

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

Annual Report

01 April 2015 - 31 March 2016



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:

This has been a relatively stable year and we are fortunate to have a very informed and well balanced membership in terms of expertise, wider experience, gender and age. We said goodbye to two valued members, Danni Collingridge-Moore and Jan Geddes and thank them for their care and wisdom in their assessment of applications and for their friendship. In March we welcomed Heather Rostron back after maternity leave and her paediatric expertise is immensely valuable. We look forward to welcoming new members in the year to come to replace those we have lost. Vera Neumann and Tony Warnock-Smith are now well established as Vice-Chair and Alternate Vice-Chair respectively. Both continue to bring experience and complementary talents to their roles and are a pleasure to work with, often going well beyond the 'call of duty'.

This ethos of service extends to the membership as a whole. No matter how long and complex the applications, these are carefully appraised and questions prepared with insight. We see a wide range of applications, from the straightforward to the challenging and, inevitably with that diversity, discussion can be intense and, at times, challenging. It is a credit to all members that they are open in their contributions, showing the highest standards of integrity. I would hope that all applicants who attend our meetings feel that they have had a full, helpful and constructive scrutiny of their studies.

The 'flip side' of this is that keeping to time can be challenging. We continue to work to refine questions and discussions without detracting from the value of individual contributions nor of the care taken in the review. When researchers are well prepared the time allocation is sufficient, poorly structured proposals are far more difficult to manage with care and rigour within the time granted.

The commitment to the Proportionate Review and Sub-committee work remains at a high level with all being willing to contribute time and expertise. The recent change giving more flexibility in terms of time has been warmly welcomed and assists us in carrying out this task with the care that is required yet to be able to reach a firm decision within the timeframe and give the best possible opinion to researchers.

We are aware that this year has been more challenging in terms of attendance at both REC meetings and training for some members and this is a matter we will look to resolve during the coming year. The concern is that we have come close to quoracy limits at one meeting and had to co-opt a member on another occasion second. Recruitment of new members to replace those who have left and working with those who find attendance challenging should help resolve this. The input into other aspects of HRA activity has increased and the full REC meeting is and, as each member has a reduced requirement to attend six full meetings, perhaps these are seen as part of the work rather than the priority they used to be. Given this shift and the problems caused by inquorate meetings and the time taken in avoiding these, a little more flexibility in membership would be welcome, one additional member would provide a much needed safety margin. I wish to thank our members for their willingness and indeed enthusiasm in maintaining the training which underpins our 'flags'. It can be challenging in today's work environment to take time for such days so their care in this regard is very welcome.

Complementary to all of this is the continued support and professionalism shown by our REC Manager Christie Ord, and Assistant Kirstie Penman, and the staff at the Jarrow Office. Despite the challenges of reorganisation they have maintained the highest standards, including keeping us to time with the ever growing workload related to amendments and reports. It is easy not to be fully aware of the volume of work behind the scenes that supports so many aspects of our work. The figures in this report indicate just how much is done, week on week, month on month.

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	
Ms Danni Collingridge Moore	Research Fellow	Lay	01/11/2013	31/03/2016
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	
Dr Jan Geddes	Retired Senior Research Fellow	Lay	12/06/2013	11/12/2015
Ms Sarah Kirkland	Project Manager, Spinal Services at NHS England	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	
Dr Vera Neumann	Consultant in Rehabilitation Medicine	Expert	20/07/2007	
Dr Jane Orton	Consultant Oncologist	Expert	29/04/2008	
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

Name	Profession	Status	Meeting date attended
Dr Rhona Bratt	Retired Multimedia Project Manager	Lay Plus	12/02/2016

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

Name	Declaration of Interest	Date
Dr Michael Clarke	none	17/02/2016
Ms Danni Collingridge Moore	Reviewer for HTA/NIHR, fellow of royal geographical society, member of society for social medicine, research fellow at IOELC at Lancaster university,	14/01/2016
Dr Martin Elliott	Medical trustee of Candle lighter's charity (Leeds) Member of NIHR Children's Cancer and Leukaemia Clinical Studies Group. Specialty Lead for Division 1 (Cancer) of the Yorkshire and Humber Clinical Research Network	06/01/2016
Dr Diane Farrar	None	14/01/2016
Dr Sheila E. Fisher	I am a member of the Trial Steering Group for the NIHR funded IMPACCT study and associated RCT. I am a member of the Trial Steering Group for the NIHR funded H&N5000 study and co-author of papers relating to that study. I carry out peer reviews for a number of funding organisations including NIHR, HTA, CRUK and Tenovus.	25/02/2016
Ms Sarah Kirkland	none	17/02/2016
Miss Emma Lundy	Currently involved as a reviewer as part of the HRA Pharmacy single technical review process.	31/03/2016
Dr Caroline Magee	My current role is working for a Research Funding organisation (NIHR Trainees Coordinating Centre) and researchers applying for REC approval may be funded by this organisation. I do not tend to know any of the researchers personally and am not involved in the peer review of their research funding application.	06/01/2016
Dr Vera Neumann	None declared.	31/03/2016
Dr Jane Orton	None declared.	31/03/2016
Mr Vishal Sharma	Work at the Clinical Trials Unit at the Uni of Leeds as a PhD Student	17/02/2016
Mr Ashley Stratton-Powell	PhD student in the Institute of Medical and Biological Engineering, University of Leeds.	25/02/2016
Dr Jonathan Thornley	Lead for research within the A&E department for Leeds Teaching Hospitals.	31/03/2016
Mr Anthony Warnock-Smith	None	14/01/2016
Mrs Heather Rostron	Returned from break in service 10.02.16 – DOI required (Requested 06.07.16)	

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

Month	Date	Number of Members Present at Meeting
April	10/04/2015	11
May	08/05/2015	13
July	10/07/2015	11
August	14/08/2015	10
September	11/09/2015	9
November	13/11/2015	10
December	11/12/2015	10
January	08/01/2016	9
February	12/02/2016	7
March	11/03/2016	10

10 full committee meetings were held during the reporting period.

Proportionate Review Sub-Committee Meetings held during 01 April 2015 - 31 March 2016:

Month	Date	Number of Members Present at Meeting
April	01/04/2015	3
April	30/04/2015	3
May	21/05/2015	3
June	10/06/2015	3
July	02/07/2015	3
August	10/08/2015	3
September	10/09/2015	3
October	20/10/2015	3
November	12/11/2015	3
December	09/12/2015	3
January	27/01/2016	3
February	24/02/2016	3
March	24/03/2016	3

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

Sub-Committee Meetings held during 01 April 2015 - 31 March 2016:

Month	Date	Number of Members Present at Meeting
April	06/04/2015	3
April	09/04/2015	2
April	15/04/2015	3
April	17/04/2015	3
April	24/04/2015	2
April	24/04/2015	3
May	01/05/2015	3

May	06/05/2015	2
May	08/05/2015	2
May	14/05/2015	3
May	22/05/2015	2
May	22/05/2015	3
May	28/05/2015	3
June	05/06/2015	2
June	19/06/2015	2
June	19/06/2015	3
July	03/07/2015	2
July	07/07/2015	3
July	17/07/2015	2
July	28/07/2015	3
July	31/07/2015	2
August	11/08/2015	3
August	14/08/2015	2
August	28/08/2015	2
September	08/09/2015	3
September	11/09/2015	2
September	16/09/2015	3
September	25/09/2015	2
October	09/10/2015	2
October	23/10/2015	3
October	23/10/2015	2
November	06/11/2015	2
November	11/11/2015	3
November	20/11/2015	3
November	20/11/2015	2
December	04/12/2015	2
December	14/12/2015	2
January	08/01/2016	2
January	14/01/2016	3
January	19/01/2016	3
January	28/01/2016	2
February	02/02/2016	2
February	16/02/2016	3
March	01/03/2016	2
March	10/03/2016	2
March	15/03/2016	2
March	16/03/2016	3
March	29/03/2016	2

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

Details of inquorate meeting held:01 April 2015 - 31 March 2016

None

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

Name	Number of Meetings Attended
Dr Jane Orton	10
Dr Sheila E. Fisher	9
Miss Emma Lundy	9
Mr Anthony Warnock-Smith	8
Dr Michael Clarke	7
Ms Sarah Kirkland	7
Dr Vera Neumann	7
Mr Vishal Sharma	7
Mr Ashley Stratton-Powell	7
Dr Caroline Magee	6
Ms Danni Collingridge Moore	5
Dr Diane Farrar	5
Dr Jan Geddes	5
Dr Jonathan Thornley	5
Dr Martin Elliott	2

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

Name	Number of Meetings Attended
Mr Anthony Warnock-Smith	5
Dr Martin Elliott	4
Dr Sheila E. Fisher	4
Dr Vera Neumann	4
Dr Jane Orton	4
Dr Jan Geddes	3
Ms Sarah Kirkland	3
Mr Vishal Sharma	3
Dr Michael Clarke	2
Dr Diane Farrar	2
Dr Caroline Magee	2
Ms Danni Collingridge Moore	1
Mr Ashley Stratton-Powell	1
Dr Jonathan Thornley	1

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

Name	Number of Meetings Attended
Dr Sheila E. Fisher	22

Dr Vera Neumann	17
Mr Anthony Warnock-Smith	15
Mr Ashley Stratton-Powell	12
Dr Diane Farrar	7
Miss Emma Lundy	7
Ms Sarah Kirkland	6
Dr Michael Clarke	5
Dr Jane Orton	5
Mr Vishal Sharma	5
Dr Jonathan Thornley	5
Ms Danni Collingridge Moore	4
Dr Jan Geddes	3
Dr Caroline Magee	3
Dr Martin Elliott	1

Training 01 April 2015 - 31 March 2016

Name of Member	Date	Event(s) attended
Dr Michael Clarke	02/07/2015	Equality and Diversity
Ms Danni Collingridge Moore	16/03/2016	National Members Training Day
Dr Diane Farrar	16/03/2016	National Members Training Day
Dr Sheila E. Fisher	04/06/2015	Local Training Day - North East and Yorkshire & Humber REC
Dr Sheila E. Fisher	16/03/2016	National Members Training
Ms Sarah Kirkland	04/06/2015	Local Training Day - North East and Yorkshire & Humber REC
Ms Sarah Kirkland	24/07/2015	Personal Data in Research - A Workshop
Ms Sarah Kirkland	03/12/2015	HRA Workshop: Pragmatic or Point of Care trials
Dr Caroline Magee	12/10/2015	Complex Cases
Dr Vera Neumann	04/06/2015	Local Training Day - North East and Yorkshire & Humber REC
Dr Jane Orton	04/06/2015	Local Training Day - North East and Yorkshire & Humber REC
Dr Jane Orton	16/03/2016	National Members Training Day
Mr Vishal Sharma	31/03/2016	Self-Directed Learning Log 2015-16
Mr Ashley Stratton-Powell	05/02/2016	Local Training Day -Social Care REC
Mr Anthony Warnock-Smith	04/06/2015	Local Training Day - North East and Yorkshire & Humber REC

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	9	18.75
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	81.25
Total Applications Reviewed	48	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	19
Number of paediatric applications reviewed	6
Number of device applications reviewed	10
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	7
Number of applications reviewed that are funded by the US DHHS	0
Number of qualitative applications reviewed	9

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	0	0.00
Favourable Opinion with Additional Conditions	3	6.25
Unfavourable Opinion	8	16.67
Provisional Opinion	37	77.08
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	48	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	29	60.42
Further Information Favourable Opinion with Additional Conditions	7	14.58
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	3	6.25
Unfavourable Opinion	8	16.67
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	2.08
Total	48	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	9
Number of studies withdrawn prior to the meeting	2
Number of student applications reviewed	13
Number of paediatric applications reviewed	5
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	16	53.33
Favourable Opinion with Additional Conditions	2	6.67
No Opinion transfer to full committee for review	4	13.33
Provisional Opinion	6	20.00
Unfavourable Opinion	2	6.67
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	4.80
Number of completed applications for full ethical review	47
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	2
Number of completed applications over 40 days as a % of total	4.17%
Number of days taken to final decision – average (mean)	31
Number of completed proportionate review applications for ethical review	26
Number of completed proportionate review applications for ethical review over 14 days	4
Number of completed proportionate review applications over 14 days as a % of total	15.38%
Number of SSAs (non-Phase 1) reviewed	4
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	112
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	4
Number of completed substantial amendments over 28 days as a % of total substantial amendments	3.57%
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 minor amendments received	111
Number of substantial amendments received for information	3
Number of substantial amendments received for new sites/PIs	33
Number of annual progress reports received	89
Number of safety reports received	39

Number of Serious Adverse Events received	9
Number of final reports received	22

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
15/YH/0111	Cervical Health: The structure and function of the internal os	31
15/YH/0123	CardiAQ TMVI System Study	35
15/YH/0178	Vertex - VX14-661-109 - Cystic Fibrosis	35
15/YH/0191	Qualitative study of unlicensed medicines use	31
15/YH/0197	UK FaND Study: Fibrin clot structure / function and NETosis in patients with Diabetic Foot Ulcer	40
15/YH/0201	TRIUMPH	22
15/YH/0214	Accuracy total Immunoglobulin Test Device	37
15/YH/0217	Dual Energy CT For Brain Iron Quantification In Neurodegeneration	32
15/YH/0312	Effectiveness of attending Occupational Therapy groups on recovery v.2	33
15/YH/0313	The care in the network - 2	31
15/YH/0348	CARS	29
15/YH/0349	IELSG 42 - Marietta	27
15/YH/0352	The use of home adaptation by people with dementia. Version 1	26
15/YH/0399	ProNOx 5: NOx Dressing for Healing of Venous Leg Ulcers	49
15/YH/0470	The lived experience of using a mental health employment service	30
15/YH/0492	TIRCON2012V1-EXT	33
15/YH/0493	LCC-CARIS-01: Molecular profiling in gynaecological cancer.	34
15/YH/0512	Augmented Microfracture for Improved Cartilage Repair (Version 1.0)	31
15/YH/0543	Microscopic colitis - survey of diagnostic pathways	35
15/YH/0547	Measurement of O3FA levels in ileostomy fluid	38
16/YH/0004	PhII_MOR00208 & Idelalisib_Patients with Relapsed Refractory CLL/SLL	34
16/YH/0005	Multi-sensory storytelling PMLD. Version 1.0	40
16/YH/0007	Conversational repair as a measure of insight in Wernicke's Aphasia	36
16/YH/0016	Socio-medical factors and survival in chronic myeloid leukaemia	26
16/YH/0039	A comparative study of MACE and gastroscopy in upper GI bleeding	26
16/YH/0049	Physical fitness prior to colorectal surgery	31
16/YH/0076	Caffeine and coronary blood flow	31
16/YH/0086	Psoriasis DiseAse Research 1.0	31
16/YH/0093	Clinical Evaluation of an Optical Coherence Tomography BGMS	35

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
15/YH/0286	The MATE study	29
15/YH/0379	Cartiva® GRIP Study, PTC-0116	32
15/YH/0405	SUI vs. RUI	30
15/YH/0516	Evaluation of an L-FABP Urine Device (ELUDe) V1	36
16/YH/0002	Developing care for stroke survivors with communication difficulties	35
16/YH/0019	Patient experience of low grade glioma and awake craniotomy	27
16/YH/0045	HIDDEN study	36

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

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
15/YH/0208	Experiences of early discharge in paediatric febrile neutropenia	27
15/YH/0357	Biomarker levels in children with cancer with febrile neutropenia	21
15/YH/0402	A Phase 2 Safety and Pharmacokinetics Study of Ataluren (COMPASS)	27

Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock
15/YH/0216	Escitalopram in anxiety associated COPD exacerbations	23
15/YH/0324	Understanding Patient Reported Outcome Measures using eye tracking	18
15/YH/0404	Envelope Mastectomy and Immediate Reconstruction (EMIR)	49
15/YH/0494	Analysis of attenders/non-attenders to a breast cancer support centre	27
15/YH/0499	Parental anxiety and expectations following children's facial injuries	27
15/YH/0536	ELAD for treatment of alcohol induced liver decompensation (VTL-308)	36
16/YH/0003	Binaural Music Therapy to help people with dementia (MBMT)	32
16/YH/0041	Type 2 Diabetes Mellitus, heart and brain function	26

Provisional Opinion		
REC Reference	Title	Number of Days on Clock

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

Withdrawn after the meeting		
REC Reference	Title	Number of Days on Clock
15/YH/0200	Efficacy of DRC+/- Bortezomib in Waldenström's Macroglobulinemia	23

Table 9.2: Breakdown of current status of all PRS applications reviewed within the reporting period

Further Information Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
15/YH/0174	Salford Kidney Health Intervention Project	11
15/YH/0255	VSEs in patients affected by chronic liver disease_version 1	15
15/YH/0390	UT and VS of the electronic versions of AQLQ12+ and ACQ-7	13
15/YH/0562	HiRes IR Imaging for diagnosis in the acute limping child - ThermLimp	14
16/YH/0137	Analysis of blood cells & serum from pathological bone disease patients	21

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
15/YH/0422	Qualitative exploration of medication adherence in PCI patients	14

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
15/YH/0167	Validating the MSK-HQ	13
15/YH/0171	Investigating functional immune profiles in Multiple Sclerosis	13
15/YH/0221	TSB - STRATFix	8
15/YH/0222	Effect of Music on Patients' Anxiety and Pain during Phlebotomy	8
15/YH/0278	PROMs	9
15/YH/0280	PredictCAT v1.1	11
15/YH/0281	Investigation of Progenitor Cells Version 1	9
15/YH/0320	EPidemiology of Cancer after solid Organ Transplantation – EPCOT study	8
15/YH/0389	CIAP	8
15/YH/0391	Modelling rare and common diseases using iPS-derived cells	8
15/YH/0393	Do food allergies cause persistent airway inflammation?	8
15/YH/0480	Shoulder Pain after Recent Stroke (SPARS)	9
15/YH/0518	A comparison of invasive and non-invasive blood pressure in children	13
15/YH/0524	Reasons for non-participation of patients in research studies	13
16/YH/0089	FASBAT	13
16/YH/0136	Adverse Drug Event Screening Tool	18

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
15/YH/0147	Ejaculatory dysfunction after BPH surgery: retrograde or Anejaculation	13
16/YH/0138	Fecal microbiota and volatile organic compounds in Parkinson's disease	21

Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock
16/YH/0044	Use of thromboelastography for monitoring NOACs	11
16/YH/0092	Personality Profiles	13

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/Q1205/69/AM15	Yorkshire and Humberside Haematology Network Register	Substantial Amendment 13	10/08/2015	14
05/Q1108/28/AM14	Characterisation of Giant cell arteritis & polymyalgia rheumatica	Amendments 14 and 15	15/06/2015	18
05/Q1205/148/AM17	Safety evaluation of tacrolimus in atopic dermatitis (Version 2)	Substantial Amendment 4.0 - 27/04/2015	27/04/2015	17
05/Q1205/148/AM18	Safety evaluation of tacrolimus in atopic dermatitis (Version 2)	Substantial Amendment 5.0 - September 2015	15/09/2015	9
06/Q1107/44/AM01	Human Liver in Drug Metabolism at CLEH (D1150-002)	Substantial Amendment 1	01/09/2015	9
07/Q1205/27/AM04	Biology of mesenchymal stem cells and their use in tissue repair	Substantial Amendment 4 - 29/02/2016	18/02/2016	22
08/H1307/135/AM19	ADMIRE Trial Version 1.0	Substantial Amendment HM08 - 03/08/2015	03/08/2015	15
08/H1307/85/AM08	12C/13C Calcium Carbonate Breath Test for Gastric Acid Secretion.Ver:1	Substantial Amendment 7 - April 2015	13/04/2015	14
09/H1307/20/AM22	SHIFT Trial	Substantial Amendment 16 - 19/02/2016	19/02/2016	25
09/H1307/54/AM14	Open-label study of Denosumab in Subjects with Giant Cell Tumor	Substantial Amendment 12	30/04/2015	27
09/H1307/54/AM15	Open-label study of Denosumab in Subjects with Giant Cell Tumor	Substantial Amendment 12	17/08/2015	11
09/H1307/54/AM16	Open-label study of Denosumab in Subjects with Giant Cell Tumor	Substantial Amendment 14	26/10/2015	11
09/H1307/60/AM02	Wear Analysis of Explanted Orthopaedic Prostheses	Substantial Amendment 2	01/02/2015	20
09/H1307/7/AM07	Drivers of eating behaviour during a period of overconsumption	Amendment 8 -	23/06/2015	19

		23/06/2015		
09/H1307/98/AM15	Disease continuum	Substantial Amendment 11	19/01/2015	18
09/H1311/58/AM06	Driving simulator performance in obstructive sleep apnoea	Substantial Amendment 2, 21/09	28/09/2015	16
09/H1311/80/AM03	GIMEMA QOL - MDS 0108	Substantial Amendment version 3 - 19/07/2015	01/07/2014	17
10/H1307/126/AM14	CC-10004-PSA-002 Apremilast in Active Psoriatic Arthritis	IBv15 - 16/03/2015	16/03/2015	11
10/H1307/138/AM11	Very Early versus Delayed Etanercept in patients with RA (VEDERA)	Substantial Amendment 9	25/02/2015	7
10/H1307/27/AM05	ROLARR (RObotic versus LAparoscopic Resection for Rectal cancer)	Substantial Amendment 4	01/07/2015	8
10/H1307/91/AM10	Compassionate Use Study of Mepolizumab in Hypereosinophilic Syndrome	Substantial Amendment 10	16/07/2015	14
11/H1307/6/AM39	SWITCH version 1.0	Substantial Amendment 32	08/04/2015	18
11/H1307/9/AM17	CC-10004-PSA-003 Apremilast in Active Psoriatic Arthritis	Updated IB v15 - 16/03/2015	16/03/2015	11
11/YH/0291/AM03	Pectoralis muscle biopsy in CHF patients	Substantial Amendment 4	07/07/2015	7
11/YH/0424/AM06	Vibration in boys with a history of fracture version 1	Substantial Amendment 4 - 10/12/2015	10/12/2015	10
11/YH/0442/AM11	ENCHANTED	Substantial Amendment 7	10/08/2015	20
11/YH/0442/AM13	ENCHANTED	Substantial Amendment 8	03/09/2015	6
12/YH/0011/AM13	Efficacy of Pomalidomide in Systemic Sclerosis (SSC), amend.1 08NOV11	Substantial Amendment 8	24/09/2015	7
12/YH/0377/AM08	CMV modulation of the immune system in ANCA-associated vasculitis - v1	Substantial Amendment 6	12/08/2015	8
12/YH/0467/AM10	Phase I/II Trial of RNActive derived vaccine in Prostate Cancer	Protocol Amendment 3	09/06/2015	28
12/YH/0467/AM11	Phase I/II Trial of RNActive derived vaccine in Prostate Cancer	Substantial	22/10/2015	10

		Amendment 10		
13/YH/0003/AM15	Ibrutinib in Chronic Lymphocytic Leukaemia/Small Lymphocytic Lymphoma	Substantial Amendment 11	03/09/2015	15
13/YH/0066/AM18	PRESSURE 2	Substantial Amendment 5, 25/09	28/09/2015	11
13/YH/0159/AM04	Adjuvant Pegylated Interferon in Ulcerated Melanoma	Substantial Amendment 2 - 14/07/2015	15/07/2015	16
13/YH/0163/AM03	A CBT resource for young people with dental anxiety	Substantial Amendment 2	23/04/2015	12
13/YH/0163/AM04	A CBT resource for young people with dental anxiety	Substantial Amendment 3 - 23/07/2015	23/07/2015	10
13/YH/0201/AM12	Study of Sativex in Children (aged 8-18) with Severe Spasticity	Substantial Amendment 6	31/03/2015	13
13/YH/0201/AM15	Study of Sativex in Children (aged 8-18) with Severe Spasticity	Substantial Amendment 12 - 31/12/2015	31/12/2015	26
13/YH/0219/AM02	Cognition in Cystic Fibrosis patients and matched controls (Version 1)	Substantial Amendment 2	07/04/2015	33
13/YH/0279/AM14	PROMOTE	Substantial Amendment 9	05/05/2015	20
13/YH/0279/AM16	PROMOTE	Substantial Amendment 11	04/02/2016	18
13/YH/0309/AM04	CORAL XT – Open-label extension trial of the CORAL trial	Substantial Amendment 4	30/06/2015	16
13/YH/0349/AM01	Atrial fibrosis and circulating collagen markers	Amendment 1, 11 Feb 2015	11/02/2015	17
13/YH/0366/AM06	Efficacy and safety of 11b-HSD1 inhibitor in IIH	Substantial Amendment 2	20/05/2015	15
13/YH/0366/AM08	Efficacy and safety of 11b-HSD1 inhibitor in IIH	Substantial Amendment 3	05/10/2015	10
13/YH/0366/AM11	Efficacy and safety of 11b-HSD1 inhibitor in IIH	Substantial Amendment 4	11/11/2015	17
13/YH/0377/AM06	Computerised aphasia therapy RCT (Big CACTUS)	Substantial Amendment 3	17/07/2015	18

13/YH/0400/AM09	Delirium prevention for older people in hospital: a feasibility study	Substantial Amendment 5	12/05/2015	17
14/YH/0006/AM08	Open Label Extension Study of Lacosamide in Paediatric Subjects	Substantial Amendment 6	27/08/2015	18
14/YH/0007/AM09	Lacosamide in Subjects ages 4 years and over and less than 17 with Epil	Substantial Amendment 6 - 22/04/2015	22/04/2015	19
14/YH/0007/AM11	Lacosamide in Subjects ages 4 years and over and less than 17 with Epil	Substantial Amendment 7	26/06/2015	23
14/YH/0011/AM01	Freedom Study	Substantial Amendment 1, 24/09	22/09/2015	19
14/YH/0034/AM04	IciCLLe -Assessment of the Mechanism of Action of Ibrutinib	Substantial Amendment 5	10/06/2015	15
14/YH/0034/AM05	IciCLLe -Assessment of the Mechanism of Action of Ibrutinib	Amendment 6 - 19/08/2015	19/08/2015	8
14/YH/0078/AM02	MICROSHOCK	Substantial Amendment 2	30/04/2015	35
14/YH/0078/AM03	MICROSHOCK	Substantial Amendment 3	10/07/2015	12
14/YH/0085/AM17	FLAIR version 1.0	HM13/10747/ Docs/030915	03/09/2015	14
14/YH/0126/AM01	The Athletes Heart Study	Substantial Amendment 1	11/01/2016	12
14/YH/0128/AM03	SaFaRI (SNS versus the FENIX MSA for adult FI)	Substantial Amendment 2	30/04/2015	18
14/YH/0128/AM05	SaFaRI (SNS versus the FENIX MSA for adult FI)	Substantial Amendment 3 - 07/03/2016	07/03/2016	11
14/YH/1025/AM03	Prodigy-I	Substantial Amendment 1	05/06/2015	15
14/YH/1027/AM01	Maiden Back Study	Substantial Amendment 1	30/06/2015	34
14/YH/1032/AM02	Services for Juvenile Huntington's Disease	Substantial Amendment 2	02/04/2015	28
14/YH/1032/AM03	Services for Juvenile Huntington's Disease	Substantial Amendment 3,	12/08/2015	34

		10/08		
14/YH/1070/AM02	Developing a new EEG method for the early diagnosis of dementia.	Substantial Amendment 1	08/06/2015	20
14/YH/1070/AM03	Developing a new EEG method for the early diagnosis of dementia.	Substantial Amendment 2 - 11/03/2016	11/03/2016	14
14/YH/1116/AM01	Drug Targets in IBD	Substantial Amendment 1	29/07/2015	15
14/YH/1126/AM06	Medicines Optimisation in Cancer Pain	Substantial Amendment	06/01/2016	8
14/YH/1126/AM08	Medicines Optimisation in Cancer Pain	Substantial Amendment 2	19/01/2016	25
14/YH/1174/AM02	The Delirium Observation Screening Scale (DOSS) Study	Substantial Amendment 1	27/03/2015	18
14/YH/1174/AM06	The Delirium Observation Screening Scale (DOSS) Study	Substantial Amendment 2	22/04/2015	10
14/YH/1174/AM09	The Delirium Observation Screening Scale (DOSS) Study	Substantial Amendment 3	10/11/2015	13
14/YH/1175/AM05	Ibrutinib in Chronic Lymphocytic Leukaemia/Small Lymphocytic Lymphoma	Substantial Amendment 4	27/04/2015	27
14/YH/1175/AM06	Ibrutinib in Chronic Lymphocytic Leukaemia/Small Lymphocytic Lymphoma	Substantial Amendment 2	27/08/2015	18
14/YH/1175/AM07	Ibrutinib in Chronic Lymphocytic Leukaemia/Small Lymphocytic Lymphoma	Substantial Amendment 6 - 09/03/2016	09/03/2016	23
14/YH/1193/AM02	Exploring the interactions between staff and patients (Version 1)	Substantial Amendment 1	27/04/2015	11
14/YH/1208/AM01	Recognising suffering at the end of life	Protocol V8 29 June 2015	29/06/2015	6
14/YH/1215/AM01	Kneeling ability following total knee arthroplasty (Replacement)	Substantial Amendment 1	16/11/2015	18
14/YH/1253/AM01	Accel-Heal: Gene Expression Study.	Substantial Amendment 1	08/06/2015	22
14/YH/1259/AM02	ALPHA	Substantial Amendment 2	04/06/2015	13
14/YH/1259/AM04	ALPHA	Substantial Amendment 4	30/07/2015	15

14/YH/1259/AM06	ALPHA	Substantial Amendment 6, 02/10	02/10/2015	13
14/YH/1259/AM09	ALPHA	Amendment 8 - 16/12/2015	16/12/2015	27
14/YH/1260/AM02	Frontier II	Amendment 3 - 16/12/2015	16/12/2015	11
14/YH/1303/AM03	VISTAKONÂ® MULTIFOCAL CONTACT LENSES USED BY FUNCTIONAL EMMETROPES	Substantial Amendment 1	26/03/2015	10
14/YH/1304/AM01	Phase 2 Study of Ataluren (PTC124) as Treatment for MPS I	Substantial Amendment 1	19/03/2015	19
15/YH/0017/AM02	Extension Paediatric study of Intrathecal IdursulfaseIT with Elaprase®	Substantial Amendment 2	31/03/2015	17
15/YH/0017/AM04	Extension Paediatric study of Intrathecal IdursulfaseIT with Elaprase®	Addendum to IB Ed 9.0	11/05/2015	8
15/YH/0017/AM05	Extension Paediatric study of Intrathecal IdursulfaseIT with Elaprase®	Substantial Amendment 4 - 24/02/2016	24/02/2016	18
15/YH/0020/AM03	Calibre	Substantial Amendment 3 - 11/03/2016	11/03/2016	18
15/YH/0037/AM01	Development of the Addiction Therapist Rating Scale (ATRS)	Substantial Amendment 1	23/04/2015	16
15/YH/0037/AM02	Development of the Addiction Therapist Rating Scale (ATRS)	Substantial Amendment 2	17/08/2105	19
15/YH/0107/AM01	Unloading shoes for intermittent claudication	Substantial Amendment 1	14/05/2015	7
15/YH/0108/AM01	FUTURE 4	Substantial Amendment 1	13/07/2015	22
15/YH/0117/AM01	REPAIR-Right vEntricular remodeling in Pulmonary Arterlal hypeRtension	Substantial Amendment 2	17/02/2015	23
15/YH/0117/AM02	REPAIR-Right vEntricular remodeling in Pulmonary Arterlal hypeRtension	Substantial Amendment 3	13/08/2015	23
15/YH/0117/AM03	REPAIR-Right vEntricular remodeling in Pulmonary Arterlal hypeRtension	Substantial Amendment 4	21/08/2015	10
15/YH/0174/AM01	Salford Kidney Health Intervention Project	Substantial Amendment 1,	01/10/2015	7

		30/09		
15/YH/0178/AM02	Vertex - VX14-661-109 - Cystic Fibrosis	Substantial Amendment 2	20/07/2015	21
15/YH/0178/AM03	Vertex - VX14-661-109 - Cystic Fibrosis	Substantial Amendment 3	08/10/2015	15
15/YH/0208/AM02	Experiences of early discharge in paediatric febrile neutropenia	Substantial Amendment 1 - 05/06/2015	08/06/2015	12
15/YH/0208/AM03	Experiences of early discharge in paediatric febrile neutropenia	Substantial Amendment 2 - 30/11/2015	30/11/2015	11
15/YH/0214/AM02	Accuracy total Immunoglobulin Test Device	Protocol Amendment 2	10/09/2015	10
15/YH/0280/AM02	PredictCAT v1.1	Substantial Amendment 1 - 15/02/2016	15/02/2016	12
15/YH/0286/AM01	The MATE study	Substantial Amendment 1	11/11/2015	11
15/YH/0286/AM02	The MATE study	Substantial Amendment 2 - 17/12/2015	17/12/2015	26
15/YH/0349/AM01	IELSG 42 - Marietta	Substantial Amendment 1, 10/09	24/09/2015	10
15/YH/0349/AM02	IELSG 42 - Marietta	Substantial Amendment 2	03/11/2015	10
15/YH/0349/AM03	IELSG 42 - Marietta	Substantial Amendment 3 - 02/02/2016	02/02/2016	26
15/YH/0349/AM06	IELSG 42 - Marietta	Substantial Amendment 5 - 17/03/2016	17/03/2016	15
15/YH/0390/AM04	UT and VS of the electronic versions of AQLQ12+ and ACQ-7	Substantial Amendment 1	12/01/2016	7
15/YH/0402/AM01	A Phase 2 Safety and Pharmacokinetics Study of Ataluren (COMPASS)	Substantial Amendment 1 - 14/03/2016	14/03/2016	14

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

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

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 14 day timeline

REC Reference	Title	Number of Days on Clock
15/YH/0255	VSEs in patients affected by chronic liver disease_version 1	15
16/YH/0136	Adverse Drug Event Screening Tool	18
16/YH/0137	Analysis of blood cells & serum from pathological bone disease patients	21
16/YH/0138	Fecal microbiota and volatile organic compounds in Parkinson's disease	21

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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