprodustat vs darbepoetin alfa	8	25/01/2018	13
16/WM/0424/AM01	Mucosal biomarkers of bowel cancer risk: 10 year follow-up of BORICC	1	11/04/2017	28
16/WM/0424/AM02	Mucosal biomarkers of bowel cancer risk: 10 year follow-up of BORICC	2	17/11/2017	10
16/WM/0433/AM03	Use of Thrombopoietin-Receptor Agonists in the management of ITP	1	30/06/2017	10
16/WM/0433/AM05	Use of Thrombopoietin-Receptor Agonists in the management of ITP	2	09/10/2017	25
16/WM/0435/AM01	The Behavioural Phenotype of Cornelia de Lange and Fragile X syndrome	1	23/03/2017	13
16/WM/0435/AM02	The Behavioural Phenotype of Cornelia de Lange and Fragile X syndrome	2	29/11/2017	31
16/WM/0448/AM03	Open label Study with Maribavir and Investigator-Assigned Tx for CMV	3	08/05/2017	22
16/WM/0448/AM05	Open label Study with Maribavir and Investigator-Assigned Tx for CMV	Protocol Amendment 3	01/03/2017	35
16/WM/0448/AM06	Open label Study with Maribavir and Investigator-Assigned Tx for CMV	5	06/12/2017	31
16/WM/0456/AM01	PIPS	PIPS Protocol V2.0	10/04/2017	27
16/WM/0456/AM02	PIPS	Substantial Amendment 2	31/05/2017	17
16/WM/0456/AM03	PIPS	Protocol V3	09/08/2017	23
16/WM/0478/AM02	LEO 90100 twice weekly maintenance regimen for psoriasis vulgaris	2	06/06/2017	33
16/WM/0479/AM02	INCLUDE: Using Lived Experience to Improve Mental Health Diagnosis V.1	2	31/05/2017	17
16/WM/0479/AM03	INCLUDE: Using Lived Experience to Improve Mental Health Diagnosis V.1	3	17/07/2017	18
16/WM/0493/AM01	360 Selfie	1	15/05/2017	8
17/WM/0032/AM02	Breath and urine organic compounds in GMP and Phe-free L-AA	Protocol version 3	14/01/2018	31
17/WM/0041/AM02	ASCEND-ID	SA 13.06.2017	13/06/2017	24

17/WM/0041/AM05	ASCEND-ID	Protocol Amendment 1	08/02/2018	32
17/WM/0077/AM02	BP39365 Phase 1b Study of RO6874281 in Metastatic Renal Cell Carcinoma	1	02/05/2017	16
17/WM/0077/AM03	BP39365 Phase 1b Study of RO6874281 in Metastatic Renal Cell Carcinoma	SA2	18/05/2017	13
17/WM/0077/AM04	BP39365 Phase 1b Study of RO6874281 in Metastatic Renal Cell Carcinoma	3	26/07/2017	37
17/WM/0077/AM05	BP39365 Phase 1b Study of RO6874281 in Metastatic Renal Cell Carcinoma	4	04/10/2017	32
17/WM/0077/AM07	BP39365 Phase 1b Study of RO6874281 in Metastatic Renal Cell Carcinoma	5	14/12/2017	28
17/WM/0079/AM03	SALIVA TO PREDICT DISEASE RISK (version 1)	1	07/07/2017	20
17/WM/0079/AM04	SALIVA TO PREDICT DISEASE RISK (version 1)	2	21/09/2017	11
17/WM/0079/AM06	SALIVA TO PREDICT DISEASE RISK (version 1)	3	03/11/2017	28
17/WM/0121/AM01	Understanding People's Experiences of the Enroll-HD Study	1	02/08/2017	19
17/WM/0134/AM03	ReSPECT evaluation	01	16/11/2017	25
17/WM/0134/AM04	ReSPECT evaluation	2	27/02/2018	25
17/WM/0137/AM01	Med reviews in Wolverhampton-based care homes - Qual evaluation v1	Protocol V4	04/08/2017	19
17/WM/0184/AM01	Lemkids	1	18/01/2018	35
17/WM/0210/AM01	Dose-escalating study evaluating safety, PK & PD in psoriasis patients	1	16/08/2017	21
17/WM/0210/AM02	Dose-escalating study evaluating safety, PK & PD in psoriasis patients	2	08/09/2017	20
17/WM/0210/AM04	Dose-escalating study evaluating safety, PK & PD in psoriasis patients	3	24/11/2017	36
17/WM/0210/AM05	Dose-escalating study evaluating safety, PK & PD in psoriasis patients	4	19/02/2018	18
17/WM/0230/AM01	Does sperm DNA integrity affect embryo cleavage patterns?	1	17/10/2017	28
17/WM/0281/AM01	PRO/GLY/004 12 May 2017 V2.0	1	05/12/2017	5
17/WM/0282/AM02	Pfizer Paediatric VTE Treatment study	2	01/12/2017	25
17/WM/0308/AM01	ALPINE 2: AZLI for children with CF and PA lung infection	1	20/10/2017	33
17/WM/0308/AM02	ALPINE 2: AZLI for children with CF and PA lung infection	2	07/03/2018	30
17/WM/0311/AM02	ASPIRE-SSI	1	30/01/2018	26
17/WM/0313/AM02	The communication of benign biopsy results in NHS Breast	1	13/02/2018	18

	Screening V.1			
17/WM/0330/AM02	Xolaris	1	19/12/2017	6
17/WM/0341/AM01	Language Processing After Trauma (LPAT)	1	02/11/2017	21
17/WM/0370/AM01	Assist-HHD	1	28/02/2018	32
17/WM/0390/AM01	Seated Physical Activity in Ageing (SPAA)	1	12/01/2018	34
17/WM/0432/AM02	5 and 10 year follow up of the WRAP trial (WRAP Up)	1	08/02/2018	27

Unfavourable opinion				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
16/WM/0026/AM01	Mechanisms of bacterial infection in patients with influenza - Pilot	1	17/02/2017	25
16/WM/0369/AM04	Comparison of X-396 to Crizotinib in ALK Positive NSCLC Patients	3	11/10/2017	35

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
16/WM/0026/AM01/1	Mechanisms of bacterial infection in patients with influenza - Pilot	1.1	26/07/2017	6

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
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Proportionate review applications for ethical review over 21 day timeline

REC Reference	Title	Number of Days on Clock
17/WM/0396	International validation of the EORTC QLQ-ANL27	22
17/WM/0435	Assessment of accommodation in anisometropia with dynamic retinoscopy	22
18/WM/0008	Co-construction of illness narratives in medical encounters	26
18/WM/0009	SoMoR – UK (Study of Management of RAASi in UK)	26
18/WM/0011	Study of blood pressure: What matters in Later Life? The SWaLLow Study	30
18/WM/0012	Developing a Dynamic Progress Feedback System v1	25
18/WM/0068	Oral biofilm study_Ansbro	34

SSAs (non Phase 1) over 25 day timeline

REC Reference	Title	Number of Days on Clock
17/WM/0178	Exploratory case-controlled longitudinal biomarker study on Alzheimer	28

SSAs (Phase 1) over 14 day timeline

REC Reference	Title	Number of Days on Clock
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Substantial Amendments over 35 day timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
17/WM/0077/AM04	BP39365 Phase 1b Study of RO6874281 in Metastatic Renal Cell Carcinoma	3	26/07/2017	37
17/WM/0210/AM04	Dose-escalating study evaluating safety, PK & PD in psoriasis patients	3	24/11/2017	36

Modified Amendments over 14 day timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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