

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

Annual Report

01 April 2017 - 31 March 2018



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 (until June 2017) Miss Rheanneon Fuller (until February 2018) Ms Jane Harker (from April 2018)
Committee Address:	NHSBT Newcastle Blood Donor Centre Holland Drive Newcastle upon Tyne NE2 4NQ
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Chair's overview of the past year:

This is my fourth and final report as Chair of Leeds (West) REC so I open by expressing my thanks to Christie Ord, our REC Manager, for her help, support and guidance throughout much of that period. She has been ably assisted by Kirstie Penman, transiently supported by Rheanneon Fuller and, at the end of the reporting year, was joined by Jane Harker.

During the year we have reviewed a wide range of applications, in accord with our flags, and these invariably raise interesting points of discussion. Sadly during this year we said goodbye to four members, Dr Diane Farrar and Ms Emma Lundy due to workload issues, Dr Mike Clarke who wished to take time to travel post-retirement and Mr Ashley Stratton-Powell as a result of relocation. We welcomed Mr Jon Cohen who brings a wealth of experience from the primary sector as well as being a Pharmacist by training. This imbalance between leavers and new members has caused some difficulties with quoracy, especially as a further member was on a period of leave whilst writing up his thesis. Our thanks go to Christie for her work in recruiting co-opted members and to those who shared their expertise with us.

Work pressures continue to be a concern for some members and, in parallel, it can be difficult to attend formal training. The e-learning courses will help and members are being encouraged to participate in such courses, especially the ones that directly support our flags.

PRSC activity was reduced for a period in view of the staff turnover but Sub-committee work remained substantial. Many applications are straightforward but those that are poorly prepared and/or complex demand much time, sometimes difficult for volunteer members, and it is a pity that the content of such meetings is not capped to ensure the workload is reasonable.

To close, it has been a great pleasure to be a member, Vice-Chair and latterly Chair of a REC that takes pride in working to the highest of standards, treating applicants with courtesy yet ensuring that applications are assessed with care and insightful questions are asked. It is always a pleasure when the response is 'why didn't I think of that' and the result a study which is improved as a result of the discussion.

I have already thanked Christie and add my warm thanks to Vera Neumann and Tony Warnock-Smith for their support through their Vice-Chair and Alternate Vice-Chair roles. Finally thank you to all members for their wisdom, their friendship and all that they bring to an excellent REC. Having served my planned 10 years, but followed by 1 extra so making a total of 11 years, it is time to move on to new ventures but I will remember my time with Leeds (West) with much pleasure and I wish the REC every continued success as it welcomes its new Chair, Dr Rhona Bratt. Rhona knows the REC very well and I feel sure she will enjoy Chairing it as much as I have done.

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	10/08/2017
Mr Jon Cohen	Partner (Pharmacist)	Expert	06/10/2017	
Mrs Kerrie Davies	Principal Clinical Scientist	Expert	01/08/2016	
Professor Peter Draper	Professor of Nursing Education	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	07/04/2017
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	20/09/2017
Dr Vera Neumann	Retired 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	06/11/2017
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: Co-opted Members

Name	Profession	Status	Meeting date attended
Dr Rhona Bratt	Retired Multimedia Project Manager	Lay Plus	11/08/2017 08/12/2017
Mrs Brenda Riley	Retired IT Trainer	Lay Plus	08/09/2017
Mr Anthony Lockett	Medical Director	Expert	11/08/2017
Mr John Warden	Clinical Trials Data and Information Systems Manager	Lay	09/03/2018
Mr Michael Davidson	Retired Personnel Manager	Lay Plus	09/03/2018

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

Name	Declaration of Interest	Date
Mr Jon Cohen	Director J & N Cohen ltd - company providing consultancy/business coaching services. The company does not undertake research of its own. Client organisations may occasionally undertake or contemplate undertaking research project which may require REC approval - in such circumstances he would ensure such applications were directed towards another REC or declare any involvement and take no part in review. The company acts in a similar way as a partner of an European Economic Interest Group (EEIG - similar structure to a UK partnership).	09/11/2017
Mrs Kerrie Davies	Principal Clinical Scientist for the Healthcare Associated Infections Research Group (University of Leeds and Leeds Teaching Hospitals). Duties include peer review of research projects within the group.	31/03/2018
Professor Peter Draper	I am a member of the academic staff of the Faculty of Health Sciences at the University of Hull. I am a member of the ethics committee of that faculty.	26/04/2017
Dr Martin Elliott	Medical trustee of Candlelighter's charity - fund research projects. Peer reviewer of research applications for :Children's Cancer and Leukaemia Group Rosie's Fund (Manchester)Member of NCRI - clinical studies groups (Children's, Neuroblastoma, New agents) - the group reviews research applications to CRUK for funding.	31/03/2018
Ms Sarah Kirkland	Clinical studies officer at Bradford District Care Trust. Her role involves some R&D governance functions and research delivery.	31/03/2018
Mrs Heather Rostron	Member of NIHR Clinical Studies Group (general paediatrics)	31/03/2018
Mr Vishal Sharma	None	31/03/2018
Mr Anthony Warnock-Smith	None.	14/11/2017

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

Month	Date	Number of Members Present at Meeting
April	07/04/2017	11
June	09/06/2017	8
July	14/07/2017	12
August	11/08/2017	8
September	08/09/2017	9
November	10/11/2017	8
December	08/12/2017	8
January	12/01/2018	9
February	09/02/2018	11
March	09/03/2018	9

10 full committee meetings were held during the reporting period.

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

Month	Date	Number of Members Present at Meeting
April	25/04/2017	3
June	29/06/2017	3
July	26/07/2017	3
August	23/08/2017	3
September	27/09/2017	3
November	22/11/2017	3
December	20/12/2017	3
January	24/01/2018	3

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

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

Month	Date	Number of Members Present at Meeting
April	03/04/2017	2
April	11/04/2017	2
April	19/04/2017	2
April	27/04/2017	3
May	02/05/2017	3
May	08/05/2017	2
May	09/05/2017	2
May	19/05/2017	3
May	24/05/2017	2
June	01/06/2017	2
June	08/06/2017	3
June	20/06/2017	2
July	04/07/2017	2

July	18/07/2017	2
July	25/07/2017	2
July	28/07/2017	3
July	28/07/2017	3
August	01/08/2017	2
August	15/08/2017	2
August	16/08/2017	3
August	17/08/2017	3
August	25/08/2017	2
August	29/08/2017	2
August	30/08/2017	3
September	12/09/2017	2
September	21/09/2017	2
September	22/09/2017	2
September	26/09/2017	2
October	10/10/2017	2
October	13/10/2017	2
October	16/10/2017	2
October	19/10/2017	2
October	24/10/2017	2
November	07/11/2017	2
November	21/11/2017	2
December	05/12/2017	2
December	19/12/2017	2
December	22/12/2017	2
January	05/01/2018	2
January	16/01/2018	2
January	30/01/2018	2
February	09/02/2018	2
February	13/02/2018	2
February	23/02/2018	3
February	27/02/2018	2
March	13/03/2018	2
March	27/03/2018	2

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

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

None

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

Name	Number of Meetings Attended
Miss Susan Partridge	10
Mrs Kerrie Davies	8
Dr Sheila E. Fisher	8
Ms Sarah Kirkland	8
Dr Jane Orton	7
Dr Jonathan Thornley	7
Mr Anthony Warnock-Smith	7
Mrs Heather Rostron	6
Dr Martin Elliott	5
Dr Vera Neumann	5
Mr Jon Cohen	4
Professor Peter Draper	4
Mr Ashley Stratton-Powell	3
Dr Michael Clarke	2
Mr Vishal Sharma	2
Dr Diane Farrar	1

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

Name	Number of Meetings Attended
Mr Anthony Warnock-Smith	6
Dr Sheila E. Fisher	3
Dr Jane Orton	3
Dr Martin Elliott	2
Ms Sarah Kirkland	2
Miss Susan Partridge	2
Mrs Kerrie Davies	1
Professor Peter Draper	1
Dr Vera Neumann	1
Mr Vishal Sharma	1
Mr Ashley Stratton-Powell	1
Dr Jonathan Thornley	1

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

Name	Number of Meetings Attended
Dr Sheila E. Fisher	19
Dr Vera Neumann	18

Mr Anthony Warnock-Smith	15
Dr Jane Orton	13
Mrs Kerrie Davies	8
Miss Susan Partridge	6
Dr Michael Clarke	4
Dr Martin Elliott	4
Ms Sarah Kirkland	4
Dr Jonathan Thornley	4
Professor Peter Draper	3
Mrs Heather Rostron	3
Mr Vishal Sharma	2
Mr Ashley Stratton-Powell	1

Training 01 April 2017 - 31 March 2018

Name of Member	Date	Event(s) attended
Mr Jon Cohen	02/11/2017	Equality and Diversity
Mr Jon Cohen	02/11/2017	Online Induction
Mr Jon Cohen	29/11/2017	Regional Training Day
Mr Jon Cohen	11/01/2018	Members Induction
Mr Jon Cohen	06/03/2018	Training - Assessing the Consequences (benefits and harms) of Research
Mrs Kerrie Davies	04/07/2017	Research Involving Adults Who Lack Capacity (including research in emergency situations)
Mrs Kerrie Davies	26/09/2017	Assessing the Consequences (benefits and harms) of Research: a Health Research Authority workshop
Professor Peter Draper	26/09/2017	Assessing the Consequences (benefits and harms) of Research: a Health Research Authority workshop
Dr Martin Elliott	25/05/2017	Equality and Diversity
Dr Martin Elliott	27/11/2017	GCP
Dr Martin Elliott	31/03/2018	SDL 2017-18 - 2 hours of reading surrounding HRA guidance on approval
Dr Sheila E. Fisher	24/11/2017	HRA National Chairs' Day and Policy Event
Dr Sheila E. Fisher	29/11/2017	Regional Training Day
Ms Sarah Kirkland	17/05/2017	GCP
Ms Sarah Kirkland	05/06/2017	Equality and Diversity
Ms Sarah Kirkland	29/11/2017	Regional Training Day
Ms Sarah Kirkland	07/02/2018	Introduction to Phase One – An Introductory Workshop for REC Members
Mr Anthony Lockett	29/11/2017	Regional Members Training Day
Miss Susan Partridge	04/04/2017	Equality and Diversity
Miss Susan Partridge	09/01/2018	MCA Training
Mrs Brenda Riley	14/09/2017	Handling Health Related Findings in Research
Mrs Brenda Riley	19/10/2017	Quantitative Research Methods and Statistics:
Mrs Brenda Riley	29/11/2017	Regional Member Training Day
Mrs Heather Rostron	29/11/2017	Regional Training Day
Mr John Warden	31/03/2018	SDL - April 17 - March 18 - 8 hours of reading (GDPR)
Mr Anthony Warnock-Smith	29/11/2017	Regional 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	20	43.48
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	1	2.17
Others	25	54.35
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	3
Number of student applications reviewed	15
Number of paediatric applications reviewed	8
Number of device applications reviewed	7
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	2
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	1	2.17
Favourable Opinion with Additional Conditions	5	10.87
Unfavourable Opinion	3	6.52
Provisional Opinion	37	80.43
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	28	60.87
Further Information Favourable Opinion with Additional Conditions	5	10.87
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	1	2.17
Favourable Opinion with Additional Conditions	5	10.87
Unfavourable Opinion	3	6.52
Provisional Opinion	2	4.35
Provisional Opinion Pending Consultation with Referee	0	0.00
Further Information response not complete	2	4.35
No decision entered on system	0	0.00
Number of studies withdrawn after the meeting	0	0.00
Total	46	100

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

Total Applications Reviewed	12
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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	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	7	58.33
Favourable Opinion with Additional Conditions	2	16.67
No Opinion transfer to full committee for review	2	16.67
Provisional Opinion	0	0.00
Unfavourable Opinion	1	8.33
Total	12	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	46
Number of completed applications for full ethical review over 60 days	0
Number of completed applications over 60 days as a % of total	0.00%
Number of days taken to final decision – average (mean)	35
Number of completed proportionate review applications for ethical review	10
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	9
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	89
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 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	84
Number of substantial amendments received for information	5
Number of substantial amendments received for new sites/PIs	30
Number of annual progress reports received	63
Number of safety reports received	33
Number of Serious Adverse Events received	2
Number of final reports received	39

Table 9.1: Breakdown of current status of all full applications reviewed within the reporting period

Further Information Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
17/YH/0116	4339: SUSTAIN 10 Semaglutide versus Liraglutide in Type 2 Diabetes	26
17/YH/0119	sarcopenia, malnutrition & outcomes in Liver transplant patients v1	41
17/YH/0120	Dupuytren's Interventions Surgery vs. Collagenase (DISC)	35
17/YH/0123	SeluDex	27
17/YH/0180	TRaCINg Study	44
17/YH/0183	DTI in Athlete's Heart	44
17/YH/0195	Proof of activity of TAK-041 in schizophrenia	40
17/YH/0196	Phase 2 TAK-831	40
17/YH/0209	T-PAC	36
17/YH/0221	How are Endings Experienced in Community PD Services?	42
17/YH/0222	ICAF - BETA	31
17/YH/0228	CALM II	44
17/YH/0262	TRITON Trial v1.0	41
17/YH/0287	Identification of biomarkers of Multiple Sclerosis and its' subtypes	41
17/YH/0289	A phase 1/2 study with Acalabrutinib and AZD6738 in high risk CLL	38
17/YH/0300	Myocardial tissue characteristics and glycaemic status	31
17/YH/0311	A Modular, Multipart, Multiarm, FTiH, Open-label study of CT7001	43
17/YH/0372	Multi-parametric MRI/Fluorine-18 Fluciclovine PET-CT in Glioblastoma	34
17/YH/0378	Validation study of the Rome IV criteria for the diagnosis of IBS	42
17/YH/0391	Norursodeoxycholic acid vs. Placebo in PSC	32
17/YH/0392	BI 1467335 in patients with diabetic retinopathy.	29
17/YH/0432	GSK3772847 in participants with Asthma with AFAD	28
17/YH/0433	Working with museums and individuals with mental health problems	54
17/YH/0435	AIN457 vs placebo in patients with active overuse tendinopathy	37
17/YH/0436	BP40234: RO6874281 in combination with atezolizumab in solid tumours	40
18/YH/0009	Evaluation of ProvayBlue safety/efficacy in acquired methemoglobinemia	44
18/YH/0055	Jazz JZP963-201	28
18/YH/0089	STEPFORWARD: Patient acceptability of a novel prosthetic device	41

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
17/YH/0227	CT1401	41
17/YH/0249	Optimisation of BOA in Adults with Learning Disabilities	41
17/YH/0263	EMI-137 in laparoscopic colonic resections	45
17/YH/0393	PUGS (Paediatric Use of the AbbottSensorBasedGlucoseMonitoringSystem)	39
18/YH/0003	Effect of the CIS on adherence in poorly controlled asthmatic patients	44

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

Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
17/YH/0278	dREAMS	21

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
17/YH/0217	Experiences of physiotherapy for AT in sedentary patients	28
17/YH/0246	TURMS Study. Version 1.0; June 2017	27
18/YH/0002	What is it like to live with Inflammatory Bowel Disease?	24
18/YH/0004	Smart Vest	24
18/YH/0027	UK CLL LTFU Study	20

Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock
17/YH/0170	Identification of biomarkers of Multiple Sclerosis and its' subtypes	28
17/YH/0395	Wholetruth, untruths and lies: A two stage ethnographic study (Vers 1)	27
18/YH/0006	Cost and Outcome of ACT informed Model of GP training for Pain	24

Provisional Opinion		
REC Reference	Title	Number of Days on Clock

18/YH/0088	The effect of ageing on acute inflammatory responses in man.	n/a
18/YH/0101	A study to evaluate QR-313 exposure in subjects with RDEB	n/a

Provisional Opinion Pending Consultation with Referee

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

REC Reference	Title	Number of Days on Clock
18/YH/0063	Enseal X1 Post Marketing Clinical Follow-up study	n/a
18/YH/0103	Nebulised HS in children with NMD and CP	n/a

Withdrawn after the meeting

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

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

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

REC Reference	Title	Number of Days on Clock
17/YH/0135	Embedding Diabetes Education	18

17/YH/0257	The genomic basis of Inflammatory Bowel Disease in Ireland	19
17/YH/0258	The Genomic Basis of Multiple Sclerosis In Ireland	19
17/YH/0283	New biomarker identification of pancreatic cancer to improve diagnosis	14
17/YH/0408	Exploring Quality of Life Markers after IV Iron in Perinatal Women	14
17/YH/0443	Vismodegib resistance in basal cell carcinoma	8
18/YH/0037	NMR spectroscopy to identify Clostridium difficile infection	15

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
17/YH/0212	Consent practice in pregnant women	10
18/YH/0039	Urine Sample Collection for Method Development	21

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
17/YH/0339	T cells restricted by unconventional antigen presenting molecules	18

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/Q1205/65/AM12	Clinical & Immunogenic Features of PsA and AS (Immunogenetics)	SA6	23/10/2017	8
04/Q1205/69/AM16	Yorkshire and Humberside Haematology Network Register	SA14	19/06/2017	20
05/Q1108/28/AM19	Characterisation of Giant cell arteritis & polymyalgia rheumatica	20	14/11/2017	8
09/H1307/54/AM19	Open-label study of Denosumab in Subjects with Giant Cell Tumor	SA17	25/07/2017	22
09/H1307/54/AM20	Open-label study of Denosumab in Subjects with Giant Cell Tumor	SA18	26/01/2018	25
09/H1307/98/AM17	RADAR	SA13	11/01/2018	23
10/H1307/104/AM03	ED95 Regional Anaesthesia	SA2	14/08/2017	8
10/H1307/132/AM07	Genetic Disorders of Human Neurological and Immune Function	Substantial Amendment 5, 29/01/2018	06/02/2018	14
10/H1307/138/AM12	Very Early versus Delayed Etanercept in patients with RA (VEDERA)	SA10 RR10/9592 v12.0	03/08/2017	11
11/YH/0025/AM05	Acellular allogeneic musculoskeletal tissues	SA5	25/05/2017	18
11/YH/0142/AM05	Cladribine Safety Registry	SA3	20/12/2017	12
11/YH/0291/AM05	Pectoralis muscle biopsy in CHF patients	SA6	15/05/2017	10
11/YH/0291/AM06	Pectoralis muscle biopsy in CHF patients	SA7	14/10/2017	13
12/YH/0015/AM02	Non-comparative study of primary TKA functional performance	SA1 Rev D	23/08/2017	7
12/YH/0438/AM08	Bone Vibration as a Novel Assessment of Bone Density in Children	SA7	04/01/2018	12
12/YH/0551/AM05	CE-MARC 2 protocol development	SA5	05/10/2017	15
12/YH/0551/AM06	CE-MARC 2 protocol development	Substantial Amendment 6, 13/11/2017	16/11/2017	27
13/YH/0030/AM05	Shoulder PAtch for Rotator Cuff tears	SA5	24/02/2017	17
13/YH/0377/AM09	Computerised aphasia therapy RCT (Big CACTUS)	SA4	31/05/2017	16
14/YH/0006/AM14	Open Label Extension Study of Lacosamide in Paediatric Subjects	SA10	05/05/2017	20

14/YH/0006/AM16	Open Label Extension Study of Lacosamide in Paediatric Subjects	SA11	30/01/2018	21
14/YH/0034/AM08	IciCLLe -Assessment of the Mechanism of Action of Ibrutinib	SA10	18/08/2017	6
14/YH/0085/AM38	FLAIR version 2.0	SA30	27/02/2017	10
14/YH/0085/AM40	FLAIR version 2.0	HM13/10747/Substantial Amendment 20/06/2017	20/06/2017	22
14/YH/0085/AM49	FLAIR version 2.0	M13/10747/Substantial Amendment 28/11/2017	28/11/2017	17
14/YH/1050/AM03	HRpQCT in Osteogenesis Imperfecta	SA3	05/01/2018	11
14/YH/1070/AM06	Developing a new EEG method for the early diagnosis of dementia.	SA04	03/04/2017	9
14/YH/1070/AM08	Developing a new EEG method for the early diagnosis of dementia.	Substantial Amendment 5, 23/01/2018	06/02/2018	34
14/YH/1110/AM06	Dose finding safety study of VAL201 in cancer patients	SA5	27/10/2017	16
14/YH/1162/AM05	SABRTOOTH v1.0	MO14/11248/G/201 70503	03/05/2017	22
14/YH/1175/AM16	Ibrutinib in Chronic Lymphocytic Leukaemia/Small Lymphocytic Lymphoma	SA11	30/03/2017	14
14/YH/1175/AM17	Ibrutinib in Chronic Lymphocytic Leukaemia/Small Lymphocytic Lymphoma	Substantial Amendment 12	09/03/2018	33
14/YH/1259/AM20	ALPHA	SA14	10/07/2017	7
15/YH/0017/AM10	Extension Paediatric study of Intrathecal IdursulfaseIT with Elaprase®	SA7 - protocol 3 28.02.17	28/02/2017	17
15/YH/0017/AM11	Extension Paediatric study of Intrathecal IdursulfaseIT with Elaprase®	SA8 SHP-609-302 HRUQ	07/08/2017	13
15/YH/0037/AM03	Development of the Addiction Therapist Rating Scale (ATRS)	SA3	21/06/2017	13
15/YH/0117/AM11	REPAIR-Right vEntricular remodeling in Pulmonary Arterial hypertension	SA9	06/10/2017	18
15/YH/0117/AM12	REPAIR-Right vEntricular remodeling in Pulmonary Arterial hypertension	SA10	21/11/2017	16
15/YH/0171/AM01	Investigating functional immune profiles in Multiple Sclerosis	Substantial Amendment 1, 13/12/2017	11/02/2018	24
15/YH/0178/AM10	Vertex - VX14-661-109 - Cystic Fibrosis	SA7_Protocol	15/08/2017	14

		v4.0, IB (VX-661)		
15/YH/0217/AM01	Dual Energy CT For Brain Iron Quantification In Neurodegeneration	SA1	22/08/2017	14
15/YH/0280/AM11	PredictCAT v1.1	SA4	06/12/2017	15
15/YH/0286/AM12	The MATE study	SA13	24/11/2017	21
15/YH/0379/AM04	Cartiva® GRIP Study, PTC-0116	SA1 PTC-0116 Rev E	14/09/2017	17
16/YH/0004/AM07	PhII_MOR00208 & Idelalisib_Patients with Relapsed Refractory CLL/SLL	SA5	23/02/2017	14
16/YH/0004/AM09	PhII_MOR00208 & Idelalisib_Patients with Relapsed Refractory CLL/SLL	SA6 Protocol 10.0	25/07/2017	26
16/YH/0004/AM10	PhII_MOR00208 & Idelalisib_Patients with Relapsed Refractory CLL/SLL	Substantial Amendment 7, 06/12/2017	26/02/2018	22
16/YH/0113/AM04	ACE-CL-208	SA4-ACE-CL-208 - IB Edition 6.	01/09/2017	22
16/YH/0113/AM05	ACE-CL-208	Substantial Amendment 5, 01/12/2017	27/02/2018	26
16/YH/0188/AM01	Novel sterilisation	SA1	30/08/2017	12
16/YH/0188/AM02	Novel sterilisation	SA2	02/11/2017	12
16/YH/0267/AM01	UK EarlySense Study - Prevention of Falls	SA1	31/03/2017	21
16/YH/0457/AM03	Profiling Neutrophil Counts In Patients on Chemotherapy (Version 1.1)	SA2	09/11/2017	7
17/YH/0022/AM04	MEDI4736-DLBCL-001 Phase 2 High-Risk Diffuse Large B-Cell Lymphoma	SA3	03/07/2017	20
17/YH/0022/AM05	MEDI4736-DLBCL-001 Phase 2 High-Risk Diffuse Large B-Cell Lymphoma	SA4	20/09/2017	7
17/YH/0022/AM06	MEDI4736-DLBCL-001 Phase 2 High-Risk Diffuse Large B-Cell Lymphoma	SA5 ICF Version 6	05/10/2017	13
17/YH/0040/AM01	Efficacy & safety study of weekly MOD-4023 in GHD - CP-4-006 - V1.0	SA1 Protocol 4.0	04/06/2017	19
17/YH/0040/AM03	Efficacy & safety study of weekly MOD-4023 in GHD - CP-4-006 - V1.0	Substantial Amendment 3, 14/11/2017	14/11/2017	8
17/YH/0062/AM01	Quantitative biomarkers in MI	SA1	19/12/2017	15

17/YH/0062/AM02	Quantitative biomarkers in MI	Substantial Amendment 2, 23/02/2018	13/03/2018	15
17/YH/0076/AM01	CALM DIEM	SA1	17/07/2017	4
17/YH/0076/AM04	CALM DIEM	SA2	02/11/2017	15
17/YH/0076/AM06	CALM DIEM	Substantial Amendment 3, 29/01/2019	27/02/2018	22
17/YH/0123/AM01	SeluDex	SA1	12/07/2017	12
17/YH/0123/AM02	SeluDex	SA2	25/10/2017	28
17/YH/0123/AM03	SeluDex	Substantial Amendment 3, 01/02/2018	07/02/2018	24
17/YH/0180/AM01	TRaCINg Study	SA1	21/08/2017	7
17/YH/0180/AM02	TRaCINg Study	SA2	26/09/2017	11
17/YH/0183/AM01	DTI in Athlete's Heart	SA1	06/10/2017	17
17/YH/0195/AM01	Proof of activity of TAK-041 in schizophrenia	SA1	03/10/2017	7
17/YH/0195/AM02	Proof of activity of TAK-041 in schizophrenia	SA2	08/12/2017	12
17/YH/0196/AM02	Phase 2 TAK-831	SA1	20/09/2017	19
17/YH/0196/AM03	Phase 2 TAK-831	SA2	19/10/2017	19
17/YH/0221/AM01	How are Endings Experienced in Community PD Services?	SA1	07/09/2017	20
17/YH/0221/AM02	How are Endings Experienced in Community PD Services?	SA2	31/01/2018	20
17/YH/0222/AM01	ICAF - BETA	BB001	22/11/2017	18
17/YH/0227/AM01	CT1401	Amendment 01	07/02/2018	7
17/YH/0228/AM01	CALM II	Substantial Amendment 1, 22/01/2018	06/02/2018	15
17/YH/0262/AM02	TRITON Trial v1.0	Substantial Amendment 2, 22/02/2018	22/02/2018	28
17/YH/0263/AM01	EMI-137 in laparoscopic colonic resections	SA1	14/12/2017	17
17/YH/0289/AM01	A phase 1/2 study with Acalabrutinib and AZD6738 in high risk CLL	SA1	19/10/2017	12
17/YH/0289/AM04	A phase 1/2 study with Acalabrutinib and AZD6738 in high risk CLL	SA4	20/12/2017	21
17/YH/0311/AM01	A Modular, Multipart, Multiarm, FTiH, Open-label study of	Substantial	23/02/2018	29

	CT7001	Amendment 1, 21/02/2018		
17/YH/0378/AM01	Validation study of the Rome IV criteria for the diagnosis of IBS	Substantial Amendment 1, 15/01/2018	15/02/2018	28
17/YH/0392/AM01	BI 1467335 in patients with diabetic retinopathy.	Substantial Amendment 1	20/02/2018	28
17/YH/0392/AM02	BI 1467335 in patients with diabetic retinopathy.	Substantial Amendment 2, 08/03/2018	09/03/2018	16
17/YH/0436/AM01	BP40234: RO6874281 in combination with atezolizumab in solid tumours	Substantial Amendment 1, 28/02/2018	28/02/2018	21

Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
17/YH/0022/AM07	MEDI4736-DLBCL-001 Phase 2 High-Risk Diffuse Large B-Cell Lymphoma	SA6	01/02/2018	28
17/YH/0283/AM01	New biomarker identification of pancreatic cancer to improve diagnosis	SA1	11/01/2018	20

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
15/YH/0178/AM09/1	Vertex - VX14-661-109 - Cystic Fibrosis	SA6 - modified	21/07/2017	4

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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