

London - Harrow Research Ethics Committee

Annual Report

01 April 2017 - 31 March 2018



Part 1 – Committee Membership and Training

Name of REC:	London - Harrow Research Ethics Committee
Type of REC:	RECs recognised to review CTIMPS in healthy volunteers - type i RECs recognised to review CTIMPS in patients - type iii
Type of Flag:	Phase 1 Studies in Healthy Volunteers Research Involving Adults Lacking Capacity
Chair:	Dr Jan Downer
Vice-Chair:	Miss Shelly Glaister-Young
Alternate Vice-Chair:	Dr Daryl Bendel
REC Manager:	Mr Alex Martin (01/08/2018 – present) Sadie McKeown-Keegan (01/09/2016 – 31/07/2017)
REC Assistant:	Mr Wai Yeung. (01/03/2018 – present) Arun Prathapan (01/03/2017 – 05/02/2018)
Committee Address:	Level 3, Block B Whitefriars Lewins Mead Bristol BS1 2NT
Telephone:	020 7104 8057
Email:	nrescommittee.london-harrow@nhs.net

Chair's overview of the past year:

Requested.

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	20/07/2017
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	
Miss Shelly Glaister-Young	Barrister	Lay Plus	01/03/2009	
Dr Debra Josephs	Academic Clinical Lecturer in Medical Oncology	Expert	19/12/2016	12/10/2017
Dr Mary Leung	Clinical Psychologist	Expert	01/06/2010	
Ms Ann Malkin	Consultant Psychologist	Expert	01/03/2009	
Miss Mia Manzi-Davies	Partnership Development Executive	Lay Plus	10/01/2018	
Reverend Catherine McBride	Vicar	Lay	01/02/2014	18/09/2017
Mr Nikhil Pawa	Registrar - General Surgery	Expert	18/04/2016	14/10/2017
Mrs Alex Sheffield	Carer	Lay Plus	10/01/2018	
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
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London - Harrow Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended
Ms Stephanie Ellis	Retired Civil Servant	Lay Plus	10/04/2018, 10/10/2017

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

Name	Declaration of Interest	Date
Dr Tom Bryce	Volunteer Awareness speaker for Prostate Cancer UK	31/03/2018
Ms Glenys Davies	Reviewing all the Living with IBD and Health Services Research Award applications received; Scoring and commenting on the applications at an annual teleconference to shortlist the very highest quality studies; Considering external peer review feedback on the shortlisted applications; Re-visiting the shortlisted applications in the light of those peer reviews, and undertaking any applicant interviews, at an annual Panel meeting in London to provide a final shortlist the CCUK Research Strategy & Funding Committee who will make recommendations for funding to the Crohn's and Colitis UK Board of Trustees. I hope this new commitment will not pose any problems for my membership of Harrow REC. I have checked with the LWIBD Panel Secretary and she informs me that most of the applications would already have received ethical approval, but possibly not all – so there is a chance that Harrow REC may be asked to approve a research project that is applying for funding from, or has actually been given funding by CCUK. I am assuming that in such a case I would be able to declare an interest and if appropriate withdraw from the discussions.	12/07/2017
Dr Jan Downer	None	31/03/2018
Miss Shelly Glaister-Young	None	26/06/2017
Dr Mary Leung	None	31/03/2018
Miss Mia Manzi Davies	None	10/02/2018
Mrs Alex Sheffield	Fundraiser, husband is a trustee at the SMA Trust	12/03/2018
Ms Monika Temple	None	31/03/2018
Mr Jim Wood	None	31/03/2018

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

Month	Date	Number of Members Present at Meeting
May	09/05/2017	9
June	13/06/2017	9
August	08/08/2017	10
September	12/09/2017	9
October	10/10/2017	7
November	14/11/2017	8
January	09/01/2018	9
February	13/02/2018	8
March	13/03/2018	9

9 full committee meetings were held during the reporting period.

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

Month	Date	Number of Members Present at Meeting
April	27/04/2017	3
May	25/05/2017	3
June	22/06/2017	3
August	18/08/2017	3
September	15/09/2017	3
October	20/10/2017	3
November	17/11/2017	3
December	15/12/2017	3
January	19/01/2018	3
February	16/02/2018	3
March	23/03/2018	3

11 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	07/04/2017	2
April	21/04/2017	2
May	05/05/2017	2
May	19/05/2017	2
May	24/05/2017	2
June	02/06/2017	2
June	16/06/2017	2
June	30/06/2017	2
July	14/07/2017	2
July	30/07/2017	2
July	30/07/2017	2

August	11/08/2017	2
August	25/08/2017	2
September	08/09/2017	2
September	22/09/2017	2
October	06/10/2017	2
October	20/10/2017	2
November	03/11/2017	2
November	03/11/2017	2
November	09/11/2017	2
November	17/11/2017	2
December	01/12/2017	2
December	15/12/2017	2
December	29/12/2017	2
January	12/01/2018	2
January	26/01/2018	2
February	09/02/2018	2
February	23/02/2018	3
March	09/03/2018	2
March	23/03/2018	2

30 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 Daryl Bendel	6
Dr Jane Berry	7
Dr Tom Bryce	7
Mr Andrew Caunce	4
Ms Glenys Davies	7
Dr Jan Downer	9
Miss Shelly Glaister-Young	5
Dr Debra Josephs	2
Dr Mary Leung	7
Ms Ann Malkin	8
Miss Mia Manzi-Davies	1
Reverend Catherine McBride	2
Mrs Alex Sheffield	1
Ms Monika Temple	7
Mr Jim Wood	4

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

Name	Number of Meetings Attended
Dr Daryl Bendel	4
Dr Jane Berry	2
Dr Tom Bryce	1
Mr Andrew Caunce	1
Ms Glenys Davies	2
Dr Jan Downer	8
Miss Shelly Glaister-Young	4
Dr Mary Leung	2
Ms Ann Malkin	2
Reverend Catherine McBride	1
Ms Monika Temple	3
Mr Jim Wood	3

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

Name	Number of Meetings Attended
Dr Daryl Bendel	10
Dr Jane Berry	4
Dr Tom Bryce	5

Mr Andrew Caunce	2
Ms Glenys Davies	3
Dr Jan Downer	14
Miss Shelly Glaister-Young	9
Dr Debra Josephs	1
Dr Mary Leung	4
Ms Ann Malkin	3
Reverend Catherine McBride	1
Ms Monika Temple	3
Mr Jim Wood	2

Training 01 April 2017 - 31 March 2018

Name of Member	Date	Event(s) attended
Dr Jane Berry	11/04/2017	Local Training Day - London - Harrow
Dr Tom Bryce	11/04/2017	Local Training Day - London - Harrow
Ms Glenys Davies	11/04/2017	Local Training Day - London - Harrow
Ms Glenys Davies	25/07/2017	Committee Members Induction
Dr Jan Downer	11/04/2017	Local Training Day
Dr Jan Downer	24/11/2017	Training - HRA National Chairs' Day and Policy Event
Miss Shelly Glaister-Young	11/04/2017	Local Training Day - London - Harrow
Dr Debra Josephs	25/07/2017	Training - Committee Members Induction
Dr Mary Leung	11/04/2017	Local Training Day - London - Harrow
Ms Ann Malkin	11/04/2017	Local Training Day
Mr Nikhil Pawa	11/04/2017	Local training day
Ms Monika Temple	11/04/2017	Local Training Day - London - Harrow
Ms Monika Temple	12/12/2017	Training - National Members Training Day
Mr Jim Wood	11/04/2017	Local training day
Mr Jim Wood	12/12/2017	Training - National Members Training Day

PART 2: REC WORKLOAD AND ACTIVITY DURING THE REPORTING PERIOD

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

Applications for full ethical review – Study Type	Number	%
Clinical Trial of Investigational Medicinal Product	9	21.43
Phase 1	5	11.90
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	0	0.00
Others	28	66.67
Total Applications Reviewed	42	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	3
Number of student applications reviewed	12
Number of paediatric applications reviewed	5
Number of device applications reviewed	2
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	10
Number of applications reviewed that are funded by the US DHHS	0
Number of qualitative applications reviewed	5

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

Decisions taken at meetings following review of applications	Number	%
Favourable Opinion with Standard Conditions	1	2.38
Favourable Opinion with Additional Conditions	2	4.76
Unfavourable Opinion	0	0.00
Provisional Opinion	39	92.86
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	42	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	27	64.29
Further Information Favourable Opinion with Additional Conditions	8	19.05
Further Information Unfavourable Opinion	1	2.38
Favourable Opinion with Standard Conditions	1	2.38
Favourable Opinion with Additional Conditions	2	4.76
Unfavourable Opinion	0	0.00
Provisional Opinion	1	2.38
Provisional Opinion Pending Consultation with Referee	0	0.00
Further Information response not complete	2	4.76
No decision entered on system	0	0.00
Number of studies withdrawn after the meeting	0	0.00
Total	42	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	0
Number of studies withdrawn prior to the meeting	2
Number of student applications reviewed	11
Number of paediatric applications reviewed	3
Number of device applications reviewed	1
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	4	20.00
Favourable Opinion with Additional Conditions	0	0.00
No Opinion transfer to full committee for review	2	10.00
Provisional Opinion	12	60.00
Unfavourable Opinion	2	10.00
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	4.67
Number of completed applications for full ethical review	42
Number of completed applications for full ethical review over 60 days	1
Number of completed applications over 60 days as a % of total	2.38%
Number of completed applications for full ethical review over 40 days	24
Number of completed applications over 40 days as a % of total	57.14%
Number of days taken to final decision – average (mean)	44
Number of completed proportionate review applications for ethical review	18
Number of completed proportionate review applications for ethical review over 21 days	7
Number of completed proportionate review applications over 21 days as a % of total	38.89%
Number of SSAs (non-Phase 1) reviewed	17
Number of completed applications for SSA review over 25 days	3
Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs	17.65%
Number of SSAs (Phase 1) reviewed	4
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	103
Number of completed substantial amendments over 35 days	5
Number of completed substantial amendments over 35 days as a % of total substantial amendments	4.85%
Number of completed substantial amendments over 28 days	34
Number of completed substantial amendments over 28 days as a % of total substantial amendments	33.01%
Number of modified amendments reviewed	3
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	117
Number of substantial amendments received for information	1
Number of substantial amendments received for new sites/PIs	10
Number of annual progress reports received	42
Number of safety reports received	40
Number of Serious Adverse Events received	0

Number of final reports received	0
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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/LO/0536	Inhaled CCI15106 - in healthy volunteers and COPD patients; version 1	48
17/LO/0715	PC786 – first doses in humans; version 1	27
17/LO/0783	LUMINITYÅ@422	54
17/LO/0795	MUKFourteen	57
17/LO/0887	Beacon Care system in general medical ICU v1.1	24
17/LO/1048	SNS feasibility study SSNSH1601	45
17/LO/1245	Metronidazole Versus lactic acid for Treating bacterial vAginosis–VITA	43
17/LO/1335	Oral fluid intake for people with dementia in hospital	53
17/LO/1424	THE LONDON COPD RSV study	30
17/LO/1452	Emodepside – repeat doses in humans; version 1	32
17/LO/1459	Absorption & elimination of radiolabelled GSK2269557; version 1	26
17/LO/1563	Crohn's Anal Fistula Quality of Life Scale (CAF-QoL)	36
17/LO/1636	Microbial immunity in inflammatory bowel disease and colorectal cancer	55
17/LO/1722	Sexually transmissible enteric infections in MSM v1.0	47
17/LO/1723	BOWEL SCOPE SCREENING: INTERVENTIONS TO INCREASE UPTAKE IN YORKSHIRE	45
17/LO/1731	Technologically-enabled epilepsy care V1	48
17/LO/1920	Phase 3 Open-label with BIVV009 in Subjects with CAgD	54
17/LO/1921	Phase 3 with BIVV009/Placebo in Subjects with CAgD	54
17/LO/1943	Phase III study of inclisiran sodium in subjects with HeFH	51
17/LO/1945	Understanding the inner world of children who stutter (Version 1.0)	52
17/LO/2114	Study to evaluate the management of patients with β^2 -thalassaemia	59
18/LO/0008	Prognostic value of pupillometry in patients with ROSC after OHCA	39
18/LO/0024	A study of JNJ-42847922 in people with major depressive disorder; v1	42
18/LO/0028	The Popular Age Registry	60
18/LO/0044	Safety and blood levels of CSL730 in Japanese volunteers; v1	40
18/LO/0054	Minimally invasive sensing of beta-lactam antibiotics	52
18/LO/0368	NICO	49

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
17/LO/0987	VIPP-FC	51

17/LO/1316	Keeping Active in Residential Elderly (KARE)	43
17/LO/1334	TOXYC: Targeted OXYgen therapy in Critical illness	36
17/LO/1725	Pacemaker therapy for drug-refractory symptoms in mid-cavity HCM	38
18/LO/0209	MUST-IPF	70
18/LO/0332	TAS0728 in Solid Tumours with HER2 or HER3 Abnormalities	35
18/LO/0395	De-roofing and curettage vs WLE for pilonidal abscess	58
18/LO/0423	Family members' experiences of post-stroke dysphagia - version 1	41

Further Information Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
17/LO/1401	COMPASS	29

Favourable Opinion with Standard Conditions

REC Reference	Title	Number of Days on Clock
17/LO/0890	Serosurveillance study of maternally derived anti-GBS antibody	24

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
17/LO/1320	Phase 2 study of ACE-536 in MPN-associated myelofibrosis & anaemia	28
17/LO/1940	PRISIM	28

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
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Provisional Opinion

REC Reference	Title	Number of Days on Clock
17/LO/1957	Gender identity development in gender variant adolescents with ASC	n/a

Provisional Opinion Pending Consultation with Referee

REC Reference	Title	Number of Days on Clock
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Further information response not complete		
REC Reference	Title	Number of Days on Clock
17/LO/0774	Assessment of CellSieve in Sepsis to Quantify Hemophagocytosis	n/a
18/LO/0120	Exploring delayed hospital discharge	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
17/LO/1565	Adult asthma patient perspectives on pharmacist involvement in care	22
17/LO/1999	Comparing visual acuity results between two tests used in children	31
17/LO/2000	Correlation between shoe size, height and femoral head diameter	31
17/LO/2013	Parent experience of CROS hearing aid for child with UHL	20
17/LO/2122	COMPOSEd - Barriers to Effective Co-morbidity Management Post-Stroke	30
18/LO/0154	Stress and the Attentional Network	21
18/LO/0162	Comparative performance & acceptance of 2 Multifocal CLs	20
18/LO/0491	The CogENT study version 1.0	26

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
17/LO/1439	Improving Uptake of Cascade Genetic Testing in HCM	21
17/LO/1829	2-View	12
17/LO/1831	ATEMPT Project:Defining adherence to exercise for musculoskeletal pain	20
18/LO/0312	The Possible Selves of Individuals with an Acquired Brain Injury	21

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/LO/0740	SCALING	4
17/LO/0748	LABPv001	23
17/LO/0751	Refinement of electrophoresis protocols to improve diagnosis.	24
18/LO/0501	Advanced MRI in surgery for posterior fossa tumours	14

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
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Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
18/LO/0304	How Are You Today	18
18/LO/0495	Feasibility study on healthy volunteers on Gaming Effects	17

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
05/Q0505/113/AM07	Molecular Genetic Analysis of Human Prion Disease	5	27/11/2017	37
05/Q0505/34/AM16	Tumour angiogenesis in non-small cell lung cancer	AM16	19/04/2017	35
06/Q0505/22/AM18	CT/PET in patients with interstitial lung disease	13	16/06/2017	31
09/H0709/56/AM23	PEXIVAS (Version 1)	16	07/08/2017	34
10/H0709/90/AM07	An investigation of the role of GABA A α 5 subunit in ASD	4	25/08/2017	13
11/LO/0330/AM10	Investigation of rheumatic disease in teenagers and adults : v1.1	3 (AM10)	01/05/2017	35
11/LO/0330/AM11	Investigation of rheumatic disease in teenagers and adults : v1.1	4	04/10/2017	34
12/LO/0167/AM02	Monocyte and macrophage phenotype and function in liver failure	Substantial Amendment 2, 20.02	20/02/2018	25
12/LO/0758/AM12	Fostamatinib in Patients with Diffuse Large B-Cell Lymphoma	7	24/10/2017	11
12/LO/0886/AM07	A study of Entonox versus midazolam in upper GI endoscopy	3	02/06/2017	5
12/LO/0886/AM08	A study of Entonox versus midazolam in upper GI endoscopy	3	18/07/2017	48
12/LO/1257/AM21	Oral UT-15C for treatment of Pulmonary Arterial Hypertension (PAH)	SA#14	16/11/2017	28
12/LO/1771/AM15	Study of Dexamethasone in Patients with AL Amyloidosis	10	04/12/2017	16
13/LO/0455/AM04	Pilot Study: Retinal Embolisation in TAVI	4 15/12/2017	22/12/2017	15
13/LO/0653/AM02	The SCI-POEM Study (v1.0)	2	19/04/2017	35
13/LO/1020/AM11	309: XL184 vs placebo in subjects with hepatocellular carcinoma	13	26/10/2017	7
13/LO/1020/AM12	309: XL184 vs placebo in subjects with hepatocellular carcinoma	Substantial amendment 09	16/02/2018	25
13/LO/1264/AM15	Olaparib maintenance monotherapy in PSR ovarian cancer	IB version 14	10/03/2017	24
13/LO/1420/AM05	Sexual and Reproductive Health in psychiatric patients	SA9	09/02/2018	30
13/LO/1670/AM06	Autologous Stem Cells in Achilles Tendinopathy	6.0 (AM06)	28/06/2017	7
13/LO/1758/AM28	A Safety and Efficacy Study of MK8931 for Prodromal AD v.019-00	18	08/06/2017	5
13/LO/1758/AM32	A Safety and Efficacy Study of MK8931 for Prodromal AD	19	19/10/2017	8

	v.019-00			
14/LO/0882/AM21	GO28915 - MPDL3280A or Docetaxel in Patients with NSCLC	10	25/05/2017	20
14/LO/0882/AM23	GO28915 - MPDL3280A or Docetaxel in Patients with NSCLC	11	26/07/2017	14
14/LO/0882/AM24	GO28915 - MPDL3280A or Docetaxel in Patients with NSCLC	12	27/11/2017	29
14/LO/0882/AM26	GO28915 - MPDL3280A or Docetaxel in Patients with NSCLC	Amendment No: 14 (substantial)	02/02/2018	24
14/LO/1378/AM14	MEASURES	13	25/10/2017	34
14/LO/1544/AM02	Contacting GPs to reduce unnecessary prescriptions of antibiotics	Amendment 2	08/02/2018	11
14/LO/1604/AM12	Open-Label Extension Study in Rheumatoid Arthritis.	6	19/10/2017	32
14/LO/1604/AM13	Open-Label Extension Study in Rheumatoid Arthritis.	7	22/01/2018	29
14/LO/2004/AM12	Methylnaltrexone for the Treatment of Opioid Induced Constipation	5	10/01/2018	27
15/LO/0217/AM02	ERIC-PPCI	2	26/10/2017	6
15/LO/0217/AM04	ERIC-PPCI	Amendment 3, 10th January 2018	10/01/2018	3
15/LO/0236/AM12	A Phase II Trial of MK-3475 in Subjects with Bladder Cancer	11	21/09/2017	32
15/LO/0236/AM13	A Phase II Trial of MK-3475 in Subjects with Bladder Cancer	SA12	17/11/2017	17
15/LO/0236/AM14	A Phase II Trial of MK-3475 in Subjects with Bladder Cancer	SA13 - Protocol 03 & PIS/CF	21/02/2018	16
15/LO/0413/AM07	Safety and Efficacy of Brimonidine-DDS in patients with GA-AMD	7	31/07/2017	9
15/LO/1244/AM08	IVA337 SSc POC	4(AM08)	24/03/2017	34
15/LO/1244/AM09	IVA337 SSc POC	SA06	28/12/2017	35
15/LO/1263/AM03	A drug utilisation study in patients treated with EXELONÂ® patch	SA2 (AM03)	20/04/2017	27
15/LO/1402/AM05	HOPE - HF	3	25/04/2017	29
15/LO/1402/AM14	HOPE - HF	Amendment No 4, 08.02.18	08/02/2018	20
15/LO/2047/AM07	Medivation - D5170C00002	AM07	01/06/2017	13
15/LO/2069/AM02	The PReSUTINeB Study (v1.0).	3	13/10/2017	28
15/LO/2069/AM03	The PReSUTINeB Study (v1.0).	4	21/12/2017	41
15/LO/2069/AM05	The PReSUTINeB Study (v1.0).	Substantial Amendment 05, 12 M	12/03/2018	20
16/LO/0004/AM02	iTACTIC v1.0	3	14/03/2017	18

16/LO/0370/AM01	Quadriceps muscle size and composition in intensive care patients	1	25/05/2017	19
16/LO/0513/AM04	VIOLET	AM04	12/12/2017	35
16/LO/0835/AM02	Research Priorities for Spinal Cord Injury in Children	1	15/01/2018	30
16/LO/0857/AM01	LISTER	AM01	16/03/2017	21
16/LO/1059/AM01	Establishing the incidence of Tako-tsubo cardiomyopathy in Scotland	1	03/05/2017	26
16/LO/1059/AM03	Establishing the incidence of Tako-tsubo cardiomyopathy in Scotland	2	23/08/2017	23
16/LO/1122/AM01	Effects of hrAnx-A1 in healthy men, v1	1	01/08/2017	8
16/LO/1386/AM03	Phase 2 with Elamipretide in subjects hospitalised with heart failure	2	10/07/2017	4
16/LO/1386/AM05	Phase 2 with Elamipretide in subjects hospitalised with heart failure	3	07/09/2017	11
16/LO/1539/AM01	Class-II invariant chain HCV vaccine study	1	10/08/2017	25
16/LO/1700/AM01	A phase II clinical trial of DARC	SA for protocol V4.0 (AM01)	20/03/2017	49
16/LO/1700/AM03	A phase II clinical trial of DARC	3	19/05/2017	32
16/LO/1820/AM06	Effects of intranasal naloxone on eating behaviours in bulimia nervosa	2	03/05/2017	23
16/LO/1820/AM08	Effects of intranasal naloxone on eating behaviours in bulimia nervosa	3	17/08/2017	22
16/LO/1820/AM11	Effects of intranasal naloxone on eating behaviours in bulimia nervosa	6	23/10/2017	13
16/LO/1820/AM12	Effects of intranasal naloxone on eating behaviours in bulimia nervosa	7	29/11/2017	28
16/LO/1820/AM13	Effects of intranasal naloxone on eating behaviours in bulimia nervosa	Substantial Amendment 8.0	22/01/2018	15
16/LO/1822/AM07	Vericiguat-Subjects With Heart Failure With Reduced Ejection Fraction	3	15/05/2017	58
16/LO/1822/AM08	Vericiguat-Subjects With Heart Failure With Reduced Ejection Fraction	4	14/06/2017	27
16/LO/1822/AM09	Vericiguat-Subjects With Heart Failure With Reduced Ejection Fraction	5	06/09/2017	7
16/LO/1822/AM11	Vericiguat-Subjects With Heart Failure With Reduced Ejection Fraction	6	18/12/2017	21

16/LO/1822/AM13	Vericiguat-Subjects With Heart Failure With Reduced Ejection Fraction	SA07	22/01/2018	25
16/LO/2135/AM01	DACC in the Prevention of Surgical Site Infection (DRESSINg)	1	25/08/2017	32
16/LO/2226/AM01	Positive risk taking and borderline personality disorder experiences	1	26/07/2017	35
16/LO/2249/AM01	Visual Impairment and Falls in the Elderly Version 1.0	AM01	12/04/2017	34
16/LO/2249/AM02	Visual Impairment and Falls in the Elderly Version 1.0	1.1	30/10/2017	28
17/LO/0030/AM03	CST in people with Intellectual disability and dementia	1	17/01/2018	31
17/LO/0038/AM01	UK P3BEP Trial	SA1 (AM01)	23/06/2017	24
17/LO/0038/AM03	UK P3BEP Trial	3	18/10/2017	11
17/LO/0070/AM01	CONSERVE: Coversin Long Term Study	1	24/05/2017	26
17/LO/0070/AM03	CONSERVE: Coversin Long Term Study	2	17/10/2017	12
17/LO/0160/AM01	A study to describe recovery of older people after cardiac surgery.	1	20/10/2017	31
17/LO/0212/AM02	Long term treatment with inclisiran and a comparison to evolocumab	01	11/05/2017	25
17/LO/0212/AM07	Long term treatment with inclisiran and a comparison to evolocumab	MDCO-PCS-16-01 Global Protocol	16/03/2018	24
17/LO/0225/AM01	Women's Experience of Post-placental Intrauterine Contraception	1	17/08/2017	32
17/LO/0225/AM02	Women's Experience of Post-placental Intrauterine Contraception	No.02 - 29/01/2018	29/01/2018	8
17/LO/0243/AM01	Dose response study of GSK2330672 for pruritus in PBC patients 201000	Substantial Amendment #01 (AM0	20/07/2017	4
17/LO/0243/AM04	Dose response study of GSK2330672 for pruritus in PBC patients 201000	02	11/01/2018	13
17/LO/0285/AM01	G1T38-02_Phase 1/2 Safety & PK Study of G1T38_Breast Cancer_3652/0002	AM01	12/04/2017	35
17/LO/0285/AM02	G1T38-02_Phase 1/2 Safety & PK Study of G1T38_Breast Cancer_3652/0002	Substantial Amendment 03 (AM02	28/06/2017	26
17/LO/0285/AM05	G1T38-02_Phase 1/2 Safety & PK Study of G1T38_Breast Cancer_3652/0002	5	21/09/2017	18
17/LO/0285/AM06	G1T38-02_Phase 1/2 Safety & PK Study of G1T38_Breast Cancer_3652/0002	Substantial Amendment 06	05/03/2018	17

17/LO/0434/AM01	Mechanisms of Movement, Balance and Orientation in Health & Disease	1	05/09/2017	12
17/LO/0438/AM05	Esperion 1002-043 (Bempedoic Acid (ETC-1002)	3	20/10/2017	24
17/LO/0536/AM01	Inhaled CCI15106 - in healthy volunteers and COPD patients; version 1	1	06/11/2017	31
17/LO/0748/AM03	LABPv001	1	21/12/2017	15
17/LO/0783/AM01	LUMINITYÂ®422	1	06/11/2017	31
17/LO/0887/AM01	Beacon Care system in general medical ICU v1.1	Substantial Amendment 1 16.01.	19/02/2018	28
17/LO/0987/AM02	VIPP-FC	1	12/01/2018	18
17/LO/1334/AM01	TOXYC: Targeted OXYgen therapy in Critical illness	001, 08 January 2018	08/01/2018	23
17/LO/1452/AM01	Emodepside – repeat doses in humans; version 1	2	21/12/2017	11

Unfavourable opinion				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
06/Q0505/12/AM03	Investigating the molecular pathogenesis of lung disease	1	21/12/2017	33
15/LO/0236/AM10	A Phase II Trial of MK-3475 in Subjects with Bladder Cancer	SA08 (AM10)	16/03/2017	28
15/LO/0799/AM04	Monitoring Air Pollution Exposure in Children	04	05/05/2017	28
15/LO/0801/AM03	Metabolic and metagenomic profiling in the characterisation of IBD	2	15/12/2017	22
17/LO/1723/AM02	BOWEL SCOPE SCREENING: INTERVENTIONS TO INCREASE UPTAKE IN YORKSHIRE	AM02	12/02/2018	33

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
06/Q0505/12/AM03/	Investigating the molecular pathogenesis of lung disease	Sub Am Number 2, 09.02.18	21/02/2018	14

1				
15/LO/0236/AM10/1	A Phase II Trial of MK-3475 in Subjects with Bladder Cancer		26/04/2017	14

Unfavourable opinion timeline				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
15/LO/0799/AM04/1	Monitoring Air Pollution Exposure in Children	4	07/06/2017	1

Table 11: Items exceeding timelines**Full applications for ethical review over 60 day timeline**

REC Reference	Title	Number of Days on Clock
18/LO/0209	MUST-IPF	70

Proportionate review applications for ethical review over 21 day timeline

REC Reference	Title	Number of Days on Clock
17/LO/0748	LABPv001	23
17/LO/0751	Refinement of electrophoresis protocols to improve diagnosis.	24
17/LO/1565	Adult asthma patient perspectives on pharmacist involvement in care	22
17/LO/1999	Comparing visual acuity results between two tests used in children	31
17/LO/2000	Correlation between shoe size, height and femoral head diameter	31
17/LO/2122	COMPOSEd - Barriers to Effective Co-morbidity Management Post-Stroke	30
18/LO/0491	The CogENT study version 1.0	26

SSAs (non Phase 1) over 25 day timeline

REC Reference	Title	Number of Days on Clock
17/LO/0712	Phase 1/2 Safety, Pharmacokine	28
17/LO/1974	Randomised, double-blind, plac	27
18/LO/0516	Randomised, double-blind, plac	44

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
05/Q0505/113/AM07	Molecular Genetic Analysis of Human Prion Disease	5	27/11/2017	37
12/LO/0886/AM08	A study of Entonox versus midazolam in upper GI endoscopy	3	18/07/2017	48
15/LO/2069/AM03	The PReSUTINeB Study (v1.0).	4	21/12/2017	41

16/LO/1700/AM01	A phase II clinical trial of DARC	SA for protocol V4.0 (AM01)	20/03/2017	49
16/LO/1822/AM07	Vericiguat-Subjects With Heart Failure With Reduced Ejection Fraction	3	15/05/2017	58

Modified Amendments over 14 day timeline				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock