

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

Annual Report

01 April 2015 - 31 March 2016



Part 1 – Committee Membership and Training

Name of REC:	Yorkshire & The Humber - Sheffield Research Ethics Committee
Type of REC:	Recognised to review CTIMPS in patients - type iii
Type of Flag:	Establishing Research Tissue Banks IRB Registered Medical Device Study Research Involving Children
Chair:	Professor Basil Sharrack
Vice-Chair:	Dr Ruth Stirton (until 02/07/2015) Dr Amaka Offiah (from 11/08/2015)
Alternate Vice-Chair:	Dr Nana Theodorou
REC Manager:	Miss Helen Penistone – April 2015 only Miss Kathryn Murray – from May 2015
REC Assistant:	Miss Ewa Grzegorska – April 2015 only Miss Donna Bennett – May – July 2015 only Miss Sarah Prothero – August – September 2015 only Miss Kerry Dunbar – from October 2015 only
Committee Address:	HRA Jarrow Jarrow Business Centre Rolling Mill Road Jarrow NE32 3DT
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Chair's overview of the past year:

The last 12 months were more challenging in view the changes to the REC administration from the Manchester to Jarrow Centre but as before we have had excellent support from the admin team at all levels.

Dr Ruth Stirton (Vice Chair) and Mrs Jennie Martin (Pharmacist) left the Committee for a better life and Mrs Katerina Wilson (Pharmacist) joined us for a more challenging one.

REC members have continued to do their best to support the work of the Committee despite the significant increase in the sub-committee work load.

The Committee remains very proud of providing support the local and national research communities.

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	
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	
Mrs Jennifer Martin	Retired Pharmacist	Expert	07/05/2010	31/12/2015
Dr Amaka Offiah	Reader in Paediatric Musculoskeletal Imaging	Expert	16/05/2011	
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	
Dr Ruth Stirton	Lecturer in Law	Lay Plus	04/10/2010	02/07/2015
Mrs Helen Teasdale	University Executive Assistance	Lay Plus	01/05/2011	
Dr Nana Theodorou	Specialist Orthoptist	Expert	01/10/2011	
Dr Steven Thomas	Consultant Vascular and Cardiac Radiologist	Expert	18/05/2006	

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

Name	Profession	Status	Meeting date attended
Mr Richard Lindley	Consultant Paediatric Surgeon	Expert	11/05/2015
Mr Richard Lindley	Consultant Paediatric Surgeon	Expert	13/04/2015

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

Name	Profession	Status	Meeting date attended
Mrs Rhona Bratt	Retired Multimedia Project Manager	Lay Plus	07/09/2015
Mr Chris Houston	Retired	Lay Plus	02/11/2015

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

Name	Declaration of Interest	Date
Dr Paul Bacon	PB is on the committee of one of the special interest groups of the British Society of Audiology (BSA) – namely the “evoked potential SIG”. The aim of the group is to promote best practice / give recommendations in this area of work but does not directly involve commissioning or funding of research projects. PB's main role as a lead clinical Scientist in Medical Physics department at the Royal Hallamshire Hospital, Sheffield Teaching Hospitals NHS Trust is with routine clinical service delivery. From time to time this may lead to service developments, leading on and supporting of local research projects.” (e.g. supervising MSc trainee student project).	31/03/2016
Mrs Jacqui Gath	Member of the following :ECMC Sheffield Committee Local Clinical Trials Executive NIHR Doctoral Funding Review Panel as Lay Member	31/03/2016
Professor Frank Jones	Patient Representative on Sheffield Genomic Institute. Member of Consumer Research Panel (CRP) - NTCR. Emeritus Professor at Sheffield University in Materials Science and support a research project on carbon fibre composites but there is no health objectives or tasks involved. Visiting Professor at Bristol University and have been consulted on aerospace composite's research. Visiting Professor at Manchester University. There are no health related aspects.	31/03/2016
Mr Pete Laud	Works as a Consultant Statistician for AstraZeneca and Unilever. Holds an unknown quantity of shares in pharmaceutical companies, held within a variety of managed investment funds (stocks & shares ISA).Employed part-time by AstraZeneca as a Contract Statistician and also part of a team of consultants providing statistical advice to Sheffield Teaching Hospitals Clinical Research Office; however, both contracts are paid direct to the main employer (University of Sheffield), rather than direct to PL.	07/01/2016
Mr Richard Lindley	Sit on the scientific advisory committee of the Children's Hospital Charity Trust that funds medical research.	18/12/2015
Dr Marie Marron	No interests declared.	11/01/2016
Dr Amaka Offiah	Owner and Director – OCIN Ltd: Provides a teleradiology reporting service for Medica Ltd Chair – Child Abuse Taskforce 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 –	16/12/2015

	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	
Professor Basil Sharrack	No interests declared.	31/03/2016
Dr Soon Song	No interests declared.	30/03/2016
Mrs Aikaterini Staikoura-Wilson	No interests declared.	08/02/2016
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	31/03/2016
Mrs Helen Teasdale	No interests declared	15/12/2015
Dr Steven Thomas	No interests declared	31/03/15
Dr Nana Theodorou	Research Coordinator at Sheffield Teaching Hospitals NHS Trust Guest Lecturer at the University of Manchester Guest Lecturer at the University of Sheffield Specialist Orthoptist at Sheffield Teaching Hospitals NHS Trust (STH) Peer reviewer for: Research Department at STH, Nursing Standard, Eye News Member of the Evidence Based council at STH Research Coordinator and lead roles in Human Tissue, Research Ethics, Medical Devices and Innovation	11/01/2016

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

Month	Date	Number of Members Present at Meeting
April	13/04/2015	10
May	11/05/2015	12
June	01/06/2015	10
July	06/07/2015	11
September	07/09/2015	8
October	05/10/2015	10
November	02/11/2015	8
December	07/12/2015	12
February	01/02/2016	10
March	07/03/2016	10

10 full committee meetings were held during the reporting period.

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

Month	Date	Number of Members Present at Meeting
April	01/04/2015	3
May	07/05/2015	3
June	11/06/2015	3
July	16/07/2015	3
October	09/10/2015	3
October	28/10/2015	3
December	04/12/2015	3
January	18/01/2016	3
February	11/02/2016	3
March	16/03/2016	3

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

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

Month	Date	Number of Members Present at Meeting
April	02/04/2015	2
April	16/04/2015	2
April	30/04/2015	2
May	14/05/2015	2
May	28/05/2015	2
June	11/06/2015	2
June	25/06/2015	2
July	09/07/2015	2
July	23/07/2015	2
August	06/08/2015	2
August	19/08/2015	3
August	20/08/2015	2

September	03/09/2015	2
September	17/09/2015	2
September	28/09/2015	2
October	01/10/2015	2
October	15/10/2015	2
October	29/10/2015	2
November	12/11/2015	2
November	26/11/2015	2
November	30/11/2015	2
November	30/11/2015	2
December	10/12/2015	2
December	21/12/2015	2
December	22/12/2015	2
January	12/01/2016	2
January	15/01/2016	3
January	26/01/2016	2
January	28/01/2016	2
February	11/02/2016	2
February	25/02/2016	2
March	10/03/2016	2
March	16/03/2016	2
March	17/03/2016	2
March	24/03/2016	2

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

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

Date	Reason	Action taken

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

Name	Number of Meetings Attended
Professor Basil Sharrack	10
Professor Frank Jones	9
Mrs Jacqui Gath	8
Mrs Yvonne Stephenson	8
Dr Nana Theodorou	8
Dr Paul Bacon	7
Mr Pete Laud	7
Dr Amaka Offiah	7
Dr Soon Song	7
Mrs Helen Teasdale	7
Dr Marie Marron	6
Dr Steven Thomas	6
Mrs Jennifer Martin	5
Mr Richard Lindley	2
Dr Ruth Stirton	2

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

Name	Number of Meetings Attended
Professor Basil Sharrack	10
Mrs Jacqui Gath	3
Mr Pete Laud	3
Mrs Helen Teasdale	3
Professor Frank Jones	2
Dr Marie Marron	2
Dr Soon Song	2
Dr Steven Thomas	2
Dr Paul Bacon	1
Dr Amaka Offiah	1
Dr Nana Theodorou	1

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

Name	Number of Meetings Attended
Professor Basil Sharrack	35
Mrs Jacqui Gath	5
Mr Pete Laud	5
Dr Nana Theodorou	5
Mrs Helen Teasdale	4
Dr Paul Bacon	3
Mrs Yvonne Stephenson	3

Dr Steven Thomas	3
Professor Frank Jones	2
Dr Marie Marron	2
Dr Amaka Offiah	2
Dr Soon Song	2
Mr Richard Lindley	1

Training 01 April 2015 - 31 March 2016

Name of Member	Date	Event(s) attended
Professor Basil Sharrack	16/03/2016	National Members Training Day
Mrs Yvonne Stephenson	04/06/2015	Regional Members Training Day
Mrs Yvonne Stephenson	06/10/2015	Quantitative Research Methods and Statistics: A Health Research Authority Workshop
Mrs Jacqui Gath	04/06/2015	Regional Members Training Day
Mrs Jacqui Gath	03/12/2015	HRA Workshop - Pragmatic or Point of Care Trials
Mr Richard Lindley	13/01/2016	Assessing the Consequences (benefits and harms) of Research: a HRA workshop
Mrs Helen Teasdale	24/07/2015	Personal Data in Research - A Workshop
Mrs Helen Teasdale	16/03/2016	National Members Training Day
Mr Pete Laud	31/03/2016	Self-Directed Learning Log
Dr Steven Thomas	31/03/2016	Self-Directed Learning Log
Dr Soon Song	24/07/2015	Personal Data in Research - A Workshop
Dr Paul Bacon	07/12/2015	Hellish Decisions in Healthcare
Dr Nana Theodorou	04/06/2015	Regional Members Training Day
Dr Nana Theodorou	15/02/2016	Equality & Diversity - General Awareness
Dr Marie Marron	04/06/2015	Regional Members Training Day
Dr Amaka Offiah	09/12/2015	National Training Day for Committee Chairs
Dr Amaka Offiah	21/12/2015	Equality & Diversity
Dr Amaka Offiah	14/01/2016	Training for New REC Chairs

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	17	29.31
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	2	3.45
Research Database (including renewals)	1	1.72
Others	38	65.52
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	3
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	17
Number of paediatric applications reviewed	14
Number of device applications reviewed	12
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	1
Number of applications reviewed that are funded by the US DHHS	1
Number of qualitative applications reviewed	2

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	4	6.90
Favourable Opinion with Additional Conditions	6	10.34
Unfavourable Opinion	3	5.17
Provisional Opinion	45	77.59
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	58	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	39	67.24
Further Information Favourable Opinion with Additional Conditions	3	5.17
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	4	6.90
Favourable Opinion with Additional Conditions	6	10.34
Unfavourable Opinion	3	5.17
Provisional Opinion	2	3.45
Provisional Opinion Pending Consultation with Referee	0	0.00
Further Information response not complete	1	1.72
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	29
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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	4
Number of studies withdrawn prior to the meeting	0
Number of student applications reviewed	19
Number of paediatric applications reviewed	7
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	10	34.48
Favourable Opinion with Additional Conditions	4	13.79
No Opinion transfer to full committee for review	4	13.79
Provisional Opinion	11	37.93
Unfavourable Opinion	0	0.00
Total	29	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 completed applications for full ethical review over 40 days	1
Number of completed applications over 40 days as a % of total	1.72%
Number of days taken to final decision – average (mean)	28
Number of completed proportionate review applications for ethical review	25
Number of completed proportionate review applications for ethical review over 14 days	0
Number of completed proportionate review applications over 14 days as a % of total	0.00%
Number of SSAs (non-Phase 1) reviewed	17
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	114
Number of completed substantial amendments over 35 days	0
Number of completed substantial amendments over 35 days as a % of total substantial amendments	0.00%
Number of completed substantial amendments over 28 days	4
Number of completed substantial amendments over 28 days as a % of total substantial amendments	3.51%
Number of modified amendments reviewed	4
Number of completed modified amendments over 14 days	0
Number of completed modified amendments over 14 days as a % of total modified amendments	0.00%
Number of minor amendments received	96
Number of substantial amendments received for information	0
Number of substantial amendments received for new sites/Pis	16
Number of annual progress reports received	78
Number of safety reports received	31
Number of Serious Adverse Events received	1
Number of final reports received	54

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

Further Information Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
15/YH/0105	NF1 in NSCLC	32
15/YH/0177	Research Tissue Bank	32
15/YH/0188	Acceptability study on Nutricomp Drink Plus in adult patients	33
15/YH/0194	R668-AD-1412 THE STUDY OF DUPILUMAB IN PAEDIATRIC PATIENTS WITH AD	36
15/YH/0218	AIT02-2001 Safety and Protective Efficacy Study of FF-3 Dry Powder	31
15/YH/0223	Innovative models of interfacing between NHS and social care (v1)	38
15/YH/0226	The effect of low-volume, high-intensity exercise on pre-diabetes (v1)	26
15/YH/0227	Defining disease progression in ADPKD	25
15/YH/0242	Long-Acting Insulin Glargine Titration Meter	36
15/YH/0243	Liberty AD Solo - Continue	35
15/YH/0257	TARGET-DLE version 1.0	32
15/YH/0258	Factors which influence attendance at a PED	30
15/YH/0259	The PRACTICE Trial	28
15/YH/0287	OLE- Open Label Extension	26
15/YH/0292	Proxy decision making for older women with breast cancer	37
15/YH/0299	Testicular Health in Adolescents A Qualitative Study (THAQS)	25
15/YH/0301	Minimising Limb-length inequality following total hip replacement.	31
15/YH/0364	BRADYCARE II	17
15/YH/0400	AF219-014 Cough Reflex Sensitivity in Healthy & Chronic Cough Subjects	23
15/YH/0401	Studying calcaneus microarchitecture with teriparatide treatment	33
15/YH/0431	Mealtimes in families where a child has difficulties eating (V1)	28
15/YH/0435	VTS270 in Subjects with Niemann-Pick Type C1 Disease.	35
15/YH/0436	FreeStyle Libre In Pregnancy Study (FLIPS), Revision A	27
15/YH/0443	R668-AD-1434 THE STUDY OF DUPILUMAB IN PAED PATIENTS WITH AD	23
15/YH/0466	Sheffield MND Care and Research Centre Database	23
15/YH/0477	Feasibility Study Using TBS for Upper Limb Spasticity Version 1.0	23
15/YH/0478	The Regenerate Study	23
15/YH/0483	Single Arm Study to Assess the efficacy of UVADEX	29
15/YH/0515	Coloplast CP266	23
15/YH/0522	Heartlight: Heart Rate Monitoring for Newborn Resuscitation	23
15/YH/0527	Mechanisms of radiotherapy resistance	23
15/YH/0533	NEWBORN-1 Study of Retosiban vs Placebo in Women in Pre-Term Labour	22

15/YH/0537	Health in Children and Young People with CAH	30
16/YH/0006	Thermal imaging as a screening tool for infections in neonates	30
16/YH/0018	Case Finding for CD using a POCT in a Pharmacy setting	32
16/YH/0021	A drug drug interaction study of INC280 with digoxin and rosuvastatin	26
16/YH/0022	A drug drug interaction study of INC 280 caffeine and Midazolam	38
16/YH/0074	Linear Persistent, v.1.0	26
16/YH/0095	BAMES study	27

Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/YH/0303	Study to identify cough sounds from ambient background noise. V2	30
15/YH/0397	Noninvasive vagal nerve stimulation for arm recovery after stroke	25
16/YH/0008	HICAM Version 1.0	28

Further Information Unfavourable Opinion

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

REC Reference	Title	Number of Days on Clock
15/YH/0207	Laser Ablation versus Mechanochemical Ablation (LAMA) trial	49
15/YH/0467	A Study of GSK3196165 in Hand Osteoarthritis	22
16/YH/0015	Salivary fluoride using different toothpaste formulations	25
16/YH/0094	EMG switch performance study (Version1)	25

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/YH/0193	Acute Pancreatitis Research Biobank	24
15/YH/0225	SUNRISE2	24
15/YH/0293	Electrical Impedance Spectroscopy in Thyroid and Parathyroid Surgery	24
15/YH/0403	Advanced MR of Metastatic Melanoma in Brain	17
15/YH/0528	999AS003 - Methodology Study in ALS	21
15/YH/0538	R668-AD-1424, Phase 3 , Dupilumab, Adults, Severe Atopic Dermatitis	16

Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock
15/YH/0185	Personality and neuropsychiatric signs in neurodegenerative disease	24
15/YH/0262	An investigative study to record and measure cough frequency data	22
15/YH/0442	Visual food cue associated reward in obesity using eye tracking	22

Provisional Opinion		
REC Reference	Title	Number of Days on Clock
16/YH/0060	Biomarker application in the management of graft-versus-host disease	n/a
16/YH/0091	Effect of bioactive enriched food on markers of metabolic syndrome	n/a

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

Further information response not complete		
REC Reference	Title	Number of Days on Clock
16/YH/0085	Development of Diagnostic Pathway for Teicoplanin Allergy	n/a

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

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

Further Information Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
15/YH/0172	Care Homes Independent Pharmacist Prescribing Service: CHIPPS	14
15/YH/0229	Vibrant Effectiveness and Reliability Study (VERS)	11
15/YH/0236	Reasoning Biases In People With Religious Beliefs	12

15/YH/0240	Cytomegalovirus glycoprotein types and disease causation	10
15/YH/0289	Patients' view to improve compliance to gluten free diet.	9
15/YH/0500	AORTA study - Aav ORal HealTh Assessment	9
15/YH/0557	Valuing the preferences of patients accessing emergency care	14
16/YH/0035	Quality of Life Measures in Barrett's Oesophagus Care Pathways	12
16/YH/0064	Children's involvement in decision making in CAMHS	13
16/YH/0066	Effect of blood flow restriction exercise on immobilised patients	14

Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/YH/0033	Investigation of bacteriophage as source of oral antimicrobials	12

Further Information Unfavourable Opinion

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

REC Reference	Title	Number of Days on Clock
15/YH/0341	Poorly absorbed carbohydrate (PAC) Version 1.0	10
15/YH/0342	Age related reference range assessment of high sensitive troponin I	10
15/YH/0465	Impact of different serum gel tubes on 25-hydroxyvitamin D analysis.V1	11
15/YH/0555	GICEE	11
15/YH/0556	Evaluation of tissue specific T cells in GI GvHD	10
16/YH/0038	Development of a web-based dental anxiety measure for children	10
16/YH/0065	Analysis of Antidepressant Prescribing Patterns in Northern Ireland	13
16/YH/0069	Elevated HOXA9 Expression as a Risk Factor in Acute Myeloid Leukemia	13
16/YH/0125	Meaning of compassion for individuals with an Eating Disorder.	10
16/YH/0129	iPLAN	10

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/YH/0150	Engaging vulnerable adolescents in research: A feasibility study	9
15/YH/0234	Nutritional knowledge in eating disorders clinicians and service users	10

15/YH/0340	Voice frequency analysis through puberty using a new smartphone app	9
15/YH/0344	Evaluation of apoptotic sperm sorting	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
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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
09/H1308/117/AM03	The Prevalence of Long QT Syndrome Gene Variants in SIDS	Substantial Amendment 3 - 13/1	18/11/2015	16
09/H1308/138/AM07	The role of angiogenesis and genome stability in breast cancer	Substantial Amendment 4, April	21/04/2015	28
09/H1308/138/AM08	The role of angiogenesis and genome stability in breast cancer	Substantial Amendment 5 - 18/2	18/02/2016	27
10/H1308/84/AM04	Open-label study of oral nilotinib in children with Ph+ CML or Ph+ ALL	Substantial Amendment - Update	21/05/2015	14
11/YH/0072/AM08	The LEONIDAS-2 study	Substantial Amendment 7, 18/05	18/06/2015	17
11/YH/0121/AM16	LDE225 in patients with basal cell carcinoma	Substantial Amendment 8 - 24/2	06/05/2015	24
12/YH/0398/AM11	ACCELERATE	Substantial Amendment - Study	19/06/2015	28
12/YH/0474/AM04	Improving detection and prevention of cognitive decline in ageing	Substantial Amendment 2 - 5/1/	05/01/2016	23
12/YH/0504/AM02	EXPLORER - diabetic foot ulcers	Substantial Amendment 2 - 9/12	09/12/2015	31
12/YH/0510/AM07	Accuracy of an implanted glucose sensor	Amendment #3, 30 March 2015	30/03/2015	19
12/YH/0510/AM09	Accuracy of an implanted glucose sensor	Substantial Amendment 4 - 12/8	12/08/2015	20
13/YH/0140/AM09	Ivabradine in heart failure with preserved ejection fraction	Amendment No 10 to Protocol	13/03/2015	28
13/YH/0140/AM12	Ivabradine in heart failure with preserved ejection fraction	Substantial	29/05/2015	17

		Amendment 12 - 29/		
13/YH/0152/AM07	FIGARO	Substantial Amendment 5, 27/05	16/06/2015	27
13/YH/0152/AM09	FIGARO	Substantial Amendment 6 - 24/1	24/11/2015	9
13/YH/0167/AM03	Cervical Electrical Impedance Measurement for Predicting Preterm Birth	Amendment 3	15/03/2015	22
13/YH/0255/AM04	Blinatumomab (MT103) in patients aged <18 years with B-Precursor ALL	Updated Investigator's Brochure	17/03/2015	29
13/YH/0263/AM10	SarCaBon: Saracatinib versus placebo for cancer-induced bone pain	Substantial Amendment AM08 - e	28/05/2015	18
13/YH/0307/AM02	Contributing clinical MRI scans to multi-centre collaboration	Substantial Amendment 2, 04/06	26/07/2015	15
13/YH/0320/AM03	28689 Phase III Study of Lebrikizumab in Uncontrolled Asthma Patients	Substantial Amendment 2 - ICF	06/05/2015	27
13/YH/0320/AM04	28689 Phase III Study of Lebrikizumab in Uncontrolled Asthma Patients	Substantial Amendment 3 - 10/9	16/11/2015	18
13/YH/0389/AM07	Pfizer B1481021 - Phase 3 PF-04950615 LDL-C lowering in HeFH	Updated Dosing Diary	19/03/2015	26
13/YH/0393/AM14	Pfizer B1481020 - Phase 3 PF-04950615 for Hyperlipidemia	Change in Chief Investigator	24/03/2015	17
13/YH/0393/AM15	Pfizer B1481020 - Phase 3 PF-04950615 for Hyperlipidemia	Updated dosing Diary	19/03/2015	26
13/YH/0393/AM17	Pfizer B1481020 - Phase 3 PF-04950615 for Hyperlipidemia	Substantial Amendment B1481020	07/05/2015	26
13/YH/0393/AM18	Pfizer B1481020 - Phase 3 PF-04950615 for Hyperlipidemia	Substantial Amendment: Increases	12/05/2015	22
13/YH/0393/AM21	Pfizer B1481020 - Phase 3 PF-04950615 for Hyperlipidemia	Substantial	20/07/2015	18

		Amendment - Change		
13/YH/0393/AM22	Pfizer B1481020 - Phase 3 PF-04950615 for Hyperlipidemia	Substantial Amendment 15	12/08/2015	9
13/YH/0393/AM24	Pfizer B1481020 - Phase 3 PF-04950615 for Hyperlipidemia	Substantial Amendment 16 - cha	09/12/2015	12
13/YH/0393/AM25	Pfizer B1481020 - Phase 3 PF-04950615 for Hyperlipidemia	Substantial Amendment 16 - cha	25/02/2016	20
14/YH/0002/AM04	IPI-145 vs Ofatumumab in CLL or SLL	Substantial Amendment 4 - Prot	24/03/2015	17
14/YH/0002/AM06	IPI-145 vs Ofatumumab in CLL or SLL	Substantial Amendment 5 - 26/11	26/11/2015	19
14/YH/0003/AM04	Extension study of IPI-145 and Ofatumumab in Patients with CLL/SLL	IPI-145-12 Protocol - Amendment	20/03/2015	18
14/YH/0003/AM05	Extension study of IPI-145 and Ofatumumab in Patients with CLL/SLL	Substantial Amendment 5 - 26/1	27/11/2015	19
14/YH/0020/AM05	ABP 501 Extension Study	IB Edition 3, PISICF	30/03/2015	28
14/YH/0091/AM02	Feasibility of an Exercise Intervention in Patients with Venous Ulcers	Substantial Amendment 4, 27/05	28/05/2015	21
14/YH/0091/AM04	Feasibility of an Exercise Intervention in Patients with Venous Ulcers	Substantial amendment 5	30/09/2015	19
14/YH/0140/AM02	POLAR - TKA Study	Substantial Amendment 2 - 15/1	20/01/2016	16
14/YH/0141/AM01	reMARQable v3.1	Amendment 4.1 dated 16 Jan 201	01/04/2015	28
14/YH/0141/AM02	reMARQable v3.1	Substantial Amendment 2 - Temp	02/07/2015	25

14/YH/0143/AM01	A novel device to analyse bradykinesia and tremor	Substantial Amendment 1 - 23/6	23/06/2015	15
14/YH/0152/AM05	Allergy Alert Test-Proof of Concept Study	Substantial Amendment 1, 14/10	20/10/2015	22
14/YH/0152/AM06	Allergy Alert Test-Proof of Concept Study	Substantial Amendment 2, 26/01	28/01/2016	19
14/YH/0161/AM09	Facet Injection Study (FIS)	Substantial Amendment 4 - 14/9	14/09/2015	28
14/YH/0161/AM10	Facet Injection Study (FIS)	Substantial Amendment 5 - 16/1	16/12/2015	28
14/YH/0172/AM03	Chronotherapeutic Lifestyle Intervention for Diabetes (Eurhythdia)	Substantial Amendment 2 ED14/1	22/06/2015	14
14/YH/0172/AM04	Chronotherapeutic Lifestyle Intervention for Diabetes (Eurhythdia)	Substantial Amendment 4, 08/07	08/07/2015	15
14/YH/1023/AM01	Endoscopic Hemospray in childhood GI bleeding	Substantial Amendment 1, 22/07	27/07/2015	20
14/YH/1034/AM02	Treosulfan-based conditioning therapy in children with blood cancer	Substantial Amendment 1 - 23/9	23/09/2015	9
14/YH/1037/AM03	A study to look at Tapentadol Liquid in Children & Adolescents in pain	Substantial Amendment C022, 16	29/05/2015	14
14/YH/1037/AM04	A study to look at Tapentadol Liquid in Children & Adolescents in pain	Substantial Amendment 4, 17/07	17/07/2015	21
14/YH/1037/AM06	A study to look at Tapentadol Liquid in Children & Adolescents in pain	Substantial Amendment 5 - 21/9	21/09/2015	23
14/YH/1037/AM07	A study to look at Tapentadol Liquid in Children & Adolescents	Substantial	27/10/2015	28

	in pain	Amendment 6 - 27/1		
14/YH/1124/AM03	EXTEND (2819-MA-1002)	APL Amendment C - Legal Repres	09/04/2015	28
14/YH/1124/AM05	EXTEND (2819-MA-1002)	Substantial Amendment APL Amen	26/06/2015	21
14/YH/1131/AM04	Comparison of Fendrix and double-dose Engerix B in HIV non-responders	Substantial Amendment 1	20/10/2015	22
14/YH/1141/AM03	Efficacy and safety of Radium 223 in mBC, compared to hormone therapy	Protocol Amendment 2, integrat	29/04/2015	21
14/YH/1141/AM05	Efficacy and safety of Radium 223 in mBC, compared to hormone therapy	Substantial Amendment 3 (29/7/	29/07/2015	25
14/YH/1165/AM05	Tapentadol for the treatment of post-surgical pain in children	Substantial Amendment 2 - 30/1	30/10/2015	27
14/YH/1192/AM04	Phase 2 Study of INCB039110 in Recurrent Non-Small Cell Lung Cancer	Substantial Amendment 3 - corr	23/04/2015	22
14/YH/1202/AM01	PREVAIL Version 1.0	Substantial Amendment 1, 27/03	22/04/2015	27
14/YH/1202/AM02	PREVAIL Version 1.0	Substantial Amendment 2, 22/04	20/05/2015	15
14/YH/1202/AM03	PREVAIL Version 1.0	Substantial Amendment 3 - 24/7	24/07/2015	22
14/YH/1202/AM05	PREVAIL Version 1.0	Substantial Amendment 4 - 19/1	19/10/2015	20
14/YH/1209/AM01	Iron and Heart Trial	Substantial Amendment 1 - 12/1	12/01/2016	25
14/YH/1237/AM03	Study to Assess the Safety of AZD9291 Vs SoC in Patients	Amendment 2	25/02/2015	24

	with NSCLC			
14/YH/1237/AM04	Study to Access the Safety of AZD9291 Vs SoC in Patients with NSCLC	Substantial Amendment 5, 18/06	19/06/2015	11
14/YH/1237/AM05	Study to Access the Safety of AZD9291 Vs SoC in Patients with NSCLC	Substantial Amendment 6 - 6/10	06/10/2015	28
14/YH/1258/AM01	Evaluation of the Birth Matters Clinic (v1)	Substantial Amendment 1, 12/06	16/06/2015	27
14/YH/1269/AM03	i.v. tapentadol for the treatment of post-surgical pain in children	Substantial Amendment 2 - 20/1	20/11/2015	26
14/YH/1269/AM04	i.v. tapentadol for the treatment of post-surgical pain in children	Substantial Amendment 3 - Prot	04/11/2015	25
14/YH/1275/AM01	Markers of relapse in melanoma	Substantial Amendment 1 - 28/10	28/10/2015	21
15/YH/0003/AM01	ZINN: Retosiban versus atosiban for spontaneous pre-term labour	Substantial Amendment 1	18/05/2015	17
15/YH/0003/AM04	ZINN: Retosiban versus atosiban for spontaneous pre-term labour	Substantial Amendment 3 - 21/1	21/10/2015	23
15/YH/0003/AM05	ZINN: Retosiban versus atosiban for spontaneous pre-term labour	Substantial Amendment 4 - 16/2	16/02/2016	23
15/YH/0004/AM04	ARIOS: Follow-up of infants born to mothers in retosiban studies	Substantial Amendment 1 - 17/8	17/08/2015	25
15/YH/0005/AM05	Liberty AD SOLO	Substantial Amendment 4, 24/07	24/07/2015	14
15/YH/0005/AM06	Liberty AD SOLO	Substantial Amendment 5 - 14/1	14/01/2016	13
15/YH/0006/AM04	CL06: OPEN-LABEL STUDY OF SEBELIPASE ALFA IN	Substantial	25/11/2015	21

	PATIENTS WITH LALD	Amendment 2 - 24/1		
15/YH/0034/AM03	The CIMPACT Study	Substantial Amendment 2	20/05/2015	15
15/YH/0034/AM04	The CIMPACT Study	Substantial Amendment 3, 23/07	23/07/2015	11
15/YH/0034/AM05	The CIMPACT Study	Substantial Amendment 4 - 9/9/	09/09/2015	12
15/YH/0045/AM01	ABLATOR	Substantial Amendment 1 - 6/11	06/11/2015	25
15/YH/0072/AM01	PuMAH	Substantial Amendment 2 - 17/1	17/11/2015	17
15/YH/0072/AM02	PuMAH	Substantial Amendment 3 - 21/2	21/02/2016	23
15/YH/0097/AM01	Brighton 3 in 1 Study in MSM	Substantial Amendment 1, 17/06	16/07/2015	18
15/YH/0097/AM02	Brighton 3 in 1 Study in MSM	Substantial Amendment 2 - 10/3	10/03/2016	10
15/YH/0194/AM02	R668-AD-1412 THE STUDY OF DUPILUMAB IN PAEDIATRIC PATIENTS WITH AD	Substantial Amendment 1, 24/07	24/07/2015	14
15/YH/0218/AM01	AIT02-2001 Safety and Protective Efficacy Study of FF-3 Dry Powder	Substantial Amendment 1, 10/07	10/07/2015	22
15/YH/0242/AM01	Long-Acting Insulin Glargine Titration Meter	Substantial Amendment 1 - 2/10	02/10/2015	18
15/YH/0242/AM04	Long-Acting Insulin Glargine Titration Meter	Substantial Amendment 2 - 11/1	11/12/2015	11
15/YH/0243/AM01	Liberty AD Solo - Continue	Substantial	18/09/2015	14

		Amendment 1 - 18/9		
15/YH/0259/AM01	The PRACTICE Trial	Substantial Amendment 1 - 28/1	28/10/2015	15
15/YH/0259/AM02	The PRACTICE Trial	Substantial Amendment 2 - 10/1	10/12/2015	28
15/YH/0259/AM03	The PRACTICE Trial	Substantial Amendment 3, 27/01	28/01/2016	18
15/YH/0287/AM01	OLE- Open Label Extension	Substantial Amendment 1 - Upda	25/09/2015	19
15/YH/0364/AM01	BRADYCARE II	Substantial Amendment 1 - 4/12	04/12/2015	29
15/YH/0401/AM02	Studying calcaneus microarchitecture with teriparatide treatment	Substantial Amendment 1 - 6/2/	06/02/2016	16
15/YH/0431/AM02	Mealtimes in families where a child has difficulties eating (V1)	Substantial Amendment 1 - 12/2	12/02/2016	16
15/YH/0435/AM01	VTS270 in Subjects with Niemann-Pick Type C1 Disease.	Substantial Amendment 1 - 02/1	02/12/2015	13
15/YH/0436/AM01	FreeStyle Libre In Pregnancy Study (FLIPS), Revision A	Substantial Amendment 1 - 30/1	30/11/2015	15
15/YH/0436/AM02	FreeStyle Libre In Pregnancy Study (FLIPS), Revision A	Substantial Amendment 2 - 10/3	14/03/2016	7
15/YH/0443/AM01	R668-AD-1434 THE STUDY OF DUPILUMAB IN PAED PATIENTS WITH AD	Substantial Amendment 1 - 17/1	17/12/2015	28
15/YH/0467/AM01	A Study of GSK3196165 in Hand Osteoarthritis	Substantial Amendment 1 - 16/1	27/11/2015	15

15/YH/0467/AM02	A Study of GSK3196165 in Hand Osteoarthritis	Substantial Amendment 2 - Prot	16/11/2015	13
15/YH/0478/AM01	The Regenerate Study	Substantial Amendment 1 - 17/1	17/12/2015	28
15/YH/0515/AM01	Coloplast CP266	Substantial Amendment 1 - 10/2	10/02/2016	28
15/YH/0538/AM01	R668-AD-1424, Phase 3 , Dupilumab, Adults, Severe Atopic Dermatitis	Substantial Amendment 1 - 15/1	15/12/2015	28
15/YH/0538/AM02	R668-AD-1424, Phase 3 , Dupilumab, Adults, Severe Atopic Dermatitis	Substantial Amendment 2 - 12/1	12/01/2016	16
16/YH/0015/AM01	Salivary fluoride using different toothpaste formulations	Substantial Amendment 1 - 25/2	25/02/2016	20

Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
12/YH/0522/AM04	PROMISE v1.0	Substantial Amendment 5, 22/04	22/04/2015	23
13/YH/0140/AM11	Ivabradine in heart failure with preserved ejection fraction	Substantial Amendment 10, Prot	16/06/2015	24
14/YH/0091/AM05	Feasibility of an Exercise Intervention in Patients with Venous Ulcers	Substantial Amendment 6 - 3/11	03/11/2015	14
14/YH/1237/AM06	Study to Assess the Safety of AZD9291 Vs SoC in Patients with NSCLC	Substantial Amendment 7 - prot	24/09/2015	30

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
12/YH/0522/AM04/1	PROMISE v1.0	Modified Substantial amendment	16/06/2015	10
13/YH/0140/AM11/1	Ivabradine in heart failure with preserved ejection fraction	Modified Substantial Amendment	03/08/2015	10
14/YH/0091/AM05/1	Feasibility of an Exercise Intervention in Patients with Venous Ulcers	Modified Amendment 1 - 17/11/1	18/11/2015	14
14/YH/0140/AM01/1	POLAR - TKA Study	Modified Substantial Amendment	24/04/2015	13

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

Table 11: Items exceeding timelines

Full applications for ethical review over 60 day timeline

REC Reference	Title	Number of Days on Clock
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Proportionate review applications for ethical review over 14 day timeline

REC Reference	Title	Number of Days on Clock
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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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