

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

Annual Report

01 April 2016 - 31 March 2017



Part 1 – Committee Membership and Training

Name of REC:	Yorkshire & The Humber - Leeds East Research Ethics Committee
Type of REC:	RECs recognised to review CTIMPS in patients - Type III
Type of Flag:	Establishing Research Tissue Banks IRB Registered Phase 1 Studies in Patients Research Involving Children Adults lacking capacity
Chair:	Dr Rhona Bratt
Vice-Chair:	Dr Deborah Jane Fox
Alternate Vice-Chair:	Dr Alexandros Chatziagorakis
REC Manager:	Ms Katy Cassidy
REC Assistant:	Miss Sarah Prothero
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Chair's overview of the past year:

This is my third annual report as Chair of the Leeds East Research Ethics Committee. My thanks go our vice-chair, Debbie Fox, and our new Alternate Vice Chair, Alex Chatziagorakis, for their support in the past 12 months. Two members left having served 10 years on the committee. I would like to thank Stuart Jamieson and Roly Squire for giving freely of their time to the research ethics service. The contributions of Stuart and Roly are greatly missed. We have had the good fortune to have new members join us, Karl Ward, Nicky Kime, and Bob Philips. They bring very different skills and experience with them and their contributions are greatly appreciated by the committee.

It should like to thank the staff who work directly with the members, as well as with the research applicants, Committee Manager Katy Cassidy and assistant Sarah Prothero. It is a tribute to their hard work that applicants are well informed of what is needed and the work of the committee members can be done efficiently. Katy and Sarah have recently steered us through our tri-annual audit – not an easy task. During this year they have worked with individual members to increase the use of the members' portal so that the time and cost of producing and dispatching hard copies of application is greatly reduced.

Research becomes ever more varied and complex and the committee members have attended many face-to-face training courses, as well as completing on-line courses, to continue their professional development in Research Ethics review. The work of the committee took place in an environment of ever-greater change but the members' steadfast commitment to reviewing the research continued as always; calm, courteous and professional as well as with a good dose of humour. All I can say to the committee is thank you for all you work.

Yorkshire & The Humber - Leeds East Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Miss Jennifer Blaikie	Senior Research Ethics Administrator	Lay Plus	01/01/2014	
Dr Rhona Bratt	Retired Multimedia Project Manager	Lay Plus	01/08/2014	
Professor Kenneth Brodlie	Retired Professor of Visualization	Lay Plus	13/06/2011	
Dr Alexandros Chatziagorakis	Specialty Trainee (ST) in General Adult Psychiatry	Expert	01/10/2014	
Dr Deborah Jane Fox	Senior Lecturer in Nursing	Expert	01/04/2011	
Dr Stuart Jamieson	Consultant Neurologist	Expert	31/07/2007	01/05/2016
Mrs Ann Kay	Retired Special Needs Coordinator	Lay Plus	01/03/2014	
Dr Nicky Kime	Senior Research Fellow	Expert	01/06/2016	
Dr Nicolas Orsi	Senior Research Fellow	Expert	01/12/2015	
Dr Robert Phillips	Senior Clinical Academic	Expert	03/10/2016	
Dr Andrew Pollard	Consultant Anaesthetist	Expert	22/09/2014	
Mr Satti Saggu	Research Project Manager	Lay Plus	11/02/2015	
Dr Anna Schuberth	Specialty Registrar in Palliative Medicine	Expert	01/03/2014	
Mr Roly Squire	Consultant Paediatric Surgeon	Expert	31/07/2007	31/12/2016
Mr Karl Ward	Senior Research Nurse	Expert	18/04/2016	
Mr Tom Wilson	Consultant ENT Surgeon	Expert	18/04/2011	
Miss Kate Woodrow	Assistant Chief Pharmacist	Expert	01/12/2012	

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

Name	Declaration of Interest	Date
Miss Jennifer Blaikie	Employed by the Research and Innovation Service at the University of Leeds	31/03/2017
Dr Rhona Bratt	None declared	31/03/2017
Professor Kenneth Brodrie	Small shareholdings in AstraZeneca and GlaxoSmithKline	31/03/2017
Dr Deborah Jane Fox	Substantive post as Senior Lecturer at Leeds Beckett University	31/03/2017
Mrs Ann Kay	None declared	31/03/2017
Dr Nicky Kime	Member of the Faculty Research Ethics Committee for Carnegie Faculty at Leeds Beckett University.	12/04/2016
Dr Nicolas Orsi	Scientific Consultant, Ostara Biomedical. Action on Womb Cancer, Trustee. Team leader/Clinical lecturer appointment at University of Leeds	30/03/2017
Dr Robert Phillips	Chair of the Martin House Research Centre Advisory Board	31/03/2017
Dr Robert Phillips	Robert conducts work with Candlelighters, Martin House, TCT and JTV Cancer Support. Peer review for CCLG and NIHR CCL group.	07/10/2016
Dr Andrew Pollard	None declared.	31/03/2017
Dr Anna Schuberth	Works at St Catherine's Hospice, Scarborough. As a palliative medicine registrar, may be involved in research.	31/03/2017
Mr Karl Ward	Senior Research Nurse at LTHT. NIHR GCP Facilitator.	26/04/2016
Mr Karl Ward	LTHT Research Executive Committee - Neuro and Trust Wide	31/03/2017
Mr Tom Wilson	None declared	31/03/2017
Miss Kate Woodrow	Local R&D and pharmacy involvement in clinical trials	31/03/2017
Dr Alexandros Chatziagorakis	None declared	Pending
Mr Satti Saggu	Research Project Manager for the Academic Unit of Elderly Care and Rehabilitation at the Bradford Institute for Health Research. Community Champion for diabetes use.	31/03/2017

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

Month	Date	Number of Members Present at Meeting
April	05/04/2016	9
May	03/05/2016	11
June	07/06/2016	9
August	02/08/2016	9
September	06/09/2016	10
October	04/10/2016	10
November	01/11/2016	11
December	06/12/2016	11
February	07/02/2017	8
March	07/03/2017	12

10 full committee meetings were held during the reporting period.

Proportionate Review Sub-Committee Meetings held during 01 April 2016 - 31 March 2017:

Month	Date	Number of Members Present at Meeting
April	22/04/2016	3
May	13/05/2016	3
June	23/06/2016	3
July	11/07/2016	3
August	15/08/2016	3
September	20/09/2016	3
October	25/10/2016	0
November	14/11/2016	3
December	15/12/2016	0
February	23/02/2017	3
March	23/03/2017	0

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

Sub-Committee Meetings held during 01 April 2016 - 31 March 2017:

Month	Date	Number of Members Present at Meeting
April	08/04/2016	2
April	11/04/2016	2
April	15/04/2016	2
April	19/04/2016	2
April	25/04/2016	2
May	03/05/2016	2
May	09/05/2016	2
May	23/05/2016	2
May	24/05/2016	2
June	06/06/2016	2

June	20/06/2016	2
July	04/07/2016	2
July	18/07/2016	2
August	01/08/2016	2
August	15/08/2016	2
August	30/08/2016	2
September	12/09/2016	2
September	14/09/2016	3
September	26/09/2016	2
October	10/10/2016	2
October	24/10/2016	2
November	07/11/2016	2
November	21/11/2016	2
December	05/12/2016	2
December	19/12/2016	2
January	09/01/2017	2
January	23/01/2017	2
February	06/02/2017	2
February	20/02/2017	2
March	06/03/2017	2
March	20/03/2017	2

31 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
Miss Jennifer Blaikie	6
Dr Rhona Bratt	9
Professor Kenneth Brodlie	9
Dr Alexandros Chatziagorakis	7
Dr Deborah Jane Fox	6
Dr Stuart Jamieson	1
Mrs Ann Kay	7
Dr Nicky Kime	6
Dr Nicolas Orsi	6
Dr Robert Phillips	2
Dr Andrew Pollard	6
Mr Satti Saggu	3
Dr Anna Schuberth	9
Mr Roly Squire	7
Mr Karl Ward	4
Mr Tom Wilson	7
Miss Kate Woodrow	5

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

Name	Number of Meetings Attended
Miss Jennifer Blaikie	1
Dr Rhona Bratt	7
Professor Kenneth Brodlie	2
Dr Alexandros Chatziagorakis	2
Dr Deborah Jane Fox	2
Mrs Ann Kay	1
Dr Nicolas Orsi	1
Dr Andrew Pollard	1
Mr Satti Saggu	1
Dr Anna Schuberth	2
Mr Roly Squire	1
Mr Tom Wilson	3

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

Name	Number of Meetings Attended
Miss Jennifer Blaikie	2

Dr Rhona Bratt	26
Professor Kenneth Brodie	3
Dr Alexandros Chatziagorakis	3
Dr Deborah Jane Fox	10
Mrs Ann Kay	3
Dr Nicky Kime	1
Dr Nicolas Orsi	4
Dr Andrew Pollard	2
Mr Satti Saggu	1
Dr Anna Schuberth	3
Mr Karl Ward	1
Mr Tom Wilson	3
Miss Kate Woodrow	1

Training 01 April 2016 - 31 March 2017

Name of Member	Date	Event(s) attended
Miss Jennifer Blaikie	06/07/2016	Local Training Day - North East and Yorkshire Regional Training
Dr Rhona Bratt	20/04/2016	Researcher Training Day
Dr Rhona Bratt	05/05/2016	Equality, Diversity and Human Rights
Dr Rhona Bratt	29/06/2016	Handling Health Related Findings
Dr Rhona Bratt	06/07/2016	Local Training Day - North East and Yorkshire Regional Training
Dr Rhona Bratt	15/09/2016	Training - Committee Members Induction
Dr Rhona Bratt	22/03/2017	Training - National Members Training Day
Dr Rhona Bratt	28/03/2017	Training - Chairs Review Programme Workshop
Professor Kenneth Brodlie	17/03/2017	Reviewing the Research Design of Clinical Trials
Professor Kenneth Brodlie	17/03/2017	Equality Diversity and Human Rights
Professor Kenneth Brodlie	22/03/2017	NRES Adults Lacking Capacity - online toolkit
Dr Alexandros Chatziagorakis	03/06/2016	Mental Capacity Act and DoLS - Level 2
Dr Deborah Jane Fox	06/07/2016	Local Training Day - North East and Yorkshire Regional Training
Dr Nicky Kime	30/06/2016	GCP Training
Dr Nicky Kime	06/07/2016	Local Training Day - North East and Yorkshire Regional Training
Dr Nicky Kime	11/08/2016	Equality and Diversity
Dr Nicky Kime	15/09/2016	Training - Committee Members Induction
Dr Nicky Kime	22/03/2017	Training - National Members Training Day
Dr Nicolas Orsi	10/01/2017	Committee Members Induction
Dr Robert Phillips	31/10/2016	Online Induction for REC Members
Dr Robert Phillips	10/01/2017	Committee Members Induction
Dr Robert Phillips	01/02/2017	Equality and Diversity
Dr Anna Schuberth	11/01/2017	Palliative Medicine Registrar teaching on research
Dr Anna Schuberth	01/02/2017	Introduction to Good Clinical Practice e-learning (secondary care)
Dr Anna Schuberth	08/02/2017	Palliative medicine registrar teaching on research
Mr Roly Squire	08/07/2016	Researcher Ethics Study Day at Leeds University
Mr Karl Ward	15/09/2016	Training - Committee Members Induction

Mr Karl Ward	22/03/2017	Training - National Members Training Day
Miss Kate Woodrow	16/02/2017	Training - National Members Training Day
Mrs Ann Kay	20/10/2016	Training - Quantitative Research Methods and Statistics: A Health Research Authority Workshop
Mrs Ann Kay	22/03/2017	Training - National Members Training Day

PART 2: REC WORKLOAD AND ACTIVITY DURING THE REPORTING PERIOD

Table 1: Applications assigned to a full committee meeting held within the reporting period:

Applications for full ethical review – Study Type	Number	%
Clinical Trial of Investigational Medicinal Product	12	22.22
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	3	5.56
Research Database (including renewals)	0	0.00
Others	39	72.22
Total Applications Reviewed	54	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	15
Number of paediatric applications reviewed	10
Number of device applications reviewed	3
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	12
Number of applications reviewed that are funded by the US DHHS	1
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	3.70
Favourable Opinion with Additional Conditions	15	27.78
Unfavourable Opinion	1	1.85
Provisional Opinion	36	66.67
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	54	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	30	55.56
Further Information Favourable Opinion with Additional Conditions	3	5.56
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	3	5.56
Favourable Opinion with Additional Conditions	15	27.78
Unfavourable Opinion	1	1.85
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	2	3.70
Total	54	100

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

Total Applications Reviewed	21
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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	2
Number of studies withdrawn prior to the meeting	1
Number of student applications reviewed	12
Number of paediatric applications reviewed	0
Number of device applications reviewed	0
Number of qualitative applications reviewed	2

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	14	66.67
Favourable Opinion with Additional Conditions	3	14.29
No Opinion transfer to full committee for review	1	4.76
Provisional Opinion	2	9.52
Unfavourable Opinion	1	4.76
Total	21	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	5.40
Number of completed applications for full ethical review	52
Number of completed applications for full ethical review over 60 days	2
Number of completed applications over 60 days as a % of total	3.70%
Number of completed applications for full ethical review over 40 days	4
Number of completed applications over 40 days as a % of total	7.41%
Number of days taken to final decision – average (mean)	26
Number of completed proportionate review applications for ethical review	20
Number of completed proportionate review applications for ethical review over 14 days (Please note, the timeline for the review of the PR applications was extended from 14 – 21 calendar days in December 2016).	1
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	12
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	146
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	0
Number of completed substantial amendments over 28 days as a % of total substantial amendments	0.00%
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	128

Number of substantial amendments received for information	11
Number of substantial amendments received for new sites/PIs	51
Number of annual progress reports received	74
Number of safety reports received	38
Number of Serious Adverse Events received	0
Number of final reports received	6

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/0112	Optimising Mesorectal Irradiation in Early Rectal Cancer	25
16/YH/0114	Posture and Mobility in Care Homes.	21
16/YH/0154	R033812GTS3001: Domperidone v Placebo in children 6 months to 12 years	46
16/YH/0162	DTI MRI of the Brain, Spinal Cord and Brachial Plexus: Pilot Study	32
16/YH/0163	Scaling the Peaks	30
16/YH/0170	Sick day e-Alert for prevention of AKI	36
16/YH/0216	Fine grained facial image analysis in Wolf-Hirschhorn syndrome	61
16/YH/0221	Exploring medicines management in advanced cancer	29
16/YH/0224	The effect of DHA- & EPA-enriched oils on cognitive function and mood	61
16/YH/0238	Journeying through Dementia	30
16/YH/0295	Automated MRI based radiotherapy planning	19
16/YH/0297	Neurodegeneration in Aging Down Syndrome (NiAD)	24
16/YH/0370	King's Invasive Aspergillosis Study II (KIASII)	22
16/YH/0376	Study Reference KIT-302-03-02	22
16/YH/0396	URoBank: Urothelial Research Tissue Bank	23
16/YH/0406	Ambulance CPAP: Use, Treatment Effect and Economics feasibility study	22
16/YH/0411	Evaluation of new highly sensitive C. difficile toxin immunoassay	23
16/YH/0416	RCT of Post-op sensitivity; Fill-Up vs conventional composite	29
16/YH/0452	VINILO	17
16/YH/0461	THE LONG TERM SAFETY OF PF-06252616 IN BOYS WITH DUCHENNE MUSCULAR DYS	17
16/YH/0465	TALENT-AC	16
16/YH/0467	DNA bank for genetic studies in idiopathic dystonia	24
16/YH/0469	1297.4 - BI695501 versus Humira in patients with active Crohns disease	38
16/YH/0489	Secukinumab-Phase IV-New Onset plaque Psoriasis-STEPIN Study	37
17/YH/0025	Laser Doppler flowmetry in assessing the vitality of traumatised teeth	21
17/YH/0031	Dysphagia in Parkinson's patients: a neurostimulation study	21
17/YH/0032	Investigating the molecular mechanisms of eye disease	25
17/YH/0046	Central fatigue in heart failure	24
17/YH/0069	Use of NGS technologies for resolving clinical phenotypes	27
17/YH/0071	Esperion 1002-050 - Phase 3 Ext Study of ETC-1002 for Hyperlipidaemia	29

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
16/YH/0319	Understanding change in adolescents using GSH for disordered eating	17
16/YH/0321	Identify fluid responsive patients with sepsis in the Emergency Depart	29
16/YH/0500	Phase 1b 2 part study to assess LAM-001 in female subjects with LAM	26

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/0189	SDM between people with psychosis and mental health staff. v1	27
16/YH/0234	TOPSAT2	27
16/YH/0453	CABI: Antibiotic duration for Complicated intra-ABdominal Infection	17

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
16/YH/0120	A Study of a Novel In-Reach Rehabilitation & Recovery Service_V1	21
16/YH/0128	Men's Decisions within Treatment and Care for Low Risk Prostate Cancer	21
16/YH/0132	The Prognosis in Palliative care Study II (PiPS2)	40
16/YH/0151	The ZOLMENO study	24
16/YH/0290	The PNH Research Tissue Bank_V1	17
16/YH/0324	Reducing stasis outcomes in depression (Version 1.0)	17
16/YH/0371	eRAPID feasibility pilot study in pelvic radiotherapy	21
16/YH/0373	Impact of Closed Circuit Television (CCTV) Inside Mental Health Wards	21
16/YH/0400	How are stroke patients supported with eating and drinking	22
16/YH/0407	LILAC: Effect on Patient Reported Outcomes of Surgery and SABR (V 1.0)	22
17/YH/0020	Proinflammatory reprogramming of platelets in ACS	21
17/YH/0024	Connected Health Cities: Data linkage of urgent care data	21
17/YH/0051	How do general hospitals respond to personality disorder?	23
17/YH/0068	Analysis of the respiratory mycobiome	23
17/YH/0078	CV markers of stroke	52

Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock
17/YH/0033	Empagliflozin vs metformin in PCOS	21

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
16/YH/0374	Sixteen Plus:Whole family approach to understanding declining capacity	21
16/YH/0435	ALN-CC5 in patients with PNH	17

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/0363	Understanding the phenomena of 'confidence' in frail older people	13
16/YH/0485	Acquisition of 3D facial geometry of patients' scheduled for RT 1.0	11

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
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Favourable Opinion with Standard Conditions

REC Reference	Title	Number of Days on Clock
16/YH/0200	Yoga for anxiety and depression 1.0	14
16/YH/0208	Evaluation of biometrics derived using Microsoft Kinect surface maps	14
16/YH/0209	Long-term outcomes in women diagnosed with non-invasive breast cancer	15
16/YH/0276	Content of SMS reminders to improve uptake in breast screening; An RCT	7
16/YH/0279	The experience of impaired sensation related to Multiple Sclerosis V.2	7
16/YH/0292	An IPA of the impact of dx with prediabetes	11
16/YH/0293	SUCCESS Questionnaire Study	11
16/YH/0364	Understanding asthma phenotypes	13
16/YH/0415	NF-kB activation in myeloid cells	10
16/YH/0420	Feasibility of an online rehabilitation program	11
16/YH/0483	Managing phosphate levels in haemodialysis: The patient's view.	11
16/YH/0484	Community Management of Acute Eye Disease.	11
16/YH/0486	The effects of a fatigue-management group on brain injury patients	10
17/YH/0052	Pre-operative patient attitudes to anaesthesia for orthopaedic surgery	4

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/YH/0168	The Evaluation of the METSÅ® Proximal Humeral System	6
16/YH/0172	(duplicate) Quantification of lamellar bodies in healthy sputum	6
16/YH/0361	Models of Generalist and Specialist Care in Smaller Acute Hospitals	13

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
16/YH/0421	DCE endometriosis	10

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

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

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
06/Q1206/106/AM08	Preclinical Assessment of Anti-cancer Cellular Vaccines	Substantial Amendment 4, 22/02	24/03/2016	11
07/H1306/137/AM13	MDS Registry for newly diagnosed patients	Substantial Amendment 11, 18/0	28/06/2016	14
07/Q1206/30/AM17	Genetic abnormalities and their consequences in early cancer ver1	Substantial Amendment 19, 13/0	09/05/2016	20
07/Q1206/53/AM31	Imatinib versus nilotinib in newly diagnosed Ph+ve CML	Protocol Amendment 11, 18/04/1	07/07/2016	9
08/H1306/127/AM14	Pre-cancer genome-oral vers 1.0	Substantial Amendment 16, 16/0	09/05/2016	20
08/H1306/147+5/AM03	Respiratory Tissue Bank	Substantial Amendment 3, 01/04	04/04/2016	7
08/H1306/147+5/AM04	Respiratory Tissue Bank	Substantial Amendment 4, 22/09	22/09/2016	14
09/H1306/110/AM16	Pulmonary Substudy: A Substudy of START	Substantial Amendment 11, 25/1	15/11/2016	6
09/H1306/64/AM44	Strategic Timing of AntiRetroviral Treatment (START)	Substantial Amendment 28, 21/1	28/10/2016	13
10/H1306/61/AM57	Collaborative care for elders - the CASPER Trial	Substantial Amendment 25, 05/0	18/07/2016	14
10/H1306/88/AM06	CONVAS	Substantial Amendment v6.0,	09/02/2017	11

		08		
11/H1306/1/AM19	CC-10004-PSA-005 Apremilast in Active Psoriatic Arthritis	Substantial Amendment - IB v17	30/04/2016	17
11/YH/0145/AM09	Study of Recombinant Factor IX Product, IB1001, in Previously Treated	Substantial Amendment 7, 04/05	28/04/2016	20
11/YH/0145/AM11	Study of Recombinant Factor IX Product, IB1001, in Previously Treated	Substantial Amendment 9, 24/08	24/08/2016	19
11/YH/0248/AM05	Bone Mineral Density: A Substudy of START	Substantial Amendment 4, 18/10	02/11/2016	8
11/YH/0290/AM10	STOMP: SCLC Trial of Olaparib (AZD2281) as Maintenance Programme.	Substantial Amendment 8, 31/05	08/07/2016	19
11/YH/0319/AM01	Fanconi and related DNA repair pathways in brain tumours	Substantial Amendment 1, 01/05	27/05/2016	7
11/YH/0373/AM13	A study of selumetinib in patients with Kaposi's sarcoma	Substantial Amendment 12, 10/0	04/04/2016	11
11/YH/0373/AM15	A study of selumetinib in patients with Kaposi's sarcoma	Substantial Amendment 13, 03/0	03/02/2017	11
12/YH/0179/AM25	0117 - Phase 3 Extension Study of GS-1101 in CLL	Protocol amendment 6, 28/03/16	06/04/2016	18
12/YH/0179/AM28	0117 - Phase 3 Extension Study of GS-1101 in CLL	Substantial Amendment 11 – IB1	09/06/2016	21
12/YH/0179/AM29	0117 - Phase 3 Extension Study of GS-1101 in CLL	Substantial Amendment 12, 05/0	30/09/2016	8
12/YH/0179/AM31	0117 - Phase 3 Extension Study of GS-1101 in CLL	Substantial Amendment 13, 24/1	11/11/2016	18

12/YH/0318/AM23	0115: Bendamustine, Rituximab and GS-1101 or placebo in CLL	Substantial Amendment 13, 12/0	12/04/2016	20
12/YH/0318/AM24	0115: Bendamustine, Rituximab and GS-1101 or placebo in CLL	Substantial Amendment 14, 03/0	26/09/2016	17
12/YH/0318/AM25	0115: Bendamustine, Rituximab and GS-1101 or placebo in CLL	Substantial Amendment 15, 24/1	16/11/2016	19
12/YH/0452/AM47	INCA	Substantial Amendment 38, 10/0	10/01/2017	11
12/YH/0471/AM01	Health Of Patients' Eyes in Glaucoma Clinics: HOPE GLAUCOMA	Substantial Amendment 1, 19/04	21/04/2016	17
12/YH/0475/AM11	GP28331 - A PHASE Ib study - CHRONIC LYMPHOCYTIC LEUKAEMIA	Substantial Amendment 7, 08/04	08/04/2016	13
12/YH/0475/AM12	GP28331 - A PHASE Ib study - CHRONIC LYMPHOCYTIC LEUKAEMIA	Substantial Amendment 8, 14/11	14/11/2016	6
12/YH/0498/AM19	MTL-005 Radiosensitization in patients with head & neck cancer	Substantial Amendment 13, 10/0	12/05/2016	25
12/YH/0498/AM20	MTL-005 Radiosensitization in patients with head & neck cancer	Substantial Amendment 14, 21/0	12/07/2016	19
12/YH/0539/AM07	ABLE Trial – Afatinib Before Lung surgEry	Substantial Amendment 4, 27/01	14/04/2016	11
13/YH/0012/AM14	Open label extension study of PCI-32765 in CLL/SLL	Substantial Amendment 2, 19/10	31/01/2017	22
13/YH/0229/AM13	GO2, Version 1.0	Substantial amendment 11, 23/0	23/03/2016	18
13/YH/0229/AM15	GO2, Version 1.0	Substantial	20/05/2016	21

		amendment 12, 20/0		
13/YH/0281/AM05	Evaluation of [18F]-FET-12AG-TOCA for the imaging of NETs	Substantial Amendment 3, 01/06	24/06/2016	19
13/YH/0314/AM14	Extension study of BAY 85-3934 in the long-term treatment of anaemia	Substantial Amendment 9, 01/06	01/06/2016	18
13/YH/0333/AM18	Long term study for participants completing SIRROUND-D and SIRROUND-T	Substantial Amendment 13, 06/0	06/03/2017	11
13/YH/0346/AM06	Sildenafil in Heart Failure	Substantial Amendment 5, 06/07	08/07/2016	18
13/YH/0348/AM01	Lymphocyte phenotype and cytokine production in patients with fatigue.	Substantial Amendment 1, 17/10	13/10/2016	15
14/YH/0088/AM05	Phase I study of KHK2823 in AML or MDS	Substantial Amendment 5, 24/03	24/03/2016	13
14/YH/0088/AM06	Phase I study of KHK2823 in AML or MDS	Substantial Amendment 6 - IB E	16/06/2016	12
14/YH/0088/AM07	Phase I study of KHK2823 in AML or MDS	Substantial Amendment 7, 19/10	19/10/2016	17
14/YH/0090/AM05	Study to test ADIPEG20 in patients with mesothelioma and NSCLC V 02	Substantial Amendment 5 - 21/0	03/10/2016	23
14/YH/0092/AM09	Reduced-dosed rivaroxaban in the long-term prevention of VTE	Substantial Amendment 6, 07/06	07/06/2016	13
14/YH/0092/AM10	Reduced-dosed rivaroxaban in the long-term prevention of VTE	Substantial Amendment 7, 11/01	11/01/2017	19
14/YH/0123/AM05	1325 - Expanded access study with Idelalisib in patients with CLL	Substantial Amendment 5,	12/04/2016	7

		25/03		
14/YH/0123/AM06	1325 - Expanded access study with Idelalisib in patients with CLL	Substantial Amendment 6, 30/11	30/11/2016	15
14/YH/0131/AM11	ACP-196 in Subjects with Chronic Lymphocytic Leukemia	Substantial Amendment 7, 10/05	10/05/2016	16
14/YH/0131/AM12	ACP-196 in Subjects with Chronic Lymphocytic Leukemia	Substantial Amendment 8, 09/08	09/08/2016	14
14/YH/1052/AM13	The MUNROS project: the questionnaires (Work Packages 4,5 and 6)	Substantial Amendment 7, 23/11	28/11/2016	22
14/YH/1056/AM08	Phase2/3 of masitinib+dexamethasone & gemcitabine in TCell lymphoma v1	Substantial Amendment 7, 13/01	04/01/2017	15
14/YH/1056/AM09	Phase2/3 of masitinib+dexamethasone & gemcitabine in TCell lymphoma v1	Substantial Amendment 8, 22/12	26/01/2017	7
14/YH/1066/AM03	eRAPID RCT in systemic cancer treatment	Substantial Amendment 1.4, 01/	17/03/2016	13
14/YH/1066/AM04	eRAPID RCT in systemic cancer treatment	Substantial Amendment 1.5, 16/	04/07/2016	14
14/YH/1066/AM05	eRAPID RCT in systemic cancer treatment	Substantial Amendment 1.6, 02/	06/12/2016	14
14/YH/1153/AM11	Open-label extension study of LMTM in Alzheimers & bvFTD patients	Substantial Amendment 10 - 28/	16/03/2016	18
14/YH/1153/AM13	Open-label extension study of LMTM in Alzheimers & bvFTD patients	Substantial Amendment 11, 24/0	05/08/2016	10
14/YH/1153/AM17	Open-label extension study of LMTM in Alzheimers & bvFTD patients	Substantial Amendment 12, 15/1	16/02/2017	16

14/YH/1157/AM02	BONES – BOne (dys)function in donor NephrectomieS	Substantial Amendment 1, 14/11	25/11/2016	6
14/YH/1199/AM11	GALACTIC version 1.0	Substantial Amendment 10, 06/0	06/07/2016	13
14/YH/1282/AM04	PF-06252616 in Boys with Duchenne Muscular Dystrophy	Substantial Amendment 4, Proto	15/03/2016	22
14/YH/1282/AM06	PF-06252616 in Boys with Duchenne Muscular Dystrophy	Substantial Amendment 6, 12/10	12/10/2016	9
14/YH/1282/AM07	PF-06252616 in Boys with Duchenne Muscular Dystrophy	Substantial Amendment 7, 27/02	27/02/2017	27
15/YH/0051/AM16	SCIMITAR Plus (version 1.0)	Substantial Amendment 17, 21/0	27/04/2016	12
15/YH/0051/AM17	SCIMITAR Plus (version 1.0)	Substantial Amendment 21, 17/0	18/05/2016	18
15/YH/0051/AM21	SCIMITAR Plus (version 1.0)	Substantial Amendment 23, 15/0	19/07/2016	9
15/YH/0051/AM23	SCIMITAR Plus (version 1.0)	Substantial Amendment 24, 22/0	25/07/2016	14
15/YH/0051/AM24	SCIMITAR Plus (version 1.0)	Substantial Amendment 25, 26/0	02/09/2016	10
15/YH/0051/AM26	SCIMITAR Plus (version 1.0)	Substantial Amendment 27, 28/1	29/11/2016	12
15/YH/0080/AM01	Leeds Multidisciplinary Research Tissue Bank	Substantial Amendment 1, 19/10	19/10/2016	21
15/YH/0125/AM07	Phase 1b/2 Participants with Waldenström Macroglobulinemia	Substantial	14/04/2016	28

	ACE-WM-001	Amendment 4, 14/04		
15/YH/0125/AM08	Phase 1b/2 Participants with Waldenström Macroglobulinemia ACE-WM-001	Substantial Amendment 5, 03/08	03/08/2016	12
15/YH/0129/AM08	Proactive Telephone Coaching & Tailored Support (PROTECTS)	Substantial Amendment 3, 19/07	22/07/2016	12
15/YH/0134/AM01	The "R-3D-2" pilot study.	Substantial Amendment 1, 26 04	10/05/2016	18
15/YH/0139/AM04	Clinical decision making on the ward round	Substantial Amendment 1, 24/11	29/11/2016	14
15/YH/0239/AM08	Comparison of dupilumab to dummy drug when added to asthma treatment	Substantial Amendment 5, 12/07	12/07/2016	18
15/YH/0239/AM09	Comparison of dupilumab to dummy drug when added to asthma treatment	Substantial Amendment 6, 09/09	04/10/2016	27
15/YH/0239/AM10	Comparison of dupilumab to dummy drug when added to asthma treatment	Substantial Amendment 7, 01/12	01/12/2016	17
15/YH/0294/AM02	Pro-Euro-DILI Registry version 1	Substantial Amendment 2, 26/01	27/01/2016	6
15/YH/0295/AM05	STEADY study	Substantial Amendment 5, 11/04	03/05/2016	6
15/YH/0306/AM02	Exercise intolerance in CHF following CRT (V1)	Substantial Amendment 2, 13/01	24/01/2017	14
15/YH/0309/AM07	Type-2 Diabetes; Adults with inadequate glycemic control on Metformin	Substantial Amendment 3, 25/04	23/06/2016	14
15/YH/0309/AM08	Type-2 Diabetes; Adults with inadequate glycemic control on Metformin	Substantial Amendment 4,	25/07/2016	15

		27/05		
15/YH/0309/AM09	Type-2 Diabetes; Adults with inadequate glycemic control on Metformin	Substantial Amendment 5, 28/09	12/10/2016	9
15/YH/0310/AM03	MB29599 - A Study to Assess Biomarkers in Patients with Severe Asthma	Substantial Amendment 3, 12/01	17/01/2017	22
15/YH/0316/AM01	REO13 Melanoma GMCSF	Substantial Amendment 1, 13/04	04/05/2016	21
15/YH/0343/AM04	Accelerating Delivery Of Psychological Therapies after Stroke (ADOPTS)	Substantial Amendment 2, 14/11	14/11/2016	11
15/YH/0359/AM02	RESPECT-21: evaluation of specialist cancer surgery reorganisation	Substantial Amendment 1, 31/05	08/06/2016	10
15/YH/0370/AM02	Surgical Wounds Healing by Secondary Intention - SWHSI	Substantial Amendment 1, 12/04	13/04/2016	12
15/YH/0370/AM04	Surgical Wounds Healing by Secondary Intention - SWHSI	Substantial Amendment 2, 12/05	17/05/2016	28
15/YH/0378/AM04	Organ Care System (OCS [®]) Liver 'REVIVE' Trial	Substantial Amendment 1, 01/11	23/10/2016	18
15/YH/0388/AM02	Ceritinib food effect study in ALK positive NSCLC patients	Substantial Amendment 2, 29/03	29/03/2016	14
15/YH/0388/AM05	Ceritinib food effect study in ALK positive NSCLC patients	Substantial Amendment 4, 14/11	14/11/2016	7
15/YH/0407/AM01	Single Dose of MK-0517 for Prevention of CINV in Paediatric Subjects	Substantial Amendment 2, 03/08	03/08/2016	11
15/YH/0407/AM02	Single Dose of MK-0517 for Prevention of CINV in Paediatric Subjects	Substantial Amendment 3, 01/09	06/09/2016	5

15/YH/0428/AM06	4228: DUALâ„ç VIII – Durability, IDegLira vs IGLar in Type 2 diabetes	Substantial Amendment 2, 16/05	16/05/2016	15
15/YH/0428/AM08	4228: DUALâ„ç VIII – Durability, IDegLira vs IGLar in Type 2 diabetes	Substantial Amendment 3, 28/06	30/06/2016	14
15/YH/0428/AM09	4228: DUALâ„ç VIII – Durability, IDegLira vs IGLar in Type 2 diabetes	Substantial Amendment 4, 29/10	29/10/2016	9
15/YH/0428/AM10	4228: DUALâ„ç VIII – Durability, IDegLira vs IGLar in Type 2 diabetes	Substantial Amendment 5, 12/01	12/01/2017	8
15/YH/0434/AM04	Dose Optimization Study of Idelalisib in Follicular Lymphoma'	Substantial Amendment 3, 23/03	23/03/2016	18
15/YH/0434/AM05	Dose Optimization Study of Idelalisib in Follicular Lymphoma'	Substantial Amendment 4, 26/07	26/07/2016	17
15/YH/0434/AM07	Dose Optimization Study of Idelalisib in Follicular Lymphoma'	Substantial Amendment 5, 29/09	29/09/2016	8
15/YH/0484/AM03	I1F-MC-RHBF Ixekizumab in patients with active psoriatic arthritis	Substantial Amendment 2, 03/05	03/05/2016	11
15/YH/0484/AM04	I1F-MC-RHBF Ixekizumab in patients with active psoriatic arthritis	Substantial Amendment 3, 04/07	04/07/2016	15
15/YH/0484/AM05	I1F-MC-RHBF Ixekizumab in patients with active psoriatic arthritis	Substantial Amendment 4, 09/03	09/03/2017	12
15/YH/0485/AM02	GP15-301 Study to compare GP2015 and EnbrelÂ® in Rheumatoid Arthritis	Substantial Amendment 1, 15/02	31/03/2016	13
15/YH/0485/AM04	GP15-301 Study to compare GP2015 and EnbrelÂ® in Rheumatoid Arthritis	Substantial Amendment 2, 23/06	23/06/2016	6
15/YH/0489/AM01	REVAKI-2	Substantial	12/09/2016	12

		Amendment 1, 14/09		
15/YH/0490/AM02	MK-3682B in Hepatitis C (GT1 or GT3) patients who have failed a DAA	Substantial Amendment 2, 05/05	05/05/2016	10
15/YH/0490/AM03	MK-3682B in Hepatitis C (GT1 or GT3) patients who have failed a DAA	Substantial Amendment 4, 06/07	06/07/2016	7
15/YH/0490/AM04	MK-3682B in Hepatitis C (GT1 or GT3) patients who have failed a DAA	Substantial Amendment 5, 02/08	02/08/2016	13
15/YH/0490/AM07	MK-3682B in Hepatitis C (GT1 or GT3) patients who have failed a DAA	Substantial Amendment 7, 20/02	20/02/2017	14
15/YH/0491/AM01	MEASURING PROGRESS IN LABOUR WITHOUT THE USE OF VAGINAL EXAMINATION	Substantial Amendment 1, 16/01	24/01/2017	14
15/YH/0530/AM02	CLARITY	Substantial Amendment 2, 20/04	29/04/2016	10
15/YH/0530/AM03	CLARITY	Substantial Amendment 3, 20/05	23/05/2016	14
15/YH/0530/AM05	CLARITY	Substantial Amendment 4, 25/11	25/11/2016	14
15/YH/0535/AM06	TRANSITION_LCZ696 pre/ post discharge in acute heart failure	Substantial Amendment 5, 20/10	20/10/2016	21
16/YH/0013/AM02	Immune Factors in Neurological Diseases v1	Substantial Amendment 1, 19/01	25/01/2017	10
16/YH/0024/AM01	233AS101 - Phase 1 Study in ALS	Substantial Amendment 1, 15/06	28/06/2016	21
16/YH/0032/AM01	Rituximab Objective Outcome measures Trial in SLE (ROOTS)	Substantial Amendment 1,	11/01/2017	12

		16/11		
16/YH/0068/AM04	A longer-term care strategy for stroke – a feasibility study	Substantial Amendment 2, 07/11	09/11/2016	18
16/YH/0068/AM09	A longer-term care strategy for stroke – a feasibility study	Substantial Amendment 7, 02/03	06/03/2017	8
16/YH/0081/AM02	TULIP-LN1	Substantial Amendment 2, 04/08	04/08/2016	10
16/YH/0081/AM03	TULIP-LN1	Substantial Amendment 3, 21/12	22/12/2016	17
16/YH/0083/AM02	PEGPH20 in patients with pancreatic cancer with high levels of HA	Substantial Amendment 2, 05/05	06/05/2016	17
16/YH/0083/AM04	PEGPH20 in patients with pancreatic cancer with high levels of HA	Substantial Amendment 4, 29/06	29/06/2016	18
16/YH/0083/AM05	PEGPH20 in patients with pancreatic cancer with high levels of HA	Substantial Amendment 5, 17/08	17/08/2016	8
16/YH/0083/AM06	PEGPH20 in patients with pancreatic cancer with high levels of HA	Substantial Amendment 6, 28/09	28/09/2016	13
16/YH/0083/AM07	PEGPH20 in patients with pancreatic cancer with high levels of HA	Substantial Amendment 7, 15/12	15/12/2016	6
16/YH/0084/AM01	Efficacy and Safety of rexlémestrocél-L in Chronic Heart Failure	Substantial Amendment 1, 12/05	12/05/2016	20
16/YH/0114/AM01	Posture and Mobility in Care Homes.	Substantial Amendment 1, 27/01	30/01/2017	21
16/YH/0121/AM01	Carers' Experiences of Unusual Beliefs	Substantial Amendment 1, 07/05	14/06/2016	13

16/YH/0128/AM01	Men's Decisions within Treatment and Care for Low Risk Prostate Cancer	Substantial Amendment 1, 15/11	04/01/2017	11
16/YH/0132/AM03	The Prognosis in Palliative care Study II (PiPS2)	Substantial Amendment 1, 11/11	30/01/2017	8
16/YH/0238/AM01	Journeying through Dementia	Substantial Amendment 1, 21/09	21/09/2016	15
16/YH/0238/AM03	Journeying through Dementia	Substantial Amendment 2, 07/12	12/01/2017	12
16/YH/0292/AM01	An IPA of the impact of dx with prediabetes	Substantial Amendment 1, 24/01	03/02/2017	20
16/YH/0364/AM01	Understanding asthma phenotypes	Substantial Amendment 1, 07/12	21/12/2016	18
16/YH/0373/AM01	Impact of Closed Circuit Television (CCTV) Inside Mental Health Wards	Substantial Amendment 1, 26/09	05/10/2016	21
16/YH/0406/AM01	Ambulance CPAP: Use, Treatment Effect and Economics feasibility study	Substantial Amendment 1, 25/11	25/11/2016	13
16/YH/0406/AM02	Ambulance CPAP: Use, Treatment Effect and Economics feasibility study	Substantial Amendment 2, 16/02	16/02/2017	20
16/YH/0420/AM03	Feasibility of an online rehabilitation program	Substantial Amendment 1, 13/01	18/01/2017	21
16/YH/0469/AM01	1297.4 - BI695501 versus Humira in patients with active Crohns disease	Substantial Amendment 1, 13/02	13/02/2017	7

Unfavourable opinion

Amendment REC	Title	Version	Date	Number of Days on
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Reference				Clock
16/YH/0068/AM01	A longer-term care strategy for stroke – a feasibility study	Substantial Amendment 1, 26/05	27/05/2016	25

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/YH/0068/AM01/1	A longer-term care strategy for stroke – a feasibility study	Modified Amendment 1, 21/07/16	22/07/2016	7

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
16/YH/0216	Fine grained facial image analysis in Wolf-Hirschhorn syndrome	61
16/YH/0224	The effect of DHA- & EPA-enriched oils on cognitive function and mood	61

Proportionate review applications for ethical review over 14 day timeline

REC Reference	Title	Number of Days on Clock
16/YH/0209	Long-term outcomes in women diagnosed with non-invasive breast cancer	15

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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