

**Yorkshire & The Humber - Leeds West Research
Ethics Committee**

Annual Report

01 April 2016 - 31 March 2017



Part 1 – Committee Membership and Training

Name of REC:	Yorkshire & The Humber - Leeds West Research Ethics Committee
Type of REC:	REC recognised to review CTIMPs in Patients - Type III
Type of Flag:	Phase 1 Studies in Patients Medical Devices Research involving Adults Lacking Capacity Research involving Children Qualitative Research
Chair:	Dr Sheila E. Fisher
Vice-Chair:	Dr Vera Neumann
Alternate Vice-Chair:	Mr Anthony Warnock-Smith
REC Manager:	Miss Christie Ord
REC Assistant:	Miss Kirstie Penman
Committee Address:	HRA Jarrow Jarrow Business Centre Rolling Mill Road Jarrow NE32 3DT
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Chair's overview of the past year:

Leeds (West) remains a lively and vibrant REC and we collectively aim to provide a thorough, fair and courteous review across the range of applications supported by our flags. This year has seen a good balance across these areas, giving members the chance to use their expertise and skills to the full but also to learn about those aspects with which they may be less familiar. Most applications are well written and presented and it is a pleasure to review them and discuss queries with the research teams. However there remain a small but significant number that lack clarity or even internal consistency. Inevitably these are demanding of time and it is our usual experience that lack of clarity in the written submission is too often accompanied by a lack of clarity in verbal answers and a lack of insight into sometimes fundamental ethical issues. It would be helpful if sponsors could agree to undertake a 'sense-check' prior to submission, as indeed, many already do.

Members' experience of PRSC work has been helped by the greater flexibility in the timeline which allows careful review to be combined with other commitments. Although anecdotal, our experience suggests that the quality of applications has improved this year and that not only facilitates the review but tracks through to positive decisions. Sub-committee work continues to increase, with some activity in most weeks. This can become burdensome, especially given our volunteer membership.

During this year we have welcomed three new members Miss Susan Partridge, Dr Peter Draper and Mrs Kerrie Davies. All settled in very quickly, bring complementary expertise and contribute actively to discussion and decisions. Sadly we lost one member, Dr Caroline Magee, and at the close of this reporting period received notice of resignation from another. It is of note that the reasons were identical. Both had additional responsibilities at work which were proving incompatible with the workload required as a fully committed member of the REC. For exactly the same reasons our Pharmacist member has been on an agreed period of long-term leave. Internally and in discussion we work with our REC Manager to prioritise workloads, however it must be accepted that the input required of a volunteer REC member is a significant burden. It is essential that this be kept as light as can be achieved, given the nature of the relationship and the generosity with which members give their time.

We welcome our new venue which has overcome many of the problems we had faced in the past. I wish to record our thanks to Mr Vishal Sharma who was able to arrange suitable rooms at the University of Leeds during the period inevitably taken to bring the new venue to fruition. This willingness to go 'above and beyond' to assist everyone in their work together is typical of our members and it is a pleasure to lead the REC.

Members have undertaken a range of training. Gaining time from paid employment can be difficult and we welcome the new e-learning modules which may mitigate this very practical problem and look forward to sharing experiences. As a REC we have contributed to developmental work within HRA and the chance to do so was welcomed. Members hold insight and wisdom across a range of areas and disciplines and have much to offer.

As ever, our Vice-Chair, Dr Vera Neumann, and Alternate Vice-Chair, Mr Tony Warnock-Smith have been generous in their support throughout the year.

Finally, but perhaps most important, is the guidance, care and support we have received from our REC Manager, Miss Christie Ord, and our REC Assistant, Miss Kirstie Penman who always look to hold us to the highest standards across the range of activities undertaken. This commitment and professionalism is supported not only by the figures in the report but notably this year by the award of Full Accreditation in the formal HRA Audit.

Yorkshire & The Humber - Leeds West Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Dr Michael Clarke	Senior Dento Legal Advisor	Expert	17/06/2013	
Mrs Kerrie Davies	Principal Clinical Scientist	Expert	01/08/2016	
Dr Peter Draper	National Teaching Fellow	Expert	24/06/2016	
Dr Martin Elliott	Consultant Paediatric Oncologist	Expert	01/04/2010	
Dr Diane Farrar	Research Programme Manager – Maternal and Child Health	Expert	18/06/2013	
Dr Sheila E. Fisher	Retired Maxillofacial Surgeon/Clinical Research Fellow	Expert	20/07/2007	
Ms Sarah Kirkland	Clinical Studies Officer	Lay Plus	01/02/2013	
Miss Emma Lundy	Advanced Clinical Pharmacist (Oncology and Clinical Trials)	Expert	09/10/2013	
Dr Caroline Magee	Communications Consultant	Lay	15/08/2013	10/02/2017
Dr Vera Neumann	Consultant in Rehabilitation Medicine	Expert	20/07/2007	
Dr Jane Orton	Retired Consultant Oncologist	Expert	29/04/2008	
Miss Susan Partridge	Research Assistant	Lay	15/06/2016	
Mrs Heather Rostron	Senior Research Nurse	Expert	22/10/2013	
Mr Vishal Sharma	Research Fellow/PhD Student	Lay	07/10/2013	
Mr Ashley Stratton-Powell	PhD Doctoral Training Centre for Tissue Engineering and Regenerative Medicine	Lay Plus	22/09/2014	
Dr Jonathan Thornley	A&E Consultant	Expert	25/07/2014	
Mr Anthony Warnock-Smith	Retired solicitor	Lay Plus	01/12/2012	

Yorkshire & The Humber - Leeds West Research Ethics Committee: Deputy Members

None.

Yorkshire & The Humber - Leeds West Research Ethics Committee: Co-opted Members

None.

Yorkshire & The Humber - Leeds West Research Ethics Committee: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Dr Michael Clarke	Mike's employers, the Medical Protection Society, do sometimes get involved with defending researchers who are referred to the medical and dental regulators (GMC and GDC). Mike no longer works in this department and he is highly unlikely to be involved in such a defence.	31/03/2017
Mrs Kerrie Davies	I am the Principal Clinical Scientist for the Healthcare Associated Infections Research group, based at the LTHT and University of Leeds. As such I conduct local peer review of research projects being performed by the group.	11/10/2016
Dr Peter Draper	As senior lecturer at university of Hull he conducts research and supervises students	07/10/2016
Dr Martin Elliott	Medical trustee of Candlelighter's charity - fund research. Specialty lead (cancer) for NIHR Y&HCRN	31/03/2017
Dr Diane Farrar	I am a National Institute for Health Research post-doctoral research fellow conducting research into hypertensive disorders of pregnancy. I am a research fellow and research programme manager at the Bradford Institute for Health research, as well as visiting research fellow at the university of York and visiting Associate Professor at the University of Leeds. I am associate editor of BMC Health Services Research. I am conducting research in the areas of gestational diabetes and infant obesity	31/03/2017
Dr Sheila E. Fisher	Peer reviewer for NIHR and a number of cancer charities. Member of Trial Steering Group for NIHR programme grant funded study. Member of Trial Strategic Group for NIHR programme grant funded study. Member of Trial Management Group for Cancer Research UK funded study.	31/03/2017
Ms Sarah Kirkland	Clinical Studies Officer at Bradford District Care NHS Foundation Trust from 3 April 2017, working on Mental Health and Community Health research projects.	31/03/2017
Dr Vera Neumann	None declared.	31/03/2017
Dr Jane Orton	None	31/03/2017
Miss Susan Partridge	None	16/11/2016
Mrs Heather Rostron	Member of medicines for children clinical studies group (general paediatrics)	31/03/2017
Mr Vishal Sharma	None.	31/03/2017
Mr Ashley Stratton-Powell	None	31/03/2017
Dr Jonathan Thornley	Regional joint Lead for NIHR Injuries and Emergencies theme for Yorkshire and Humber. Leeds Teaching Hospitals NHS Trust A&E Lead for Research	31/03/2017
Mr Anthony Warnock-Smith	None.	31/03/2017

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

Month	Date	Number of Members Present at Meeting
April	08/04/2016	10
June	10/06/2016	8
July	08/07/2016	8
August	12/08/2016	9
September	09/09/2016	14
November	11/11/2016	13
December	09/12/2016	15
January	13/01/2017	11
February	10/02/2017	13
March	10/03/2017	9

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
May	04/05/2016	3
May	26/05/2016	3
June	21/06/2016	3
July	20/07/2016	3
August	24/08/2016	3
September	22/09/2016	3
December	12/12/2016	3
January	27/01/2017	3
February	27/02/2017	3

9 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	12/04/2016	2
April	15/04/2016	3
April	26/04/2016	2
May	10/05/2016	2
May	24/05/2016	2
May	26/05/2016	3
June	07/06/2016	3
June	21/06/2016	2
July	04/07/2016	3
July	05/07/2016	2
July	11/07/2016	3
July	19/07/2016	2

August	02/08/2016	2
August	02/08/2016	2
August	12/08/2016	2
August	16/08/2016	2
August	30/08/2016	2
September	02/09/2016	3
September	13/09/2016	2
September	13/09/2016	2
September	14/09/2016	2
September	27/09/2016	2
October	11/10/2016	2
October	25/10/2016	2
October	27/10/2016	3
November	08/11/2016	2
November	22/11/2016	2
December	06/12/2016	2
December	20/12/2016	2
January	03/01/2017	2
January	13/01/2017	3
January	17/01/2017	2
January	31/01/2017	2
February	08/02/2017	3
February	14/02/2017	2
February	28/02/2017	2
March	01/03/2017	3
March	14/03/2017	2
March	28/03/2017	2

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

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

0

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

Name	Number of Meetings Attended
Dr Sheila E. Fisher	9
Mr Ashley Stratton-Powell	9
Dr Michael Clarke	8
Ms Sarah Kirkland	8
Dr Vera Neumann	8
Dr Jane Orton	8
Mr Vishal Sharma	8
Mr Anthony Warnock-Smith	7
Mrs Kerrie Davies	6
Dr Martin Elliott	6
Dr Caroline Magee	6
Miss Susan Partridge	6
Mrs Heather Rostron	6
Dr Peter Draper	5
Dr Diane Farrar	5
Miss Emma Lundy	3
Dr Jonathan Thornley	2

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

Name	Number of Meetings Attended
Dr Sheila E. Fisher	3
Ms Sarah Kirkland	3
Dr Vera Neumann	3
Mr Ashley Stratton-Powell	3
Mr Anthony Warnock-Smith	3
Dr Diane Farrar	2
Mrs Heather Rostron	2
Mr Vishal Sharma	2
Dr Jonathan Thornley	2
Dr Michael Clarke	1
Dr Martin Elliott	1
Dr Caroline Magee	1
Dr Jane Orton	1

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

Name	Number of Meetings Attended
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Mr Anthony Warnock-Smith	15
Dr Sheila E. Fisher	14
Dr Vera Neumann	13
Dr Michael Clarke	11
Dr Jane Orton	7
Mr Vishal Sharma	7
Mr Ashley Stratton-Powell	5
Dr Jonathan Thornley	4
Dr Caroline Magee	3
Dr Martin Elliott	2
Dr Diane Farrar	2
Ms Sarah Kirkland	2
Mrs Heather Rostron	2
Miss Emma Lundy	1

Training 01 April 2016 - 31 March 2017

Name of Member	Date	Event(s) attended
Dr Michael Clarke	06/07/2016	Regional Training Day
Dr Michael Clarke	12/10/2016	Equality and Diversity
Mrs Kerrie Davies	06/04/2016	Equality and Diversity
Mrs Kerrie Davies	18/08/2016	Online Induction
Mrs Kerrie Davies	10/01/2017	Induction Training
Dr Peter Draper	12/10/2016	Equality and Diversity
Dr Peter Draper	06/12/2016	Members Induction
Dr Martin Elliott	31/03/2017	Self Directed Learning Log 2016-17 – E-Learning, private reading,
Dr Sheila E. Fisher	07/04/2016	Equality and Diversity
Dr Sheila E. Fisher	06/07/2016	Regional Training Day
Dr Sheila E. Fisher	19/10/2016	HARP Member Portal Demonstration
Dr Sheila E. Fisher	09/11/2016	NREAP/Practicalities of Running a REC
Dr Sheila E. Fisher	01/12/2016	Chair's Training Day
Ms Sarah Kirkland	13/10/2016	Equality and Diversity
Dr Vera Neumann	06/07/2016	Regional Training Day
Dr Vera Neumann	01/12/2016	Chair's Training Day
Dr Jane Orton	06/07/2016	Regional Training Day
Miss Susan Partridge	06/10/2016	Online Induction
Miss Susan Partridge	10/01/2017	Members Induction
Mr Vishal Sharma	06/07/2016	Regional Training Day
Mr Vishal Sharma	19/10/2016	HARP Member Portal Demonstration
Mr Ashley Stratton-Powell	31/03/2017	Self Directed Learning Log 2016/17 – One weeks placement surrounding the law on medical devices.
Dr Jonathan Thornley	31/03/2017	SDL 2016-17 Private reading surrounding CTIMPS, Tissue Banks and student research.
Mr Anthony Warnock-Smith	01/10/2017	SDL – Private reading surrounding devices, ABPI guidelines for secondary use of data for research purposes.
Mrs Heather Rostron	06/07/2016	Regional training event

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	%
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Clinical Trial of Investigational Medicinal Product	7	15.22
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	39	84.78
Total Applications Reviewed	46	100

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

Number of applications made invalid by the REC Manager	1
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	18
Number of paediatric applications reviewed	10
Number of device applications reviewed	7
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	8
Number of applications reviewed that are funded by the US DHHS	0
Number of qualitative applications reviewed	6

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	2	4.35
Favourable Opinion with Additional Conditions	6	13.04
Unfavourable Opinion	8	17.39
Provisional Opinion	30	65.22
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	46	100
Number of studies sent back to full committee meeting for final opinion	0	

Table 4: Summary of current status of applications reviewed during the reporting period

Status of applications at date of generation of report	Number	%
Further Information Favourable Opinion with Standard Conditions	20	43.48
Further Information Favourable Opinion with Additional Conditions	7	15.22
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	2	4.35
Favourable Opinion with Additional Conditions	6	13.04
Unfavourable Opinion	8	17.39
Provisional Opinion	1	2.17
Provisional Opinion Pending Consultation with Referee	0	0.00
Further Information response not complete	1	2.17
No decision entered on system	0	0.00
Number of studies withdrawn after the meeting	1	2.17
Total	46	100

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

Total Applications Reviewed	18
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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	5
Number of paediatric applications reviewed	5
Number of device applications reviewed	0
Number of qualitative applications reviewed	3

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	10	55.56
Favourable Opinion with Additional Conditions	3	16.67
No Opinion transfer to full committee for review	1	5.56
Provisional Opinion	3	16.67
Unfavourable Opinion	1	5.56
Total	18	100

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

Average number of applications reviewed per full meeting	4.60
Number of completed applications for full ethical review	45
Number of completed applications for full ethical review over 60 days	0
Number of completed applications over 60 days as a % of total	0.00%
Number of completed applications for full ethical review over 40 days	8
Number of completed applications over 40 days as a % of total	17.39%
Number of days taken to final decision – average (mean)	32

Number of completed proportionate review applications for ethical review	17
Number of completed proportionate review applications for ethical review over 14 days (Please note, the timeline for the review of PR applications was extended from 14 to 21 calendar days in December 2016)	2
Number of completed proportionate review applications for ethical review over 21 days	0
Number of completed proportionate review applications over 21 days as a % of total	0.00%

Number of SSAs (non-Phase 1) reviewed	3
Number of completed applications for SSA review over 25 days	0
Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs	0.00%

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

Number of substantial amendments reviewed	101
Number of completed substantial amendments over 35 days	0
Number of completed substantial amendments over 35 days as a % of total substantial amendments	0.00%
Number of completed substantial amendments over 28 days	5
Number of completed substantial amendments over 28 days as a % of total substantial amendments	4.95%

Number of modified amendments reviewed	0
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	84
Number of substantial amendments received for information	4
Number of substantial amendments received for new sites/PIs	33
Number of annual progress reports received	73
Number of safety reports received	24
Number of Serious Adverse Events received	2
Number of final reports received	23

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/YH/0113	ACE-CL-208	35
16/YH/0210	Novel exercise intervention for traumatic brain injury	39
16/YH/0229	Cancer Patienthood in the Post-Genomics Era v.1	40
16/YH/0235	Psychological support as an intervention in IBD fatigue management	42
16/YH/0239	ePRIME remote monitoring development & intervention	46
16/YH/0258	A clinical investigation of a novel FES system	25
16/YH/0346	e-Module Validation in Clinic - eMViC	35
16/YH/0388	MUK eleven	35
16/YH/0470	Evaluation of the use of an EMG switch	42
16/YH/0473	A Measure of Self for People With Dementia-Version 2	39
16/YH/0488	Pilot study comparing types of microbiome sample	48
16/YH/0508	Guided Acceptance and Commitment Therapy Self-Help	40
16/YH/0511	Dance Movement Psychotherapy in acute adult psychiatry.	30
17/YH/0008	Efficacy and safety of AX-8 in patients with chronic cough.	37
17/YH/0017	Examining the relational needs and networks of forensic inpatients	31
17/YH/0022	MEDI4736-DLBCL-001 Phase 2 High-Risk Diffuse Large B-Cell Lymphoma	25
17/YH/0038	The INSPIRE Study	30
17/YH/0062	Quantitative biomarkers in MI	41
17/YH/0076	CALM DIEM	40
17/YH/0079	OHRQoL following dental treatment under GA - Child Measure Version 1	40

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
16/YH/0097	COSY+ Version 1.8	41
16/YH/0130	Tai chi for stroke survivors version 2.0	43
16/YH/0225	I-BiT Plus version 1.0	32
16/YH/0252	Knowledge Sharing in Eczema	26
16/YH/0377	The use of virtual reality for the treatment of visual vertigo	42
17/YH/0023	Team Formulation for Older People: A Case Series Approach	32
17/YH/0040	Efficacy & safety study of weekly MOD-4023 in GHD - CP-4-006 - V1.0	33

Further Information Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
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Favourable Opinion with Standard Conditions

REC Reference	Title	Number of Days on Clock
16/YH/0462	Addressing the polypharmacy challenge v1	27
16/YH/0507	The Changing Face of Our Neighbourhoods (v1)	25

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/YH/0211	Experience of Talking about Recovery in Psychosis to Professionals v1	25
16/YH/0328	Women's behaviour towards diet and physical activity during pregnancy	21
16/YH/0339	MRI and MBW to assess ventilation in cystic fibrosis	21
16/YH/0390	LoTS2Care Feasibility Trial - A Process Evaluation	28
16/YH/0457	Profiling Neutrophil Counts In Patients on Chemotherapy (Version 1.1)	28
16/YH/0474	C-peptide status in HypoCOMPASS	28

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
16/YH/0150	Cytokine storm and its effects in critical illness	26
16/YH/0254	SENSE-Cog Needs analysis and Intervention development	22
16/YH/0281	Binaural Music Therapy to help people with dementia (MBMT)	28
16/YH/0326	Guilt and shame after perinatal loss: comparing womens' experiences	28
16/YH/0372	Group RO-DBT vs CBT-E in Adolescent Inpatients with Anorexia Nervosa	28
16/YH/0510	Qualitative interviews with patients who have cholestatic pruritus	25
17/YH/0045	Eosinophilic and Immune Mechanistic Study (BREAD)	19
17/YH/0053	Use of oxygen in acute heart failure: pilot inpatient study, OXY-AHF	26

Provisional Opinion

REC Reference	Title	Number of Days on Clock
17/YH/0004	Parental perspectives on End of Life care in Neonates.	n/a

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

Further information response not complete		
REC Reference	Title	Number of Days on Clock
16/YH/0255	PRODIGY MRI	n/a

Withdrawn after the meeting		
REC Reference	Title	Number of Days on Clock
16/YH/0333	PPM - GED0507 for treatment of active ulcerative colitis	24

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/YH/0269	The PALM Study (Palatability and Acceptability of Liquid Methotrexate)	10
16/YH/0314	FAST:Fast Assessment of ocular Surface Trouble	13
16/YH/0425	The Manchester Paediatric AKI Study	14

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock

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
16/YH/0187	Retrospective study to evaluate the safety of Perampanel in Epilepsy	13

16/YH/0188	Novel sterilisation	14
16/YH/0223	Does peer knowledge of type1 diabetes affect 14-17yr olds with type1?	14
16/YH/0311	Use of NCI Material from NHSBT	12
16/YH/0318	Inflammatory biomarkers in IBS and IBD. Version 1	13
16/YH/0378	A Comparison of Squint Tests	14
16/YH/0381	Talking about decisions	14
16/YH/0417	A Mixed Methods Exploration of the Use of Pain Measures (Version 1)	11
17/YH/0028	Patients experience of taking part in a breast cancer clinical trial	16
17/YH/0056	Investigating the ASSR as an indicator for 'Hidden' hearing loss	15

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/YH/0192	Carbohydrate Awareness Advice	13
16/YH/0267	UK EarlySense Study - Prevention of Falls	8
16/YH/0382	A study of antibiotic requirements for bronchiectasis	14

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
16/YH/0517	Immune dysfunction in Chronic Hepatitis B & HCC	14

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
05/Q1108/28/AM15	Characterisation of Giant cell arteritis & polymyalgia rheumatica	SA16	06/09/2016	20
05/Q1205/148/AM20	Safety evaluation of tacrolimus in atopic dermatitis (Version 2)	SA6	06/10/2016	20
08/H1307/92/AM05	The Genetic Architecture of Sub Arachnoid Haemorrhage	Protocol Version 5	28/06/2016	31
08/H1311/86/AM07	IMMUNOMODULATORY EFFECTS GENERATED BY EXTRACORPOREAL PHOTOPHERESIS	SA5	13/04/2016	13
09/H1307/54/AM17	Open-label study of Denosumab in Subjects with Giant Cell Tumor	Substantial Amendment 15	27/06/2016	15
09/H1307/54/AM18	Open-label study of Denosumab in Subjects with Giant Cell Tumor	Substantial Amendment 16	19/07/2016	21
09/H1307/98/AM16	RADAR	SA12	24/02/2017	13
10/H1307/112/AM07	VANTAGE (version AA)	Amendment 6	26/05/2016	23
10/H1307/126/AM17	CC-10004-PSA-002 Apremilast in Active Psoriatic Arthritis	IB 17	10/03/2016	27
10/H1307/91/AM12	Compassionate Use Study of Mepolizumab in Hypereosinophilic Syndrome	SA12	04/10/2016	20
10/H1307/91/AM18	Compassionate Use Study of Mepolizumab in Hypereosinophilic Syndrome	SA14	30/11/2016	7
11/H1307/12/AM09	CC-10004-PSA-004 Apremilast in Active PsA with lesion	IB17	10/03/2016	27
11/H1307/9/AM21	CC-10004-PSA-003 Apremilast in Active Psoriatic Arthritis	IB17	10/03/2016	27
11/YH/0291/AM04	Pectoralis muscle biopsy in CHF patients	SA05	24/04/2016	29
11/YH/0413/AM04	The epidemiology of viral RTIs in immunocompromised patients	SA2	29/09/2016	18
12/YH/0438/AM07	Bone Vibration as a Novel Assessment of Bone Density in Children	SA6	08/08/2016	25
12/YH/0467/AM12	Phase I/II Trial of RNActive derived vaccine in Prostate Cancer	SA10	11/04/2016	15
12/YH/0551/AM02	CE-MARC 2 protocol development	SA2	04/08/2016	13
12/YH/0551/AM03	CE-MARC 2 protocol development	Substantial Amendment 3	12/09/2016	11
12/YH/0551/AM04	CE-MARC 2 protocol development	SA4	16/02/2017	20
13/YH/0159/AM07	Adjuvant Pegylated Interferon in Ulcerated Melanoma	SA04	07/06/2016	13

13/YH/0159/AM10	Adjuvant Pegylated Interferon in Ulcerated Melanoma	SA05	14/02/2017	11
13/YH/0201/AM18	Study of Sativex in Children (aged 8-18) with Severe Spasticity	SA12	19/01/2017	10
13/YH/0279/AM17	PROMOTE	Amendment 12	26/07/2016	21
13/YH/0284/AM05	Pilot trial of omeprazole in idiopathic pulmonary fibrosis	Substantial Amendment 5	05/08/2015	18
13/YH/0292/AM08	BRU ACDC-Study	Substantial Amendment 2	10/11/2016	18
13/YH/0334/AM04	Hemostasis of Active GI Luminal Tract Bleeding (HALT)(study # 10-017)	Substantial Amendment 1	03/05/2016	22
13/YH/0334/AM05	Hemostasis of Active GI Luminal Tract Bleeding (HALT)(study # 10-017)	SA2	12/10/2016	19
13/YH/0334/AM06	Hemostasis of Active GI Luminal Tract Bleeding (HALT)(study # 10-017)	SA3	11/01/2017	12
13/YH/0334/AM07	Hemostasis of Active GI Luminal Tract Bleeding (HALT)(study # 10-017)	SA4	30/01/2017	15
13/YH/0366/AM17	Efficacy and safety of 11b-HSD1 inhibitor in IIH	SA5	23/05/2015	21
13/YH/0366/AM18	Efficacy and safety of 11b-HSD1 inhibitor in IIH	SA6	01/12/2016	13
14/YH/0006/AM11	Open Label Extension Study of Lacosamide in Paediatric Subjects	SA07	29/04/2016	12
14/YH/0006/AM12	Open Label Extension Study of Lacosamide in Paediatric Subjects	SA08	10/08/2016	26
14/YH/0006/AM13	Open Label Extension Study of Lacosamide in Paediatric Subjects	SA9	20/01/2017	11
14/YH/0007/AM14	Lacosamide in Subjects ages 4 years and over and less than 17 with Epil	SA08	29/04/2016	12
14/YH/0007/AM15	Lacosamide in Subjects ages 4 years and over and less than 17 with Epil	SA09	05/12/2016	15
14/YH/0034/AM06	IciCLLe -Assessment of the Mechanism of Action of Ibrutinib	SA8	11/10/2016	16
14/YH/0085/AM33	FLAIR version 2.0	HM13/10747/ Docs/160929	29/09/2016	19
14/YH/0085/AM35	FLAIR version 2.0	HM13/10747/docs/ 161130	30/11/2016	14
14/YH/0101/AM01	Targeted Sequencing of Known Cancer Genes in Anaplastic Meningioma	SA1	01/10/2016	7
14/YH/1032/AM04	Services for Juvenile Huntington's Disease	Substantial	03/05/2016	25

		Amendment 3		
14/YH/1032/AM05	Services for Juvenile Huntington's Disease	SA4	02/08/2016	10
14/YH/1070/AM04	Developing a new EEG method for the early diagnosis of dementia.	SA3	06/10/2016	20
14/YH/1110/AM04	Dose finding safety study of VAL201 in cancer patients	Substantial Amendment 2	15/04/2016	27
14/YH/1110/AM05	Dose finding safety study of VAL201 in cancer patients	Protocol Amendment 4.0	24/06/2016	29
14/YH/1126/AM09	Medicines Optimisation in Cancer Pain	Substantial Amendment 3	26/05/2015	17
14/YH/1162/AM03	SABRTOOTH v1.0	Substantial amendment 2	12/05/2016	16
14/YH/1162/AM04	SABRTOOTH v1.0	MO14/11248/G/20160620	27/06/2016	16
14/YH/1175/AM09	Ibrutinib in Chronic Lymphocytic Leukaemia/Small Lymphocytic Lymphoma	Substantial Amendment 07	27/06/2016	14
14/YH/1175/AM10	Ibrutinib in Chronic Lymphocytic Leukaemia/Small Lymphocytic Lymphoma	SA 8	06/09/2016	35
14/YH/1175/AM11	Ibrutinib in Chronic Lymphocytic Leukaemia/Small Lymphocytic Lymphoma	SA9	05/10/2016	19
14/YH/1175/AM14	Ibrutinib in Chronic Lymphocytic Leukaemia/Small Lymphocytic Lymphoma	SA10	03/01/2017	14
14/YH/1208/AM02	Recognising suffering at the end of life	SA02	27/05/2016	24
14/YH/1253/AM02	A Comparative Pilot Study Investigating the Presence of S100 Proteins in the Blood of Subjects with Complex Wounds in Comparison with Age-Matched Controls with No Wounds	SA2	30/09/2016	19
14/YH/1259/AM13	ALPHA	SA10	08/06/2016	17
14/YH/1259/AM16	ALPHA	Substantial Amendment 11	19/09/2016	7
14/YH/1263/AM10	GlySure study in Acute Care Setting patients	SA01	27/05/2016	18
14/YH/1278/AM01	Validation of TEG 6s in Interventional Cardiology	SA1	16/02/2017	21
14/YH/1298/AM03	RSI - Does ultrasound improve identification of conventional landmarks?	Substantial Amendment 2	08/09/2016	17
15/YH/0017/AM07	Extension Paediatric study of Intrathecal IdursulfaseIT with Elaprase®	Protocol Amendment 2	25/05/2016	21

15/YH/0017/AM09	Extension Paediatric study of Intrathecal IdursulfaseIT with Elaprase®	SA6	15/12/2016	16
15/YH/0020/AM05	Calibre	SA04	06/12/2016	16
15/YH/0108/AM02	FUTURE 4	SA2	01/07/2016	27
15/YH/0117/AM06	REPAIR-Right vEntricular remodeling in Pulmonary Arterial hypertension	SA5	29/03/2016	14
15/YH/0117/AM07	REPAIR-Right vEntricular remodeling in Pulmonary Arterial hypertension	SA6	16/06/2016	24
15/YH/0117/AM08	REPAIR-Right vEntricular remodeling in Pulmonary Arterial hypertension	Substantial Amendment 7	25/08/2016	12
15/YH/0117/AM09	REPAIR-Right vEntricular remodeling in Pulmonary Arterial hypertension	SA8	04/12/2016	12
15/YH/0178/AM06	Vertex - VX14-661-109 - Cystic Fibrosis	Substantial Amendment 4	08/06/2016	13
15/YH/0178/AM08	Vertex - VX14-661-109 - Cystic Fibrosis	SA5	17/08/2016	19
15/YH/0201/AM02	TRIUMPH	SA1	13/01/2017	16
15/YH/0280/AM05	PredictCAT v1.1	SA2	27/10/2016	22
15/YH/0280/AM06	PredictCAT v1.1	SA3	13/12/2016	16
15/YH/0281/AM02	Investigation of Progenitor Cells Version 1	SA1	09/09/2016	12
15/YH/0286/AM05	The MATE study	Substantial Amendment 6	12/05/2016	19
15/YH/0286/AM09	The MATE study	SA10	27/10/2016	24
15/YH/0349/AM09	IELSG 42 - Marietta	SA6	08/09/2016	6
15/YH/0349/AM11	IELSG 42 - Marietta	SA7	02/02/2017	7
15/YH/0389/AM01	CIAP	SA1	29/07/2016	25
15/YH/0390/AM16	UT and VS of the electronic versions of AQLQ12+ and ACQ-7	Substantial Amendment 2	06/12/2016	14
15/YH/0402/AM02	A Phase 2 Safety and Pharmacokinetics Study of Ataluren (COMPASS)	Substantial Amendment 2	23/09/2016	27
15/YH/0493/AM01	LCC-CARIS-01: Molecular profiling in gynaecological cancer.	SA1	29/03/2016	10
15/YH/0516/AM03	Evaluation of an L-FABP Urine Device (ELUDe) V1	Substantial Amendment 1	19/07/2016	25
16/YH/0004/AM02	PhII_MOR00208 & Idelalisib_Patients with Relapsed Refractory CLL/SLL	SA2	24/03/2016	21
16/YH/0004/AM04	PhII_MOR00208 & Idelalisib_Patients with Relapsed Refractory CLL/SLL	SA3	01/08/2016	19

16/YH/0004/AM05	PhII_MOR00208 & Idelalisib_Patients with Relapsed Refractory CLL/SLL	SA4 - IB8	07/11/2016	19
16/YH/0045/AM01	HIDDEN study	Substantial Amendment 1	09/08/2016	17
16/YH/0089/AM01	FASBAT	Substantial Amendment 1	26/05/2016	13
16/YH/0089/AM07	FASBAT	SA2	03/01/2017	13
16/YH/0113/AM02	ACE-CL-208	SA2	23/06/2016	13
16/YH/0113/AM03	ACE-CL-208	SA03	06/02/2017	11
16/YH/0192/AM01	Carbohydrate Awareness Advice	SA1	19/08/2016	26
16/YH/0210/AM02	Novel exercise intervention for traumatic brain injury	SA1	16/12/2016	15
16/YH/0225/AM01	I-BiT Plus version 1.0	SA1	20/12/2016	15
16/YH/0229/AM01	Cancer Patienthood in the Post-Genomics Era v.1	SA1	21/12/2016	23
16/YH/0239/AM02	ePRIME remote monitoring development & intervention	Substantial Amendment 1	08/09/2016	18
16/YH/0252/AM02	Knowledge Sharing in Eczema	SA1	15/11/2016	21
16/YH/0258/AM01	A clinical investigation of a novel FES system	SA1	23/11/2016	17
16/YH/0390/AM03	LoTS2Care Feasibility Trial - A Process Evaluation	SA1	20/03/2017	10
16/YH/0457/AM01	Profiling Neutrophil Counts In Patients on Chemotherapy (Version 1.1)	SA1	19/12/2016	23

Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
15/YH/0178/AM09	Vertex - VX14-661-109 - Cystic Fibrosis	SA6	14/01/2017	32

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
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Unfavourable opinion timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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Table 11: Items exceeding timelines

Full applications for ethical review over 60 day timeline

REC Reference	Title	Number of Days on Clock
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Proportionate review applications for ethical review over 21 day timeline

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

REC Reference	Title	Number of Days on Clock
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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
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Modified Amendments over 14 day timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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