

**Yorkshire & The Humber - Sheffield Research
Ethics Committee**

Annual Report

01 April 2017 - 31 March 2018



Part 1 – Committee Membership and Training

Name of REC:	Yorkshire & The Humber - Sheffield Research Ethics Committee
Type of REC:	Establishing Research Tissue Banks IRB Registered Medical Device Study Research Involving Children
Type of Flag:	RECs recognised to review CTIMPS in patients - type iii
Chair:	Professor Basil Sharrack
Vice-Chair:	Dr Amaka Offiah
Alternate Vice-Chair:	Dr Nana Theodorou
REC Manager:	Miss Kerry Dunbar
REC Assistant:	Miss Donna Bennett
Committee Address:	NHS Blood and Transplant Blood Donor Centre Holland Drive Newcastle upon Tyne Tyne and Wear NE2 4NQ
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Chair's overview of the past year:

During the last 12 months, Sheffield REC Committee through the hard work of its members and admin staff, has continued to support the local and national research communities.

Despite the continuous changes to the HRA approval process and the uncertainty about the impact of BREXIT, the Committee has been able to adapt to the new working framework with the support of the dedicated admin team.

Yorkshire & The Humber - Sheffield Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Dr Paul Bacon	Lead Clinical Scientist in Audiological Science, Medical Physics	Expert	01/06/2011	
Mrs Jacqui Gath	Retired Senior Systems Analyst	Lay Plus	15/06/2011	
Mrs Veronica Gilmour	Staff Nurse	Expert	15/06/2016	
Professor Frank Jones	Retired Professor of Polymers and Composites	Lay	31/01/2014	
Mr Pete Laud	Statistical Consultant	Expert	01/04/2011	
Dr Marie Marron	BHF Research Fellow	Lay	01/03/2014	
Dr Amaka Offiah	Reader in Paediatric Musculoskeletal Imaging	Expert	16/05/2011	
Mrs Brenda Riley	Retired IT Trainer	Lay Plus	01/05/2016	
Professor Basil Sharrack	Consultant Neurologist	Expert	29/06/2006	
Dr Soon Song	Consultant Diabetologist	Expert	25/08/2006	
Mrs Aikaterini Staikoura-Wilson	Pharmacist	Expert	01/02/2016	
Mrs Yvonne Stephenson	Lead Technician in the Department of Infection and Immunity	Expert	16/05/2011	
Mrs Helen Teasdale	University Executive Assistance	Lay Plus	01/05/2011	
Dr Nana Theodorou	Research & Innovation Coordinator	Expert	01/10/2011	
Dr Steven Thomas	Consultant Vascular and Cardiac Radiologist	Expert	18/05/2006	
Ms Liz Williams	Senior Lecturer in Human Nutrition	Lay	13/09/2016	

Nana transferred across to Leeds East on 01/06/18

Yorkshire & The Humber - Sheffield Research Ethics Committee: Deputy Members

Name	Profession	Status	Meeting date attended
Mr Richard Lindley	Consultant Paediatric Surgeon	Expert	04/12/2017 & 15/01/2018

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

Name	Declaration of Interest	Date
Mrs Jacqui Gath	NIHR Funding Panels ECMC Executive – Sheffield CCTE Executive -ECMC PPI Team YH Consumer Research Panel	30/03/2018
Mrs Veronica Gilmour	None - works as a nurse in a hospital setting where research is carried out - members of a PPI group at the hospital for communicable diseases.	30/03/2018
Mr Pete Laud	Works as a consultant statistician for AstraZeneca and Unilever None outside managed investment funds (stocks & shares ISA) Employed part-time by AstraZeneca as a contract statistician. Part of a team of consultants providing statistical advice to Sheffield Teaching Hospitals Clinical Research Office. Both contracts are paid to my employer (University of Sheffield) rather than directly to me.	30/03/2018
Mr Richard Lindley	Scientific advisory board meeting for the Children's Charity at Sheffield Children's Hospital Expert specialism - Paediatric surgery	30/03/2018
Dr Marie Marron	None	30/03/2018
Dr Marie Marron	None	22/12/2017
Dr Amaka Offiah	Director – OCIN Ltd: Provides a teleradiology reporting service for Medica Ltd Owner – OCIN Ltd: Provides a teleradiology reporting service for Medica Ltd Chair – Child Abuse Taskforce of European Society of Paediatric Radiology;; Chair – Publications Committee of European Society of Paediatric Radiology;; Convenor/Chair – Skeletal Dysplasia Group for Teaching and Research Academic Research Lead – Pharmacy, Diagnostics & Genetics Division, Sheffield Children's Hospital NHS Foundation Trust; ; Member – British Paediatric and Adolescent Bone Group; ; Member – HRpQCT International Working Group; ; Member – International Consortium for Vertebral Anomalies and Scoliosis; ; Member – NICE Standing Committee for Guideline Updates;; Member – Sheffield Children's Hospital Scientific Advisory Committee;; Member – Sheffield Children's Hospital Research & Innovation Committee; ; Member – University of Sheffield Ethnic Equality & Diversity Board ; ; Partner Governor – Sheffield Children's NHS Foundation Trust; ; Research Lead – Imaging Department, Sheffield Children's NHS Foundation Trust	30/03/2018
Mrs Brenda Riley	Member of the steering committee for MIDFUT (Multiple Interventions of Diabetic Foot Ulcer Treatment Trial) which has already been REC approved by Leeds REC. Member of Sheffield Hospital Trust. Previously involved in various Focus groups and as a subject participant in 3 studies. - Associate member of Diabetes UK Sheffield, which is a branch of the national Charity Diabetes UK and	30/03/2018

	are registered as such. - Member of Online PPI (Patient and Public Involvement) Group. Advisory group. - Member of LADDER (Lay ADvice for Diabetes and Endocrine Research) PPI. advisory group. - Member of Perfect Patient Pathway (PPP) TAG (Technology Advisory Group) Champion for Diabetes - but the PPP relates to evaluation; not research. - Member of DAFNEplus PPI. Also involved in testing the technology. This is already the subject of a grant	
Professor Basil Sharrack	None - Expertise in Neurology	30/03/2018
Mrs Aikaterini Staikoura-Wilson	None	30/03/2018
Mrs Yvonne Stephenson	Work in the Department of Infection and Immunity and Cardiovascular Disease, Medical School, Sheffield University which is involved in the conduct of research. Member of Sheffield University Ethics committee	30/03/2018
Mrs Helen Teasdale	None	30/03/2018
Dr Nana Theodorou	Works in the Sheffield clinical research office - specialist in strabismus, human tissue and medical devices	30/03/2018
Dr Steven Thomas	None	14/12/2017
Dr Steven Thomas	None	30/03/2018
Ms Liz Williams	I am employed as a Senior Lecturer in Human Nutrition at the University of Sheffield. In my role as an academic I seek funding for my research and review grant applications on behalf of a number of grant funders, both charitable and Research Council. I also review research manuscripts for a number of journals prior to publication. I conduct ethics reviews of research taking place within the Medical School of the University of Sheffield and also, on a consultancy basis, for the Health and Safety Laboratories, Buxton.	30/03/2018

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

Month	Date	Number of Members Present at Meeting
April	03/04/2017	10
May	08/05/2017	10
June	05/06/2017	12
July	03/07/2017	13
September	04/09/2017	10
October	02/10/2017	11
November	06/11/2017	10
December	04/12/2017	15
January	15/01/2018	11
March	05/03/2018	14

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
May	11/05/2017	3
June	23/06/2017	3
July	20/07/2017	3
August	29/08/2017	3
October	23/10/2017	3
November	24/11/2017	3
December	22/12/2017	3
January	22/01/2018	3
February	28/02/2018	3
March	16/03/2018	3

10 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	06/04/2017	2
April	20/04/2017	2
May	04/05/2017	2
May	18/05/2017	2
June	01/06/2017	2
June	09/06/2017	3
June	15/06/2017	2
June	29/06/2017	2
July	13/07/2017	2
July	31/07/2017	2
August	02/08/2017	2

August	02/08/2017	2
August	10/08/2017	2
August	23/08/2017	2
September	07/09/2017	2
September	21/09/2017	2
October	02/10/2017	3
October	05/10/2017	2
October	19/10/2017	2
November	03/11/2017	2
November	16/11/2017	2
November	30/11/2017	2
December	18/12/2017	2
January	10/01/2018	2
January	24/01/2018	2
February	07/02/2018	2
February	21/02/2018	2
March	07/03/2018	2
March	21/03/2018	2

29 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
Dr Paul Bacon	2
Mrs Jacqui Gath	9
Mrs Veronica Gilmour	8
Professor Frank Jones	7
Mr Pete Laud	7
Mr Richard Lindley	2
Dr Marie Marron	5
Dr Amaka Offiah	6
Mrs Brenda Riley	10
Professor Basil Sharrack	10
Dr Soon Song	8
Mrs Aikaterini Staikoura-Wilson	6
Mrs Yvonne Stephenson	8
Mrs Helen Teasdale	7
Dr Nana Theodorou	9
Dr Steven Thomas	3
Ms Liz Williams	9

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

Name	Number of Meetings Attended
Mrs Jacqui Gath	2
Professor Frank Jones	2
Mr Pete Laud	2
Dr Marie Marron	1
Professor Basil Sharrack	10
Dr Soon Song	2
Mrs Yvonne Stephenson	1
Mrs Helen Teasdale	2
Dr Nana Theodorou	2
Dr Steven Thomas	3
Ms Liz Williams	3

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

Name	Number of Meetings Attended
Mrs Jacqui Gath	7
Mrs Veronica Gilmour	3

Professor Frank Jones	1
Mr Pete Laud	3
Dr Marie Marron	1
Dr Amaka Offiah	2
Mrs Brenda Riley	3
Professor Basil Sharrack	28
Dr Soon Song	1
Mrs Yvonne Stephenson	4
Mrs Helen Teasdale	3
Dr Nana Theodorou	2
Dr Steven Thomas	1
Ms Liz Williams	1

Training 01 April 2017 - 31 March 2018

Name of Member	Date	Event(s) attended
Mrs Jacqui Gath	30/03/2018	SDL - 2017-2018 - clinical trials workshop (3 days)
Mrs Rona Gilmour	26/09/2017	Assessing the Consequences (benefits and harms) of Research: A Health Research Authority workshop
Mrs Rona Gilmour	20/02/2018	Human Tissue Act
Professor Frank Jones	29/11/2017	Regional Member Training Day
Professor Frank Jones	30/11/2017	Genetic and Genomic Research
Mr Pete Laud	29/11/2017	Regional Member Training Day
Dr Robert Phillips	29/11/2017	Training - Regional Members Training Day
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
Professor Basil Sharrack	12/12/2017	National Members' Training Day
Mrs Aikaterini Staikoura-Wilson	19/10/2017	Quantitative Research Methods and Statistics
Mrs Yvonne Stephenson	18/12/2017	Equality, Diversity and Human Rights
Mrs Yvonne Stephenson	30/03/2018	SDL - GDPR Training
Mrs Helen Teasdale	18/12/2017	Equality, Diversity and Human Rights
Dr Nana Theodorou	30/03/2018	SDL - Genomics and Biobank Training
Dr Steven Thomas	30/06/2017	Equality and Diversity Training
Dr Steven Thomas	31/08/2017	GCP Training
Ms Liz Williams	30/03/2018	SDL - workplace practice and teaching surrounding ethical issues

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	34.48
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	2	3.45
Others	36	62.07
Total Applications Reviewed	58	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	2
Number of student applications reviewed	14
Number of paediatric applications reviewed	11
Number of device applications reviewed	9
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	0
Number of applications reviewed that are funded by the US DHHS	1
Number of qualitative applications reviewed	4

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	3	5.17
Favourable Opinion with Additional Conditions	8	13.79
Unfavourable Opinion	1	1.72
Provisional Opinion	46	79.31
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	58	100
Number of studies sent back to full committee meeting for final opinion	1	

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	37	63.79
Further Information Favourable Opinion with Additional Conditions	9	15.52
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	3	5.17
Favourable Opinion with Additional Conditions	8	13.79
Unfavourable Opinion	1	1.72
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	0	0.00
Total	58	100

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

Total Applications Reviewed	18
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Table 6: Breakdown of PRS applications and other activity during reporting period:

Number of applications made invalid by the REC Manager	3
Number of studies withdrawn prior to the meeting	3
Number of student applications reviewed	8
Number of paediatric applications reviewed	1
Number of device applications reviewed	0
Number of qualitative applications reviewed	4

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	9	50.00
Favourable Opinion with Additional Conditions	1	5.56
No Opinion transfer to full committee for review	3	16.67
Provisional Opinion	5	27.78
Unfavourable Opinion	0	0.00
Total	18	100

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

Average number of applications reviewed per full meeting	5.80
Number of completed applications for full ethical review	58
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)	33
Number of completed proportionate review applications for ethical review	15
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	6
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	124
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	2
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	80
Number of substantial amendments received for information	0
Number of substantial amendments received for new sites/PIs	21
Number of annual progress reports received	71
Number of safety reports received	28
Number of Serious Adverse Events received	5
Number of final reports received	29

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/0070	Executive Function in Offenders with Intellectual Disabilities	52
17/YH/0083	The Barrier Optimizing skincare for Newborn Development (BOND) trial	38
17/YH/0098	VISTAX version 1.0	31
17/YH/0103	PENNY PCI Study	44
17/YH/0138	Long term extension study of Filgotinib in RA patients	34
17/YH/0142	Assessing the clinical utility of CMR and CT in the 3D-lab	33
17/YH/0144	UK Women's Cohort study - HES	37
17/YH/0146	Micronutrient Supplement Effects on Cognitive Outcomes in TBI	32
17/YH/0155	TEEMS	23
17/YH/0182	A Phase 1/2 of NKTR-214 and Nivolumab	26
17/YH/0208	assessment of gait after two types of total knee arthroplasty	27
17/YH/0210	Self-reported patient wellness and clinical measures	24
17/YH/0226	Distraction technique in transnasal flexible fiberoptic laryngoscopy	57
17/YH/0230	Health benefits of HIT for breast cancer patients	37
17/YH/0266	Lung MRI imaging for patient benefit	37
17/YH/0280	A Clinical Study of a Temperature Logging Vaginal Ring	34
17/YH/0295	CR6086-2-02	40
17/YH/0299	PROBIt-ProKids Version 1	43
17/YH/0308	"HOPE" of human livers_V1	48
17/YH/0318	Clinical and radiological review of Axioma TT glenoid implants	38
17/YH/0330	An Imaging DEvice for Acne Spots - the IDEAS study	44
17/YH/0346	SHINE (BWI_2017_01)	27
17/YH/0347	Effect of intranasal insulin on cognitive processes and appetite	23
17/YH/0381	GAP Study: Gabapentin in Post Surgery Pain	25
17/YH/0385	A Phase 3, Open Labelled study in children and adolescents with PNH	20
17/YH/0387	Phase 3 Study of Pembrolizumab/Epacadostat/Chemotherapy in NSCLC	19
17/YH/0394	Clinical Evaluation of Custom-made NIV masks for children	40
17/YH/0400	Psychiatric morbidity in a recurrent miscarriage clinic	44
17/YH/0409	A study of the effect of 20 mg ambroxol hydrochloride on cough reflex	40
17/YH/0414	Safe exercise in Hypertrophic Cardiomyopathy (SAFE-HCM)	32
17/YH/0430	Exploring prioritising of symptoms in GP consultations	38
18/YH/0001	Unspoken Voices: User perspectives on AAC equipment and services	34

18/YH/0007	Neuropsychological Consequences of Gluten Consumption in NCGS V1.4	42
18/YH/0012	ECZTRA 3 (ECZema TRAlokinumab trial no. 3)	40
18/YH/0073	Paediatric ADHD Sleep Study	35
18/YH/0098	Staff experiences in robotic theatres version 1.0 - 08/01/2018	35
18/YH/0099	Generation 2 - CNP520 in participants at risk of Alzheimer's	38

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
17/YH/0085	TRIUMPH	41
17/YH/0147	Live-HCM/LIVE-LQTS	35
17/YH/0179	Magnetic Impedance Spectroscopy for Predicting Preterm Birth	28
17/YH/0181	TAK-659 for DLBCL patients after 2 prior lines of chemotherapy	32
17/YH/0203	CIVIL	33
17/YH/0204	RAPID-AF (CF-171)	42
17/YH/0309	161505 - Long-Term Tolerability and Safety of HYQVIA/HyQvia in CIPD	34
17/YH/0365	Cardiac arrhythmias in T1D and impaired awareness of hypoglycaemia	23
17/YH/0377	Applying NET to Intimate Partner Violence	33

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/0150	BEAR Men B	23
17/YH/0184	Strength training effects on function within Pulmonary Rehabilitation	21
18/YH/0013	The DUAL-ACS2 Trial	27

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
17/YH/0338	Access to paediatric allergy services for South Asian families	23
17/YH/0345	COLUMBA	23
17/YH/0389	A Phase 2/3 study of Dupilumab in children aged 6m-6ys with severe AD	16

17/YH/0426	R668-AD-1652, Investigate the Efficacy and Safety of Dupilumab	25
18/YH/0010	DEFINE	27
18/YH/0011	Exploring heterogeneity in bladder cancer	27
18/YH/0069	GLOW: JNJ-54179060 - CLL3011	29
18/YH/0081	Can Social Stories Improve the Experience of an Autism Assessment? V1	29

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
17/YH/0185	Fluorescence targeted lymphatic mapping in colonic cancer	21

Provisional Opinion

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

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

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

REC Reference	Title	Number of Days on Clock
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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
17/YH/0206	Attentional bias to threatening faces in body dysmorphic disorder	20
17/YH/0251	Cystatin C Measurement in Nutrition Support Patients	12
17/YH/0291	Views and Experiences of Penicillin Allergy Testing (EXPERT)	11

17/YH/0413	Validating MRI muscle analysis in peripheral nerve injury	12
17/YH/0451	Seasonal variation in response to occlusion treatment	11

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/0154	Immune cell dysfunction in hepatocellular carcinoma (HCC)	13
17/YH/0161	Caring for an extremely premature infant at home.	13
17/YH/0162	Are insulin attitudes related to glycaemic control? v 1.2	13
17/YH/0207	The use of early pregnancy HbA1c in predicting excessive fetal growth	9
17/YH/0368	Treatment patterns of SCLC patients in Europe	13
17/YH/0415	Colorectal cancer immunophenotyping - CRUK Accelerator	10
18/YH/0032	Identifying wound and surrounding skin microbiome	13
18/YH/0034	Study of psychosocial issues following admission for DFU V1	14
18/YH/0122	Blood transfusion after aortic valve replacement	8

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
17/YH/0293	POCARI_V1	10

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
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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
08/H1308/193+5/AM03	STH-ObS (renewal)	Substantial Amendment 15, 25/09/2017	11/10/2017	11
09/H1308/138/AM09	The role of angiogenesis and genome stability in breast cancer	Substantial Amendment 6 - 18/04/2017	18/04/2017	8
13/YH/0273/AM06	Using MRI to investigate energy metabolism in MND	Substantial Amendment 4 - 31/07/2017	31/07/2017	24
13/YH/0419/AM01	Improving bone marrow stem cells performance	Substantial Amendment 1 - 11/5/17	11/05/2017	21
14/YH/0002/AM08	IPI-145 vs Ofatumumab in CLL or SLL	Substantial Amendment 7 - 9/2/17	09/02/2017	10
14/YH/0002/AM09	IPI-145 vs Ofatumumab in CLL or SLL	Substantial Amendment 8, 12/09/2017	21/11/2017	16
14/YH/0002/AM10	IPI-145 vs Ofatumumab in CLL or SLL	Substantial Amendment 9 - 22/01/2018	19/02/2018	16
14/YH/0003/AM09	Extension study of IPI-145 and Ofatumumab in Patients with CLL/SLL	Substantial Amendment 8, 12/09/2017	21/11/2017	16
14/YH/0003/AM10	Extension study of IPI-145 and Ofatumumab in Patients with CLL/SLL	Substantial Amendment 9 - 19/02/2018	19/02/2018	16
14/YH/0143/AM02	A novel device to analyse bradykinesia and tremor	Substantial Amendment 2 - 27/2/17	27/02/2017	15
14/YH/1034/AM07	Treosulfan-based conditioning therapy in children with blood cancer	Substantial amendment 6 -	20/09/2017	23

		20.09.17		
14/YH/1108/AM05	Simple Hysterectomy And Pelvic node dissection in Early cervix cancer	Substantial Amendment 3, 11/01/2018	15/01/2018	13
14/YH/1141/AM11	Efficacy and safety of Radium 223 in mBC, compared to hormone therapy	Substantial Amendment 10 - 12/4/17	12/04/2017	22
14/YH/1141/AM12	Efficacy and safety of Radium 223 in mBC, compared to hormone therapy	Substantial Amendment 11 - 23/5/17	23/05/2017	25
14/YH/1178/AM01	SPLENDOR: Survival imProvement in Lung canCEr iNduced by DenOsUmab theRapy	Substantial Amendment 1 - 01/08/2017	01/08/2017	15
14/YH/1202/AM09	PREVAIL Version 1.0	Substantial amendment 1 - 24/04/2017	26/04/2017	7
14/YH/1209/AM05	Iron and Heart Trial	Substantial Amendment 3 - 27/3/17	27/03/2017	13
14/YH/1237/AM07	Study to Access the Safety of AZD9291 Vs SoC in Patients with NSCLC	Substantial Amendment 8 - Updated IB Ed 7 - 23/3/17	23/03/2017	20
14/YH/1237/AM08	Study to Access the Safety of AZD9291 Vs SoC in Patients with NSCLC	Substantial Amendment 9 - 12/5/17	12/05/2017	30
14/YH/1269/AM07	i.v. tapentadol for the treatment of post-surgical pain in children	Substantial Amendment 6 - 22/2/17	22/02/2017	20
15/YH/0004/AM12	ARIOS: Follow-up of infants born to mothers in retosiban studies	Substantial Amendment 9 - 11/8/15	11/08/2015	22
15/YH/0004/AM13	ARIOS: Follow-up of infants born to mothers in retosiban studies	Substantial Amendment 10 - GDPR Letter, 18/10/2017	18/10/2017	26
15/YH/0034/AM16	The CIMPACT Study	Substantial	17/10/2017	27

		Amendment 11, 17/10/2017		
15/YH/0034/AM17	The CIMPACT Study	Substantial Amendment 12 - Change of Sponsor, 19/01/2018	19/01/2018	22
15/YH/0096/AM01	Biomechanical testing of the human spine	Substantial Amendment 1, 20/12/2017	30/01/2018	14
15/YH/0105/AM02	NF1 in NSCLC	Substantial Amendment 1, 21/08/2017	10/10/2017	18
15/YH/0177/AM03	Donation of waste surgical tissue for research purposes	Substantial Amendment 2, 22/01/2018	25/01/2018	32
15/YH/0193/AM01	Acute Pancreatitis Research Biobank	Substantial Amendment 1 - 21/07/2017	21/07/2017	30
15/YH/0257/AM06	TARGET-DLE version 1.0	Substantial Amendment 4, 05/01/2018	09/01/2018	20
15/YH/0287/AM15	OLE- Open Label Extension	Substantial Amendment 8 - 29/6/17	29/06/2017	25
15/YH/0287/AM16	OLE- Open Label Extension	Substantial Amendment 9.0, 25/09/2017	25/09/2017	18
15/YH/0287/AM17	OLE- Open Label Extension	Substantial Amendment 10.0, 07/11/2017	07/11/2017	24
15/YH/0435/AM05	VTS270 in Subjects with Niemann-Pick Type C1 Disease.	Substantial Amendment 4 - 1/11/16	01/11/2016	15
15/YH/0435/AM06	VTS270 in Subjects with Niemann-Pick Type C1 Disease.	Substantial Amendment 5 -	29/06/2017	20

		29/6/17		
15/YH/0435/AM08	VTS270 in Subjects with Niemann-Pick Type C1 Disease.	Substantial Amendment 6 - 01/12/2017	01/12/2017	12
15/YH/0443/AM05	An Open-label Extension Study to Assess the Long-Term Safety and Efficacy of Dupilumab in Patients ≥6 Months to <18 Years of Age with Atopic Dermatitis	Substantial Amendment 3 - Protocol Amendment 1 - 27/3/17	27/03/2017	29
15/YH/0443/AM07	An Open-label Extension Study to Assess the Long-Term Safety and Efficacy of Dupilumab in Patients ≥6 Months to <18 Years of Age with Atopic Dermatitis	Substantial Amendment 5 - protocol amendment 3/IB Edition 11, 14/09/2017	29/11/2017	22
15/YH/0478/AM12	The Regenerate Study	Substantial Amendment 9 - 3/8/17	03/08/2017	27
15/YH/0478/AM13	The Regenerate Study	Substantial Amendment 10 - Urgent Safety Measure, 25/09/2017	09/10/2017	14
15/YH/0478/AM14	The Regenerate Study	Substantial Amendment 11, 07/11/2017	07/11/2017	23
15/YH/0483/AM05	Single Arm Study to Assess the efficacy of UVADEX	Substantial Amendment 2, 27/07/2017	26/09/2017	26
16/YH/0035/AM01	Quality of Life Measures in Barrett's Oesophagus Care Pathways	Substantial Amendment 1 - 5/4/17	05/04/2017	17
16/YH/0035/AM04	Quality of Life Measures in Barrett's Oesophagus Care Pathways	Substantial Amendment 4 - 24/08/2017	24/08/2017	19
16/YH/0035/AM06	Quality of Life Measures in Barrett's Oesophagus Care Pathways	Substantial Amendment 5,	13/11/2017	32

		10/11/2017		
16/YH/0085/AM01	Development of Diagnostic Pathway for Teicoplanin Allergy	Substantial Amendment 1 - 15/3/17	15/03/2017	16
16/YH/0101/AM02	Visual Perception Sensitivity in the Autism Spectrum	Substantial Amendment 2 - 4/4/17	04/04/2017	18
16/YH/0127/AM01	De-threaded Screw Fixation of Slipped Capital Femoral Epiphyses – Comp	Substantial Amendment 1, 31/10/2017	31/10/2017	22
16/YH/0159/AM03	The posturing after retinal detachment (PostRD) trial Version 1.1	Substantial Amendment 3, 21/12/2017	16/01/2018	13
16/YH/0169/AM01	Multi-channel Stimulation for Post Stroke Spasticity (MUSTS)	Substantial Amendment 1 - 1/4/17	01/04/2017	28
16/YH/0186/AM06	PLUS (178-MA-1008)	Substantial Amendment 4 - 13/4/17	13/04/2017	16
16/YH/0186/AM07	PLUS (178-MA-1008)	Substantial Amendment 6 - 17/5/17	17/05/2017	15
16/YH/0186/AM08	PLUS (178-MA-1008)	Substantial Amendment 7 - 10/5/17	10/05/2017	9
16/YH/0186/AM10	PLUS (178-MA-1008)	Substantial Amendment 8, 24/10/2017	22/11/2017	19
16/YH/0186/AM11	PLUS (178-MA-1008)	Substantial Amendment 1 - 18/12/2017	20/12/2017	19
16/YH/0186/AM12	PLUS (178-MA-1008)	Substantial Protocol Amendment 4, 22/01/2018	12/02/2018	7
16/YH/0196/AM04	Emotion processing in patients with functional symptoms	Substantial Amendment 2,	10/07/2018	16

		28.02.17		
16/YH/0196/AM05	Emotion processing in patients with functional symptoms	Substantial Amendment 3, 28/09/2017	02/10/2017	18
16/YH/0206/AM01	BONES: The British Osteonecrosis Study.	Substantial Amendment 1 - 12/3/17	12/03/2017	13
16/YH/0206/AM02	BONES: The British Osteonecrosis Study.	Substantial Amendment 5, 20/11/2017	17/01/2018	27
16/YH/0217/AM02	MAPS: 6 -YEAR FOLLOW UP	Substantial Amendment 1 - 3/6/17	03/06/2017	35
16/YH/0217/AM04	MAPS: 6 -YEAR FOLLOW UP	Substantial Amendment 2 - 12/02/2018	12/02/2018	7
16/YH/0240/AM02	Outcome measures for clinical trials in childhood BKC	Substantial Amendment 1 - 16/5/17	16/05/2017	19
16/YH/0261/AM02	Raman in muscle	Substantial Amendment 1, 09/11/2017	13/11/2017	29
16/YH/0265/AM01	High-Å-resolution retinal imaging of inherited retinal degenerations	Substantial Amendment 1 - 20/2/17	20/02/2017	16
16/YH/0310/AM02	Investigating microorganisms present in vulvovaginal candidiasis v1	Substantial Amendment 2 - 24/4/17	24/04/2017	23
16/YH/0401/AM03	Filgotinib with Methotrexate in RA patients	Substantial Amendment 3 - 7/8/17	07/08/2017	17
16/YH/0401/AM04	Filgotinib with Methotrexate in RA patients	Substantial Amendment 4, 17/10/2017	17/10/2017	27
16/YH/0401/AM06	Filgotinib with Methotrexate in RA patients	Substantial Amendment 6, 21/02/2018	21/02/2018	14

16/YH/0402/AM02	Filgotinib with csDMARDs in RA patients	Substantial Amendment 2 - 19/7/17	19/07/2017	13
16/YH/0402/AM03	Filgotinib with csDMARDs in RA patients	Substantial Amendment 3, 17/10/2017	17/10/2017	27
16/YH/0403/AM03	Phase 3 study in participants with RA	Substantial Amendment 3 - 19/7/17	19/07/2017	13
16/YH/0403/AM04	Phase 3 study in participants with RA	Substantial Amendment 4, 17/10/2017	17/10/2017	27
16/YH/0412/AM01	Pilot survey of mothers and babies	Substantial Amendment 1 - 30/3/17	30/03/2017	18
16/YH/0431/AM01	GRAICE - guided rehabilitation after intensive care.	Substantial Amendment 1 - 5/4/17	05/04/2017	16
16/YH/0450/AM03	Blinatumomab in High-risk Diffuse Large B-Cell Lymphoma (DLBCL)	Substantial Amendment 2 - 29/6/17	29/06/2017	25
16/YH/0454/AM04	VitalScan MCG rule-out multi-centre pivotal study - version 1.0	Substantial Amendment 2, 17/11/2017	23/11/2017	17
16/YH/0456/AM01	Evaluating Brain food groups for memory service clients	Substantial Amendment 1 - 26/7/17	26/07/2017	10
16/YH/0459/AM03	OPTION-DM	Substantial Amendment 2 - 5/5/17	05/05/2017	15
16/YH/0459/AM05	OPTION-DM	Substantial Amendment 3 - 16/6/17	16/06/2017	25
16/YH/0459/AM08	OPTION-DM	Substantial amendment 5, 23/10/2017	23/10/2017	18
16/YH/0459/AM10	OPTION-DM	Substantial	02/02/2018	16

		Amendment 7, 01/02/2018		
16/YH/0502/AM02	Safety and Efficacy of BMN 111 in Children with Achondroplasia	Substantial Amendment 2 - 3/7/17	03/07/2017	21
16/YH/0502/AM03	Safety and Efficacy of BMN 111 in Children with Achondroplasia	Substantial Amendment 3 - 18/8/17	18/08/2017	33
16/YH/0503/AM02	RA101495 Open-Label Study of Paroxysmal Nocturnal Haemoglobinuria	Substantial Amendment 2 - 16/3/17	16/03/2017	27
16/YH/0503/AM04	RA101495 Open-Label Study of Paroxysmal Nocturnal Haemoglobinuria	Substantial Amendment 3 - 2/6/17	02/06/2017	19
16/YH/0503/AM05	RA101495 Open-Label Study of Paroxysmal Nocturnal Haemoglobinuria	Substantial Amendment 4 - 15/8/17	15/08/2017	30
16/YH/0504/AM02	Open-Label, Uncontrolled Extension Study of RA101495	Substantial Amendment 2 - 16/3/17	16/03/2017	27
16/YH/0504/AM04	Open-Label, Uncontrolled Extension Study of RA101495	Substantial Amendment 3 - 15/8/17	15/08/2017	35
16/YH/0506/AM02	PT009 vs PT005 treatment of Moderate to Very Severe COPD (SOPHOS)	Substantial Amendment 2 - 7/4/17	07/04/2017	18
16/YH/0506/AM06	PT009 vs PT005 treatment of Moderate to Very Severe COPD (SOPHOS)	Substantial Amendment 4 - 14/8/17	14/08/2017	9
16/YH/0506/AM07	PT009 vs PT005 treatment of Moderate to Very Severe COPD (SOPHOS)	Substantial Amendment 5, 23/01/2018	23/01/2018	34
16/YH/0518/AM01	Reversing PCOS	Substantial Amendment 1 - 07/08/17	07/08/2017	13
17/YH/0074/AM01	SPIRIT trial - Version 1.0	Substantial Amendment 1 - 12	12/06/2017	26

		June 2017		
17/YH/0074/AM02	SPIRIT trial - Version 1.0	Substantial Amendment 2 - 10.02.2018	10/02/2018	9
17/YH/0098/AM01	VISTAX version 1.0	Substantial Amendment 1 - 19/6/17	19/06/2017	31
17/YH/0098/AM02	VISTAX version 1.0	Substantial Amendment 2 - 23/8/17	23/08/2017	23
17/YH/0103/AM01	PENNY PCI Study	Substantial Amendment 1 - 29/6/17	29/06/2017	25
17/YH/0103/AM02	PENNY PCI Study	Substantial Amendment 2 - 17/7/17	17/07/2017	15
17/YH/0138/AM02	Long term extension study of Filgotinib in RA patients	Substantial Amendment 1 - 7/8/17	07/08/2017	17
17/YH/0147/AM01	Live-HCM/LIVE-LQTS	Substantial Amendment 1 - 05/07/17	05/07/2017	26
17/YH/0147/AM02	Live-HCM/LIVE-LQTS	Substantial Amendment 2 - 1/8/17	01/08/2017	23
17/YH/0155/AM01	TEEMS	Substantial Amendment 1 - 15/5/17	15/05/2017	29
17/YH/0161/AM02	Caring for an extremely premature infant at home.	Substantial Amendment 1 - 27/6/17	27/06/2017	27
17/YH/0181/AM01	TAK-659 for DLBCL patients after 2 prior lines of chemotherapy	Substantial Amendment 1, 28/11/2017	28/11/2017	23
17/YH/0182/AM01	A Phase 1/2 of NKTR-214 and Nivolumab	Substantial Amendment 1 - 11/7/17	11/07/2017	21

17/YH/0182/AM02	A Phase 1/2 of NKTR-214 and Nivolumab	Substantial Amendment 2 - 28/7/17	28/07/2017	9
17/YH/0182/AM03	A Phase 1/2 of NKTR-214 and Nivolumab	Substantial Amendment 3 - 15/9/17	15/09/2017	26
17/YH/0182/AM06	A Phase 1/2 of NKTR-214 and Nivolumab	Substantial Amendment 5, 29/01/2018	29/01/2018	24
17/YH/0291/AM01	Views and EXperiences of PEnicillin alleRgy Testing (EXPERT)	Substantial Amendment 1, 06/03/2018	09/03/2018	32
17/YH/0345/AM01	COLUMBA	Substantial Amendment 1, 21/11/2017	21/11/2017	16
17/YH/0345/AM02	COLUMBA	Substantial Amendment 2, 08/03/2018	08/03/2018	26
17/YH/0346/AM01	SHINE (BWI_2017_01)	Substantial Amendment 1 - IB-RevB,ProtAm2_20 Dec2017, Revised PIS and GP letter	20/12/2017	26
17/YH/0377/AM01	Applying NET to Intimate Partner Violence	Substantial Amendment 1, 03/01/2018	05/01/2018	21
17/YH/0381/AM01	GAP Study: Gabapentin in Post Surgery Pain	Substantial Amendment 1 - 30/11/2017	30/11/2017	20
17/YH/0381/AM02	GAP Study: Gabapentin in Post Surgery Pain	Substantial Amendment 2, 15/01/2018	15/01/2018	12
17/YH/0387/AM01	Phase 3 Study of Pembrolizumab/Epacadostat/Chemotherapy in NSCLC	Substantial Amendment 1 - 21/12/2017	21/12/2017	18
17/YH/0387/AM03	Phase 3 Study of Pembrolizumab/Epacadostat/Chemotherapy in NSCLC	Substantial Amendment 3 -	22/01/2018	30

		Protocol 02, 22/01/2018		
17/YH/0387/AM05	Phase 3 Study of Pembrolizumab/Epacadostat/Chemotherapy in NSCLC	Substantial Amendment 5, 07/03/2018	07/03/2018	27
17/YH/0389/AM01	A Phase 2/3 study of Dupilumab in children aged 6m-6ys with severe AD	Substantial Amendment 4.0, 13/12/2017	15/12/2017	24
17/YH/0426/AM01	R668-AD-1652, Investigate the Efficacy and Safety of Dupilumab	Substantial Amendment 1 - 09/11/2017	09/11/2017	19

Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
14/YH/1269/AM09	i.v. tapentadol for the treatment of post-surgical pain in children	Substantial Amendment 7 - 22/02/2018	22/02/2018	34
15/YH/0004/AM11	ARIOS: Follow-up of infants born to mothers in retosiban studies	Substantial Amendment 8 - 30/3/17	30/03/2017	28
16/YH/0035/AM03	Quality of Life Measures in Barrett's Oesophagus Care Pathways	Modified Amendment 1 - Substantial Amendment 3 - 27/7/17	12/06/2017	35
16/YH/0282/AM07	VP-VEC-162-2102 Jetlag proof of concept	Modified Amendment 1 - Substantial Amendment 3 - 25/07/17	26/04/2017	34

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/0035/AM03/1	Quality of Life Measures in Barrett's Oesophagus Care Pathways	Modified Amendment 1 - Substantial Amendment 3 - 27/7/17	27/07/2017	2
16/YH/0282/AM07/1	VP-VEC-162-2102 Jetlag proof of concept	Modified Amendment 1 - Substantial Amendment 3 - 25/07/17	25/07/2017	8

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

Table 11: Items exceeding timelines

Full applications for ethical review over 60 day timeline

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

REC Reference	Title	Number of Days on Clock
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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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