

London - Harrow Research Ethics Committee

Annual Report

01 April 2016 - 31 March 2017



Part 1 – Committee Membership and Training

Name of REC:	London - Harrow Research Ethics Committee
Type of REC:	REC recognised to review CTIMPS in healthy volunteers - type i REC recognised to review CTIMPS in patients - type iii
Type of Flag:	Phase 1 involving healthy volunteers Adults Lacking Capacity
Chair:	Dr Jan Downer
Vice-Chair:	Miss Shelly Glaister-Young
Alternate Vice-Chair:	Dr Daryl Bendel
REC Manager:	Georgina Castledine (01/04/2016- 01/09/2016) Sadie McKeown-Keegan (01/09/2016 – present)
REC Assistant:	Lucy Roberts (01/04/2016– 01/09/2016) Mr David Jellings (01/09/2016 – 01/01/2017) Arun Prathapan (01/03/2017 – present)
Committee Address:	Level 3, Block B Whitefriars Lewins Mead Bristol BS1 2NT
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Chair's overview of the past year:

London Harrow REC had yet another busy year reviewing 5 or 6 applications per meeting though the average is 4.6 as one meeting a year is reserved for training. Clinical Trials of Investigational Medical Products (CTIMPS) including phase 1 studies accounted for 40% of the studies reviewed and 15% involved adults who lacked capacity to give consent.

This year in spite of working hard to give a favourable opinion the vast majority of the decisions given about studies reviewed at a full committee meeting have been provisional opinions, in part this is because of the very tight criteria required for any conditions that the Committee might wish to add to be able to give a study a favourable opinion. In contrast for the 20 studies reviewed at proportionate review sub-committee meetings 45% received a favourable opinion, 30% a provisional opinion while 30% were transferred to a full committee meeting.

There have been fewer substantial amendments to review (97) but as these often come with 20 to 30 or more documents per amendment these along with the proportionate review meetings contributed to a significant amount of work outside the monthly REC meetings. The HRA assessments have just begun and very few have been available at the time of the Committee meetings however it has at times added rather than decreased the work of the committee and its officers. The Committee is able because of the wide expertise of the REC members to thoroughly review a wide variety of studies. All the work of the Committee relies very heavily upon the commitment of the members and special thanks should go to the committee vice chair and alternate vice-chair for their support throughout the year. The committee also wishes to thank the co-opted members who gave their assistance during the year.

The REC were pleased that most researchers were able to attend the REC meeting the resulting discussions were very helpful in being able to clarify points about the research proposal especially for those studies involving adults who lack capacity to give consent.

The REC welcomed Ms Sadie McKeown-Keegan as its new REC administrator and said goodbye to Ms Georgina Castledine the previous REC administrator.

Dr Jan Downer

London - Harrow Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Mr David Anderson-Ford	Director of Research Ethics and Governance	Lay Plus	01/03/2009	
Dr Daryl Bendel	Consultant in Pharmaceutical and Translational Medicine	Expert	20/10/2014	
Dr Jane Berry	Director of Medicines and Development Centre (Retired)	Lay	01/01/2016	
Dr Tom Bryce	Head of Bioanalytical Department (Retired)	Lay	01/01/2016	
Mr Andrew Counce	Chief Pharmacist	Expert	01/03/2009	
Ms Glenys Davies	Publications Manager (Retired)	Lay Plus	01/11/2016	
Dr Jan Downer	Consultant Anaesthetist	Expert	01/03/2009	
Dr Annette Gilmore	Research Nurse	Expert	11/11/2011	18/10/2016
Miss Shelly Glaister-Young	Barrister	Lay Plus	01/03/2009	
Dr Debra Josephs	Academic Clinical Lecturer in Medical Oncology	Expert	19/12/2016	
Dr Mary Leung	Clinical Psychologist	Expert	01/06/2010	
Ms Ann Malkin	Consultant Psychologist	Expert	01/03/2009	
Reverend Catherine McBride	Vicar	Lay	01/02/2014	
Mr Nikhil Pawa	Registrar - General Surgery	Expert	18/04/2016	
Ms Monika Temple	Civil Servant (Retired)	Lay	01/01/2016	
Mr Jim Wood	Retired IT Consultant	Lay Plus	01/03/2009	

London - Harrow Research Ethics Committee: Deputy Members

Name	Profession	Status	Meeting date attended

London - Harrow Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended
Ms Jane Batchelor	Centre Administrator, Advanced Cardiovascular Imaging	Lay Plus	24/02/2016, 24/08/2016
Ms Stephanie Ellis	Former Civil Servant	Lay Plus	19/10/2016, PR 22/06/2016
Mr Chris Foy	Medical Statistician	Expert	19/10/2016
Dr John Sheridan	Consultant Toxicologist and Chemist	Lay	PR 26/05/2016

London - Harrow Research Ethics Committee: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Mr David Anderson-Ford	Council member of Association for research ethics Director of Research Ethics and Governance - Brunel University London	31/03/2017
Dr Daryl Bendel	Director (and owner) of Xidea Solutions Limited, which is a consultancy providing support for the BioPharmaceutical industry. A consultant in Pharmaceutical and translational medicine who advises clients on matters that includes clinical trials. Dr Bendel has 2 clients currently involved with ongoing clinical trials in the UK. None of his other clients are currently intending to conduct trials in the UK. One is a UK company called London Pharma. The other is the Surrey Clinical Research Centre. Dr Bendel is a Consultant Medical Director. This clinic is accredited by the MHRA and he is named as the principal investigator for higher risk studies on the accreditation document. Primarily his role is to oversee clinical studies being conducted in the Clinic by other investigators. He oversees the overall clinical governance. He is a lecturer on the MSc Pharmaceutical Medicine course at the University of Surrey, dealing with the topics of 'Declaration of Helsinki: Ethics and Standards in human pharmacology study' and 'Principles of informed consent'. He is also Faculty of Pharmaceutical Medicine approved educational supervisor.	31/03/2017
Dr Jane Berry	Owner of GSK shares	31/03/2017
Dr Tom Bryce	Volunteer Awareness speaker for Prostate Cancer UK	31/03/2017
Mr Andrew Counce	None	31/03/2017
Ms Glenys Davies	Lay member/patient representative on the ECLIPSE (Exploring the Current Landscape of Intravenous Infusion Practices & Errors) Study Steering Committee. (NIHR HS&DR ref 12/209/27) Member of CRAG (Constipation Research Advisory Group) a patient group working with Bowel and Cancer Research and the National Centre for Bowel Research and Surgical Innovation (NCBSRI). CRAG's main remit is to provide advice and guidance to the Programme Steering Committee for the Chronic Constipation Treatment Pathway (CapaCITY) Research Programme.	26/10/2016
Dr Jan Downer	None	31/03/2017
Miss Shelly Glaister-Young	None	09/08/2016
Dr Debra Josephs	PhD (2009-2013) was partly funded by Cancer Research UK	02/02/2017
Dr Mary Leung	HCPC re-registration period 01/06/15 to 31/05/17 Offer specialist advise on post stroke depression	31/03/2017

Ms Ann Malkin	Chair, Board of Trustees, Communicare Counselling Service	31/03/2017
Reverend Catherine McBride	Ordinary shares in GSK	31/03/2017
Mr Nikhil Pawa	None	24/05/2016
Ms Monika Temple	Bank policy advisor at the HRA	31/03/2017
Mr Jim Wood	Shares in Astra Zeneca GSK Membership of Brunel University Research Ethics Committee	31/03/2017

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

Month	Date	Number of Members Present at Meeting
May	10/05/2016	10
June	14/06/2016	10
August	09/08/2016	8
September	13/09/2016	8
October	11/10/2016	9
October	19/10/2016	8
December	13/12/2016	7
January	10/01/2017	11
February	14/02/2017	9
March	14/03/2017	11

10 full committee meetings were held during the reporting period.

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

Month	Date	Number of Members Present at Meeting
April	20/04/2016	3
May	26/05/2016	3
June	22/06/2016	3
August	24/08/2016	3
September	21/09/2016	3
November	23/11/2016	3
December	14/12/2016	3
January	26/01/2017	3
February	23/02/2017	3

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

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

Month	Date	Number of Members Present at Meeting
April	08/04/2016	2
April	15/04/2016	3
April	25/04/2016	2

May	10/05/2016	2
May	27/05/2016	2
June	03/06/2016	2
June	13/06/2016	4
June	24/06/2016	3
June	30/06/2016	2
July	15/07/2016	4
July	22/07/2016	2
July	27/07/2016	2
August	12/08/2016	2
August	15/08/2016	2
September	05/09/2016	2
September	09/09/2016	2
September	09/09/2016	2
September	26/09/2016	2
October	21/10/2016	2
October	26/10/2016	3
October	31/10/2016	2
November	03/11/2016	4
November	04/11/2016	2
November	11/11/2016	3
November	16/11/2016	3
November	18/11/2016	2
December	02/12/2016	2
December	16/12/2016	2
December	30/12/2016	2
January	13/01/2017	3
January	27/01/2017	2
February	08/02/2017	2
February	10/02/2017	2
February	24/02/2017	2
February	28/02/2017	5
March	10/03/2017	3
March	31/03/2017	4

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

Details of inquorate meeting held: 01 April 2016 - 31 March 2017

Date	Reason	Action taken
11/10/2016	Members had to leave before the end of the meeting	Decisions for affected applications ratified at a teleconference meeting.

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

Name	Number of Meetings Attended
Dr Daryl Bendel	7
Dr Jane Berry	7
Dr Tom Bryce	9
Mr Andrew Counce	4
Ms Glenys Davies	4
Dr Jan Downer	10
Dr Annette Gilmore	1
Miss Shelly Glaister-Young	7
Dr Debra Josephs	2
Dr Mary Leung	5
Ms Ann Malkin	7
Reverend Catherine McBride	8
Mr Nikhil Pawa	5
Ms Monika Temple	7
Mr Jim Wood	4

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

Name	Number of Meetings Attended
Dr Daryl Bendel	6
Dr Jane Berry	2
Dr Tom Bryce	1
Mr Andrew Counce	3
Dr Jan Downer	4
Miss Shelly Glaister-Young	4
Ms Ann Malkin	2
Mr Nikhil Pawa	1
Ms Monika Temple	1
Mr Jim Wood	3

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

Name	Number of Meetings Attended
Dr Daryl Bendel	18
Dr Jane Berry	5
Dr Tom Bryce	2
Mr Andrew Counce	4
Dr Jan Downer	26

Miss Shelly Glaister-Young	9
Dr Mary Leung	9
Ms Ann Malkin	8
Reverend Catherine McBride	5
Mr Nikhil Pawa	1
Ms Monika Temple	5

Training 01 April 2016 - 31 March 2017

Name of Member	Date	Event(s) attended
Dr Daryl Bendel	12/04/2016	Local training day
Dr Jane Berry	12/04/2016	Local training day
Dr Jane Berry	16/02/2017	National Members Day
Dr Tom Bryce	12/04/2016	Local training day
Dr Tom Bryce	24/05/2016	Training - Introduction to Phase 1 Research
Mr Andrew Caunce	12/04/2016	Local training day
Dr Jan Downer	12/04/2016	Local training day
Dr Jan Downer	20/04/2016	Training - Researcher Training Day
Dr Jan Downer	07/11/2016	The Practicalities of Running a REC
Dr Jan Downer	01/12/2016	National Training Day for Committee Chairs
Miss Shelly Glaister-Young	12/04/2016	Local training day
Dr Mary Leung	12/04/2016	Local training day
Ms Ann Malkin	12/04/2016	Local training day
Reverend Catherine McBride	12/04/2016	Local training day
Ms Monika Temple	12/04/2016	Local training day
Mr Jim Wood	16/02/2017	National Members 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	16	34.78
Phase 1	2	4.35
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	0	0.00
Others	28	60.87
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	0
Number of student applications reviewed	14
Number of paediatric applications reviewed	3
Number of device applications reviewed	1
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	7
Number of applications reviewed that are funded by the US DHHS	0
Number of qualitative applications reviewed	1

Table 3: Decisions given at meetings held within the reporting period

Decisions taken at meetings following review of applications	Number	%
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	1	2.17
Unfavourable Opinion	2	4.35
Provisional Opinion	41	89.13
Provisional Opinion Pending Consultation with Referee	2	4.35
Total	46	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	20	43.48
Further Information Favourable Opinion with Additional Conditions	16	34.78
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	1	2.17
Unfavourable Opinion	2	4.35
Provisional Opinion	5	10.87
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	20
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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	0
Number of student applications reviewed	8
Number of paediatric applications reviewed	2
Number of device applications reviewed	1
Number of qualitative applications reviewed	1

Table 7: Decisions given at proportionate review sub-committee meetings held within the reporting period

Decisions taken at proportionate review sub-committee meetings	Number	%
Favourable Opinion with Standard Conditions	8	40.00
Favourable Opinion with Additional Conditions	1	5.00
No Opinion transfer to full committee for review	5	25.00
Provisional Opinion	6	30.00
Unfavourable Opinion	0	0.00
Total	20	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	1
Number of completed applications over 60 days as a % of total	2.17%
Number of completed applications for full ethical review over 40 days	13
Number of completed applications over 40 days as a % of total	28.26%
Number of days taken to final decision – average (mean)	38
Number of completed proportionate review applications for ethical review	15
Number of completed proportionate review applications for ethical review over 14 days [please note, the timeline for the review of PR was extended from 14 to 21 calendar days in December 2016]	2
Number of completed proportionate review applications for ethical review over 21 days	1
Number of completed proportionate review applications over 14 days as a % of total	13.33%
Number of SSAs (non-Phase 1) reviewed	2
Number of completed applications for SSA review over 25 days	1
Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs	50.00%
Number of SSAs (Phase 1) reviewed	3
Number of completed applications for SSA review over 14 days	1
Number of completed applications for SSA review over 14 days as % of all Phase 1 SSAs	33.33%
Number of substantial amendments reviewed	97
Number of completed substantial amendments over 35 days	11
Number of completed substantial amendments over 35 days as a % of total substantial amendments	11.34%
Number of completed substantial amendments over 28 days	28
Number of completed substantial amendments over 28 days as a % of total substantial amendments	28.87%
Number of modified amendments reviewed	0
Number of completed modified amendments over 14 days	0
Number of completed modified amendments over 14 days as a % of total modified amendments	0.00%
Number of non substantial amendments received	116

Number of substantial amendments received for information	1
Number of substantial amendments received for new sites/PIs	18
Number of annual progress reports received	49
Number of safety reports received	28
Number of Serious Adverse Events received	1
Number of final reports received	4

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

Further Information Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
16/LO/0513	VIOLET	32
16/LO/0721	Effect of LML134 on brain H3 receptor occupancy in healthy volunteers	37
16/LO/0835	Research Priorities for Spinal Cord Injury in Children	64
16/LO/0857	LISTER	42
16/LO/0873	Psychosis and Diabetes Study	35
16/LO/1003	Factors associated with observation of side-effects: child flu vaccine	39
16/LO/1047	Open Label Extension Study with SCD Patients from GBT440-001	30
16/LO/1122	Effects of hrAnx-A1 in healthy men, v1	52
16/LO/1319	Iluvien for IRD	30
16/LO/1386	Phase 2 with Elamipretide in subjects hospitalised with heart failure	33
16/LO/2111	Staphylococcus aureus concealed carriage estimation study v1.0	31
16/LO/2127	RIPCOM 1	33
16/LO/2159	Prospective Early Pregnancy Cardiac Imaging & Anatomy Screening PRECISE	23
16/LO/2189	Better Endings	34
16/LO/2226	Positive risk taking and borderline personality disorder experiences	21
17/LO/0030	CST in people with Intellectual disability and dementia	37
17/LO/0038	UK P3BEP Trial	46
17/LO/0070	CONSERVE: Coversin Long Term Study	24
17/LO/0243	Dose response study of GSK2330672 for pruritus in PBC patients 201000	36
17/LO/0285	G1T38-02_Phase 1/2 Safety & PK Study of G1T38_Breast Cancer_3652/0002	34

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
16/LO/1097	Kaposi sarcoma herpesvirus (KSHV) infection and immunity	52
16/LO/1118	PAGE	52
16/LO/1397	Feasibility study for Intermittent Very Low Energy Diet in CKD	30
16/LO/1458	Efficacy and Safety Assessment of T1580 vs Vehicle in DED treatment	60
16/LO/1488	V1. An observational study of adults with LD and challenging behaviour	48
16/LO/1490	Changes in Microbiome with Treatment in Chronic Lung Diseases	39
16/LO/1539	Class-II invariant chain HCV vaccine study	44
16/LO/1589	SPINET	55

16/LO/1700	A phase II clinical trial of DARC	55
16/LO/1707	Ageing, senescence and the behaviour of human muscle stem cells	38
16/LO/1820	Effects of intranasal naloxone on eating behaviours in bulimia nervosa	40
16/LO/1822	Vericiguat-Subjects With Heart Failure With Reduced Ejection Fraction	40
16/LO/1975	Brain-based predictors of the ability to learn a new skill in stroke	25
16/LO/2156	Exploring anxiety and depression in patients with glaucoma	29
17/LO/0299	Using Virtual Reality biofeedback for patients with motor neglect.	32
17/LO/0365	Improving Fundamental Care in Hospitals	40

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
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Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
17/LO/0212	Long term treatment with inclisiran and a comparison to evolocumab	24

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
16/LO/1316	Brain-based predictors of the ability to learn a new skill in stroke	27
16/LO/1591	Surgical Quality Assurance in COLOR III Trial	28

Provisional Opinion

REC Reference	Title	Number of Days on Clock
17/LO/0297	A study to describe recovery of older women after gynaecology surgery	n/a
17/LO/0431	Hyperpolarised 13C-Pyruvate MRI study	n/a
17/LO/0434	Mechanisms of Movement, Balance and Orientation in Health & Disease	n/a
17/LO/0438	Esperion 1002-043 (Bempedoic Acid (ETC-1002))	n/a
17/LO/0439	Sensory system abnormalities in childhood dystonia	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/LO/1821	PTNS vs Renew Anal Insert: a randomised blinded pilot study	n/a
17/LO/0160	A study to describe recovery of older people after cardiac surgery.	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
16/LO/0696	Tear film osmolarity in patients with facial palsy	12
16/LO/0704	Development of a lateral flow device for the detection of CMV in Urine	11
16/LO/0733	Feasibility study on HELICA ablative treatment for VAIN	14
16/LO/1057	Lived experience of patients with toe amputation a result of diabetes	12
16/LO/1059	Establishing the incidence of Tako-tsubo cardiomyopathy in Scotland	6

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
16/LO/1772	Myotrace CT Correlation	26

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

Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
16/LO/0984	PaNACeA	10
16/LO/1219	Antibody and T cell receptor library creation	10
16/LO/1773	Myotrace Causality	18
16/LO/2135	DACC in the Prevention of Surgical Site Infection (DRESSINg)	7
17/LO/0197	Efficacy of a dietary supplement to increase resilience	10
17/LO/0223	A survey to explore the impact of an In-Practice Prevention project	11
17/LO/0225	Women's Experience of Post-placental Intrauterine Contraception	6
17/LO/0227	Analysis of plasma samples from multi-centre cancer study	8

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
16/LO/2249	Visual Impairment and Falls in the Elderly Version 1.0	10

Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock

Provisional Opinion		
REC Reference	Title	Number of Days on Clock

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

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

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
00/0158/AM02	Voluntary saliva testing for HIV antibody - in gay men	2	22/07/2016	33
05/Q0502/102/AM22	Remote postconditioning in the clinical setting	17	01/05/2016	38
05/Q0502/88/AM23	Hypoxia-ischaemia in children: neuropathology and memory impairment	22	31/03/2016	46
05/Q0505/34/AM13	Tumour angiogenesis in non-small cell lung cancer	AM 13 Amendment 12	08/11/2016	18
05/Q0505/57/AM23	Biomarkers for cancer	19	11/05/2016	17
05/Q0505/57/AM24	Biomarkers for cancer	20 (AM24)	08/02/2017	12
05/Q0505/58/AM15	Risk Factors for Ovarian Cancer Version 1, 23/05/2005	14	02/11/2016	35
07/H0714/81/AM02	Case-control study of biomarkers in endometrial cancer	2	11/05/2016	17
08/H0719/37/AM04	Multimodal Optical and Spectroscopic Imaging of Human Cancer Tissues	AM04 Version 5 11.10.2016	11/10/2016	36
09/H0715/37/AM03	Impact of smoking cessation on skeletal muscle	Substantial Amendment 1	28/09/2016	35
10/H0710/9/AM06	EVALUATING THE AGE EXTENSION OF THE NHS BREAST SCREENING PROGRAMME	4	01/07/2016	41
10/H0715/57/AM17	MDV3100 for chemotherapy-naïve patients with prostate cancer	AM17 Ed9	27/10/2016	22
11/LO/0330/AM08	Investigation of rheumatic disease in teenagers and adults : v1.0	AM08 Amendment 2	04/11/2016	20
11/LO/1310/AM03	Preoperative treatment of a low haemoglobin in cardiac surgery	12.0 AM03	09/05/2016	15
12/LO/0066/AM01	AXMUS-C	1	04/08/2016	2
12/LO/0538/AM01	TSPO and macrophage phenotype version 1	AM01 v.2	29/11/2016	23
12/LO/1257/AM19	Oral UT-15C for treatment of Pulmonary Arterial Hypertension (PAH)	AM19 Version # 12	15/12/2016	28
12/LO/1325/AM13	Open Label Extension Study - Oral UT-15C for PAH	v7	15/12/2016	27
12/LO/1361/AM04	Cardioprotection in CABG and AVR patients with RIPC	3	11/08/2016	43
12/LO/1378/AM18	Evaluation of PBS: a cluster RCT	8	25/04/2016	29
12/LO/1756/AM03	Muscle control in people with musculoskeletal problems	AM03 Version 3	20/10/2016	28

12/LO/1771/AM12	Study of Dexamethasone in Patients with AL Amyloidosis	Ixazomib IB Version 9.0 Addend	20/04/2016	13
12/LO/1771/AM14	Study of Dexamethasone in Patients with AL Amyloidosis	Amendment 4 (AM14)	27/01/2017	5
13/LO/0021/AM13	PRESENT	NA Temporary Halt	30/06/2016	40
13/LO/0100/AM12	A study of ISIS 420915 in patients with Amyloid Polyneuropathy	8	07/03/2016	31
13/LO/0100/AM13	A study of ISIS 420915 in patients with Amyloid Polyneuropathy	9	13/05/2016	33
13/LO/0100/AM14	A study of ISIS 420915 in patients with Amyloid Polyneuropathy	AM 14 Rev 8	19/12/2016	15
13/LO/0279/AM04	Development and validation of a national survey of people with HIV	Amendment 3 (AM04)	20/06/2016	30
13/LO/0455/AM03	Pilot Study: Retinal Embolisation in TAVI	3	29/03/2016	27
13/LO/0503/AM11	Asfotase Alfa in infants and children (≥ 5 Years of Age) with HPP	IB Edition 8.1	19/05/2016	49
13/LO/1020/AM09	309: XL184 vs placebo in subjects with hepatocellular carcinoma	AM09 Version 2.0	12/07/2016	22
13/LO/1264/AM13	Olaparib maintenance monotherapy in PSR ovarian cancer	3	12/04/2016	28
13/LO/1670/AM05	Autologous Stem Cells in Achilles Tendinopathy	5	15/04/2016	41
13/LO/1758/AM20	A Safety and Efficacy Study of MK8931 for Prodromal AD v.019-00	14	22/03/2016	8
13/LO/1758/AM22	A Safety and Efficacy Study of MK8931 for Prodromal AD v.019-00	SA15 PET substudy - 18.08.16	13/09/2016	41
13/LO/1758/AM26	A Safety and Efficacy Study of MK8931 for Prodromal AD v.019-00	Protocol Am 11 (AM26)	20/02/2017	7
13/LO/1891/AM04	MORE-CRT MPP	4	13/04/2016	11
14/LO/0185/AM05	PROXIMUS - Protective role of OXcabazepine In Multiple Sclerosis	3	06/07/2016	28
14/LO/0314/AM07	Risk of Seizure Among Subjects with mCRPC	5	18/11/2016	19
14/LO/0710/AM02	Decision making, context and psychosis	2	22/04/2016	20
14/LO/0882/AM15	GO28915 - MPDL3280A or Docetaxel in Patients with NSCLC	7	25/02/2016	1
14/LO/0882/AM18	GO28915 - MPDL3280A or Docetaxel in Patients with NSCLC	8	23/08/2016	17
14/LO/0882/AM19	GO28915 - MPDL3280A or Docetaxel in Patients with NSCLC	SA09 Protocol v7	11/01/2017	23
14/LO/1249/AM03	CATS29 Crohns Phase IIb, Multicentre, Randomized, Double-	3	13/04/2016	8

	blind Study			
14/LO/1378/AM05	MEASURES	Substantial Amendment number :	13/01/2017	26
14/LO/1597/AM06	Phase 2a/2b study of alkaline phosphatase in patients with SA-AKI	3	03/02/2016	35
14/LO/1604/AM07	Open-Label Extension Study in Rheumatoid Arthritis.	4	12/05/2016	14
14/LO/1834/AM23	SAD and MAD study of GBT440 in healthy volunteers and SCD Patients	10	21/03/2016	14
14/LO/1834/AM26	SAD and MAD study of GBT440 in healthy volunteers and SCD Patients	11	17/05/2016	25
14/LO/1834/AM28	SAD and MAD study of GBT440 in healthy volunteers and SCD Patients	12	20/06/2016	14
14/LO/1834/AM31	SAD and MAD study of GBT440 in healthy volunteers and SCD Patients	SA 13 - Protocol amendment	22/09/2016	40
14/LO/2004/AM03	Methylnaltrexone for the Treatment of Opioid Induced Constipation	1	04/04/2016	6
14/LO/2004/AM10	Methylnaltrexone for the Treatment of Opioid Induced Constipation	Substantial Amendment 4.0 (AM1)	25/01/2017	4
14/LO/2218/AM07	ENZAMET Trial	5	30/06/2016	14
14/LO/2218/AM08	ENZAMET Trial	SA06 (AM08)	12/10/2016	30
15/LO/0236/AM06	A Phase II Trial of MK-3475 in Subjects with Bladder Cancer	5	27/06/2016	19
15/LO/0413/AM04	Safety and Efficacy of Brimonidine-DDS in patients with GA-AMD	1- Patient Recruitment Material	02/05/2016	28
15/LO/0440/AM02	Advanced OCT and Adaptive Optics Imaging in Retinal Disease	1	19/07/2016	35
15/LO/0769/AM02	Left Atrial Appendage Occlusion Study III (LAAOS III)	1	11/05/2016	19
15/LO/0781/AM03	Evaluation of the safety and efficacy of PAD ciclosporin in dry eye patients	2	14/06/2016	23
15/LO/0799/AM03	Monitoring Air Pollution Exposure in Children	AM03 Amendment 2	30/11/2016	9
15/LO/1012/AM02	Acupuncture for cancer patients undergoing Radiotherapy Treatment	2	23/03/2016	21
15/LO/1015/AM03	AQUA	2	21/03/2016	34

15/LO/1015/AM04	AQUA	3	06/06/2016	4
15/LO/1015/AM05	AQUA	Amendment no. 4	16/08/2016	34
15/LO/1027/AM03	The Abatacept Systemic SclErosis Trial (ASSET)	UK Specific version 1.5 based	16/05/2016	14
15/LO/1401/AM03	LAIV PROTECT	3	29/07/2016	29
15/LO/1401/AM04	LAIV PROTECT	7 (AM04)	29/07/2016	22
15/LO/1402/AM04	HOPE - HF	Amendment No. 2	16/01/2017	10
15/LO/1441/AM03	Phase III with ALX0681 in Acquired Thrombotic Thrombocytopenic Purpura	3	09/05/2016	20
15/LO/1441/AM04	Phase III with ALX0681 in Acquired Thrombotic Thrombocytopenic Purpura	4	20/07/2016	23
15/LO/1540/AM01	Research to evaluate the Active for Health Pathway	AM01	21/12/2016	28
15/LO/1830/AM03	202007 - FTIH of GSK3389404 in HV	1	08/04/2016	17
15/LO/1952/AM02	Phase II ALNPCSSC placebo-controlled, double-blind, cardiology trial	2	12/04/2016	29
15/LO/2047/AM01	Medivation - D5170C00002	1	26/04/2016	17
15/LO/2047/AM02	Medivation - D5170C00002	2: Protocol Amendment 1	18/11/2015	33
15/LO/2069/AM01	The PReSUTINeB Study (v1.0).	AM01 Substantial Amendment 02	05/01/2017	14
16/LO/0050/AM01	Safety, blood levels and effects of Coversin, v1	1	08/04/2016	23
16/LO/0050/AM03	Safety, blood levels and effects of Coversin, v1	AM03 Version 5.0	03/11/2016	13
16/LO/0153/AM01	MS-DOUBT	1	10/06/2016	20
16/LO/0227/AM01	A Feasibility Study of DBT-SE for PD	AM01 Amendment1	23/12/2016	9
16/LO/0231/AM01	Trial of Psychological Workshops for Adolescents in Clinics V1	1	29/04/2016	17
16/LO/0406/AM02	RELAX-OAB 105-0010	Substantial Amendment 1 dated	30/08/2016	27
16/LO/0411/AM03	Assertive outreach treatment for alcohol related admissions	1 (AM03)	01/03/2017	8
16/LO/0446/AM02	Child and Family Views Project	1 (AM02)	27/09/2016	23
16/LO/0513/AM01	VIOLET	1	01/07/2016	15
16/LO/0513/AM02	VIOLET	Amendment 02	16/08/2016	17
16/LO/1003/AM01	Factors associated with observation of side-effects: child flu vaccine	AM01 Version 1	27/10/2016	4
16/LO/1047/AM01	Open Label Extension Study with SCD Patients from GBT440-	Protocol V2	28/09/2016	33

	001			
16/LO/1047/AM02	Open Label Extension Study with SCD Patients from GBT440-001	SA to add Sickle Cell Website	11/11/2016	15
16/LO/1319/AM01	Iluvien for IRD	SA1	26/10/2016	15
16/LO/1386/AM01	Phase 2 with Elamipretide in subjects hospitalised with heart failure	AM01 Substantial Amendment 1	06/01/2017	28
16/LO/1589/AM01	SPINET	SA REC UK01 (AM01)	04/01/2017	26
16/LO/1820/AM03	Effects of intranasal naloxone on eating behaviours in bulimia nervosa	Substantial Amendment 1	31/01/2017	6
85/0938/AM03	The Whitehall II Study (The Stress and Health Study)	Protocol amend 1.1	28/06/2016	42
99/0305/AM01	SLICC Registry for atherosclerosis in SLE	Version 25.10.2016	25/10/2016	23

Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
14/LO/1785/AM02	MUSCLE MRI sequence study	3 (AM02)	22/06/2016	35

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
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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
16/LO/0835	Research Priorities for Spinal Cord Injury in Children	64

Proportionate review applications for ethical review over 21 day timeline

REC Reference	Title	Number of Days on Clock
16/LO/1772	Myotrace CT Correlation	26

SSAs (non Phase 1) over 25 day timeline

REC Reference	Title	Number of Days on Clock
16/LO/2284	A Feasibility Study of Dialect	27

SSAs (Phase 1) over 14 day timeline

REC Reference	Title	Number of Days on Clock
16/LO/0921	A Double-Blind, Placebo-Controlled, Dose-Escalation, First Time in Human Study GSK3389404 in Healthy Subjects	17

Substantial Amendments over 35 day timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
05/Q0502/102/AM22	Remote postconditioning in the clinical setting	17	01/05/2016	38
05/Q0502/88/AM23	Hypoxia-ischæmia in children: neuropathology and memory impairment	22	31/03/2016	46
08/H0719/37/AM04	Multimodal Optical and Spectroscopic Imaging of Human Cancer Tissues	AM04 Version 5 11.10.2016	11/10/2016	36
10/H0710/9/AM06	EVALUATING THE AGE EXTENSION OF THE NHS BREAST SCREENING PROGRAMME	4	01/07/2016	41
12/LO/1361/AM04	Cardioprotection in CABG and AVR patients with RIPC	3	11/08/2016	43
13/LO/0021/AM13	PRESENT	NA Temporary Halt	30/06/2016	40

13/LO/0503/AM11	Asfotase Alfa in infants and children (â‰¥5 Years of Age) with HPP	IB Eddition 8.1	19/05/2016	49
13/LO/1670/AM05	Autologous Stem Cells in Achilles Tendinopathy	5	15/04/2016	41
13/LO/1758/AM22	A Safety and Efficacy Study of MK8931 for Prodromal AD v.019-00	SA15 PET substudy - 18.08.16	13/09/2016	41
14/LO/1834/AM31	SAD and MAD study of GBT440 in healthy volunteers and SCD Patients	SA 13 - Protocol amendment	22/09/2016	40
85/0938/AM03	The Whitehall II Study (The Stress and Health Study)	Protocol amend 1.1	28/06/2016	42

Modified Amendments over 14 day timeline				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
	None			