

London - Chelsea Research Ethics Committee

Annual Report

01 April 2016 - 31 March 2017



Part 1 – Committee Membership and Training

Name of REC:	London - Chelsea 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 in patients and healthy volunteers
Chair:	Dr Shelley Dolan (until 12/09/2016) Dr Michael Schachter (13/09/2016 – present)
Vice-Chair:	Mrs Patricia Pank
Alternate Vice-Chair:	Dr Michael Schachter (until 13/09/2016) Vacant (13/09/2016 – present)
REC Manager:	Miss Aliko Sifostratoudaki (01/01/2015 – 31/12/2016) Vacant (01/01/2017 - 23/02/2017) Mrs Sarah Graves (24/02/2017 – present)
REC Assistant:	Mr Alex Martin (01/06/2016 – present)
Committee Address:	Research Ethics Committee (REC) Bristol Centre Level 3, Block B Whitefriars Lewins Mead Bristol BS1 2NT
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Chair's overview of the past year:

This has been a year of very extensive and often unexpected change. I have replaced Shelley Dolan as Chair after her move to King's as Head of Nursing. Another colleague retired, one left the Committee and very sadly our oldest member, Jeremy Butler, died after a long illness. We are recruiting one or two new members to ensure that our total number remains 15 and with the correct distribution. We have also had transitions among our managers, from Alik Sifostratoudaki to Alex Martin (as a stand-in REC Manager) and then to Sarah Graves. However, despite all this change the Committee has functioned well with a monthly review of usually of 6 projects, with an emphasis on CTIMPs but also including many other types of quantitative and qualitative research. We have had to co-opt outside colleagues to be quorate for a small amount of meetings and have been able to issue opinions in a timely fashion. Communications within the Committee and with Bristol have been very good, almost without exception, and we look forward to a busy and successful year.

Dr Michael Schachter.

London - Chelsea Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Mr Roger A'Hern	Medical Statistician	Expert	01/06/2010	
Dr Judy Allfrey	Retired Civil Servant	Lay	01/06/2013	
Dr. Sonya Babu-Narayan	Clinical Senior Lecturer and Consultant Cardiologist	Expert	01/06/2010	
Mr Jeremy Butler	Former NHS Non-Executive Director	Lay	01/06/2010	25/03/2017
Dr Shelley Dolan	Chief Nurse	Expert	01/06/2010	12/09/2016
Dr Adam Jacobs	Senior Principal Statistician	Expert	01/06/2010	12/09/2016
Ms Karen Lipworth	Lead Medical Writer	Lay	01/04/2015	
Mr Serge Miodragovic	Ophthalmology Clinical Research Coordinator	Lay	22/05/2013	
Mrs Patricia Pank	Retired University Lecturer	Lay	01/06/2010	
Mrs Paula Rogers	Cardiology Research Nurse	Expert	01/06/2010	
Ms Cate Savidge	CT Scanning Superintendent	Expert	01/06/2010	
Dr Michael Schachter	Clinical Pharmacologist	Expert	01/12/2010	
Dr Elliot Shinebourne	Consultant Paediatric Cardiologist	Expert	01/06/2010	10/10/2016
Dr Mary Taj	Consultant Paediatric Oncologist	Expert	01/06/2010	
Miss Isobel Vass	Magistrate	Lay	19/06/2013	
Ms Mary Watkinson	Teacher	Lay Plus	09/10/2015	
Mr Fraser Wilson	Retired Civil Servant	Lay Plus	05/01/2015	

London - Chelsea Research Ethics Committee: Deputy Members

Name	Profession	Status	Meeting date attended
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London - Chelsea Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended
Mrs Ravina Barrett	Pharmacist	Expert	13/06/2016
Ms Stephanie Ellis	Civil Servant (Retired)	Lay Plus	09/01/2017 13/02/2017 10/04/2017
Ms Fanny Mitchell	Retired NHS Manager	Lay Plus	12/12/2016

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

Name	Declaration of Interest	Date
Mr Roger A'Hern	Retired as ICRCBU Senior Statistician 30/09/2013 but still active in field part time.	12/12/2016
Dr Judy Allfrey	Lay member on Kings College London Research Ethics Sub-Committee.	12/12/2016
Dr. Sonya Babu-Narayan	British Heart Foundation funded awardee Peer reviewer for grant applications (Wellcome Trust, MRC, BHF and Academy Medical sciences)	12/12/2016
Mr Jeremy Butler	Member of Hospital Managers' Panels - reviewing patients detained under the Mental Health Act 1983 (as amended). Lay Member of Health Quality Improvement Partnership Steering Group for the National Confidentiality Inquiry into Suicides and Homicides (NCISH). Governor of the Royal Berkshire NHS Foundation Trust.	11/07/2016
Mrs Christine Gratus	Reviewer for NIHR, ad-hoc member of award panels as requested and selection of chairs for NIHR funding panels.	31/03/2017
Ms Karen Lipworth	Self- employed healthcare communications consultant and medical writer. Clients include pharma and CROs and from time to time does provide advice and writing support for clinical studies.	31/03/2017
Mr Serge Miodragovic	NED at Central & Cecil Housing Trust as well as Clinical Trials Manager Ophthalmology Imperial College NHS Trust.	31/03/2017
Mrs Patricia Pank	Trustee: Helen Bamber Foundation. University College Foundation Trust, clinical governance emergency services division	31/03/2017
Mrs Paula Rogers	Associate member for Foundation and Nursing studies. Received funding from the British Heart Foundation. Works full time in roles such as assessing feasibility of new research studies, ethical research delivery. Regular contact with local R&D office, completion of REC applications and Site Specific Assessments. Involved with Local Clinical Research Network - Workforce Development Group. Change of role: From Senior Research Nurse to Research Nurse Manager - (MSc Qualification)	31/03/2017
Ms Cate Savidge	None	11/07/2016
Dr Michael Schachter	None	31/03/2017
Dr Mary Taj	Mentor/ member of My Child Matter- charity run by Sanofi Aventis	31/03/2017
Miss Isobel Vass	None	31/03/2017
Ms Mary Watkinson	None	12/12/2016
Mr Fraser Wilson	Member of the Imperial College Research Ethics Committee. It does not consider proposals for medical research within the NHS.	31/03/2017

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

Month	Date	Number of Members Present at Meeting
April	11/04/2016	15
May	09/05/2016	14
June	13/06/2016	14
July	11/07/2016	13
September	12/09/2016	13
October	10/10/2016	7
December	12/12/2016	13
January	09/01/2017	8
February	13/02/2017	10

9 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	26/04/2016	3
May	24/05/2016	3
June	21/06/2016	3
July	19/07/2016	3
September	20/09/2016	3
October	25/10/2016	3
November	22/11/2016	3
December	19/12/2016	3
February	24/02/2017	3
March	27/03/2017	3

10 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	01/04/2016	2
April	08/04/2016	2
April	15/04/2016	2
April	22/04/2016	2
April	29/04/2016	2
May	06/05/2016	2
May	13/05/2016	2
May	20/05/2016	2
May	27/05/2016	2
June	03/06/2016	2
June	10/06/2016	2
June	17/06/2016	2

June	24/06/2016	2
July	01/07/2016	2
July	08/07/2016	2
July	15/07/2016	2
July	22/07/2016	2
July	29/07/2016	2
August	05/08/2016	2
August	12/08/2016	2
August	19/08/2016	2
August	26/08/2016	2
September	02/09/2016	2
September	16/09/2016	2
September	23/09/2016	2
September	30/09/2016	2
October	07/10/2016	2
October	14/10/2016	2
October	20/10/2016	2
October	21/10/2016	2
October	28/10/2016	2
October	28/10/2016	2
November	04/11/2016	2
November	11/11/2016	2
November	18/11/2016	2
November	25/11/2016	2
December	02/12/2016	2
December	09/12/2016	2
December	16/12/2016	2
December	23/12/2016	2
December	30/12/2016	2
January	13/01/2017	2
January	18/01/2017	2
January	19/01/2017	2
January	27/01/2017	2
February	10/02/2017	2
February	24/02/2017	2
February	26/02/2017	2
March	03/03/2017	2
March	09/03/2017	3
March	10/03/2017	2
March	13/03/2017	3
March	17/03/2017	2
March	24/03/2017	2
March	31/03/2017	2

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

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

None

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

Name	Number of Meetings Attended
Mr Roger A'Hern	6
Dr Judy Allfrey	7
Dr. Sonya Babu-Narayan	7
Mr Jeremy Butler	5
Dr Shelley Dolan	4
Dr Adam Jacobs	3
Ms Karen Lipworth	6
Mr Serge Miodragovic	8
Mrs Patricia Pank	8
Mrs Paula Rogers	6
Ms Cate Savidge	9
Dr Michael Schachter	6
Dr Elliot Shinebourne	5
Dr Mary Taj	6
Miss Isobel Vass	7
Ms Mary Watkinson	7
Mr Fraser Wilson	4

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

Name	Number of Meetings Attended
Mr Roger A'Hern	4
Dr Judy Allfrey	2
Dr. Sonya Babu-Narayan	1
Ms Alison Higgs	1
Dr Adam Jacobs	1
Ms Karen Lipworth	2
Mr Serge Miodragovic	1
Mrs Paula Rogers	3
Ms Cate Savidge	2
Dr Michael Schachter	9
Dr Mary Taj	1
Miss Isobel Vass	1
Ms Mary Watkinson	1
Mr Robert Wosley	1

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

Name	Number of Meetings Attended
Mr Roger A'Hern	7
Dr Judy Alfrey	2
Dr Adam Jacobs	1
Ms Karen Lipworth	6
Mr Serge Miodragovic	9
Mrs Patricia Pank	50
Mrs Paula Rogers	8
Ms Cate Savidge	6
Dr Michael Schachter	7
Dr Elliot Shinebourne	4
Dr Mary Taj	1
Miss Isobel Vass	5
Ms Mary Watkinson	6

Training 01 April 2016 - 31 March 2017

Name of Member	Date	Event(s) attended
Mr Roger A'Hern	14/11/2016	Local Training Day - London - Chelsea
Dr Judy Allfrey	06/04/2016	Training - Handling Health-Related Findings in Research (Joint MRC/HRA)
Dr Judy Allfrey	14/11/2016	Local Training Day - London - Chelsea
Dr. Sonya Babu-Narayan	14/11/2016	Local Training Day - London - Chelsea
Mr Jeremy Butler	10/09/2016	Equality and Diversity online module
Mr Jeremy Butler	14/11/2016	Local Training Day - London - Chelsea
Ms Karen Lipworth	14/11/2016	Local Training Day - London - Chelsea
Mrs Patricia Pank	14/11/2016	Local Training Day - London - Chelsea
Mrs Patricia Pank	18/11/2016	Local training day - Camberwell
Mrs Patricia Pank	16/02/2017	Training - National Members Training Day
Ms Cate Savidge	14/11/2016	Local Training Day - London - Chelsea
Dr Michael Schachter	14/11/2016	Local Training Day - London - Chelsea
Dr Mary Taj	14/11/2016	Local Training Day - London - Chelsea
Miss Isobel Vass	14/11/2016	Local Training Day - London - Chelsea
Ms Mary Watkinson	05/09/2016	Local Training Day - London - Riverside

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	23	46.00
Phase 1	2	4.00
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	2	4.00
Others	23	46.00
Total Applications Reviewed	50	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	0
Number of student applications reviewed	8
Number of paediatric applications reviewed	2
Number of device applications reviewed	5
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	0
Number of applications reviewed that are funded by the US DHHS	0
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	2	4.00
Favourable Opinion with Additional Conditions	15	30.00
Unfavourable Opinion	0	0.00
Provisional Opinion	33	66.00
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	50	100
Number of studies sent back to full committee meeting for final opinion	0	

Table 4: Summary of current status of applications reviewed during the reporting period

Status of applications at date of generation of report	Number	%
Further Information Favourable Opinion with Standard Conditions	28	56.00
Further Information Favourable Opinion with Additional Conditions	4	8.00
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	2	4.00
Favourable Opinion with Additional Conditions	15	30.00
Unfavourable Opinion	0	0.00
Provisional Opinion	1	2.00
Provisional Opinion Pending Consultation with Referee	0	0.00
Further Information response not complete	0	0.00
No decision entered on system	0	0.00
Number of studies withdrawn after the meeting	0	0.00
Total	50	100

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

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

Number of applications made invalid by the REC Manager	4
Number of studies withdrawn prior to the meeting	2
Number of student applications reviewed	9
Number of paediatric applications reviewed	4
Number of device applications reviewed	0
Number of qualitative applications reviewed	3

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

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

Average number of applications reviewed per full meeting	5.56
Number of completed applications for full ethical review	50
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	9
Number of completed applications over 40 days as a % of total	18.00%
Number of days taken to final decision – average (mean)	33
Number of completed proportionate review applications for ethical review	17
Number of completed proportionate review applications for ethical review over 14 days (Please note, the timeline for the review of PR applications was extended from 14 to 21 calendar days in December 2016)	6
Number of completed proportionate review applications for ethical review over 21 days	3
Number of completed proportionate review applications over 14 days as a % of total	35.29%
Number of SSAs (non-Phase 1) reviewed	4
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	162
Number of completed substantial amendments over 35 days	3
Number of completed substantial amendments over 35 days as a % of total substantial amendments	1.85%
Number of completed substantial amendments over 28 days	20
Number of completed substantial amendments over 28 days as a % of total substantial amendments	12.35%
Number of modified amendments reviewed	1
Number of completed modified amendments over 14 days	0
Number of completed modified amendments over 14 days as a % of total modified amendments	0.00%
Number of non substantial amendments received	119

Number of substantial amendments received for information	2
Number of substantial amendments received for new sites/PIs	32
Number of annual progress reports received	27
Number of safety reports received	5
Number of Serious Adverse Events received	0
Number of final reports received	0

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/0586	Multiple Sclerosis Study Using Ocrelizumab	40
16/LO/0595	monarchER: Phase 2, 3-Arm, Study in Women with Advanced Breast Cancer	40
16/LO/0673	Pilot trial of targeted sexual risk reduction intervention package	42
16/LO/0779	QGE031 long term safety study in CSU patients E1	41
16/LO/0784	I2PETPG – Imidazoline2 Binding Site in patient group	29
16/LO/0788	Exercise training in patients awaiting complex aortic surgery	26
16/LO/0798	Optical Biopsy Retargeting and Recognition for GI Endoscopy	30
16/LO/0886	101SK202 Acute Ischemic Stroke	35
16/LO/0994	A Phase 1 study evaluating the safety of DTX-SPL8783 in patients with	33
16/LO/0998	Diagnostic accuracy of POC enzymatic test for NG tube placement.	32
16/LO/1031	Alcobase	31
16/LO/1424	Clearing Lungs With ENaC Inhibition in Primary Ciliary Dyskinesia	28
16/LO/1686	BARCODE 2	35
16/LO/1785	MRI Pouchography	23
16/LO/1791	Prognosis communication in COPD	39
16/LO/2129	Study to Investigate Efficacy, Safety and Pharmacokinetics of BT595	44
16/LO/2137	A Phase 1 Study of Durvalumab & IPH2201 in Adults with advance tumours	29
16/LO/2148	Intraprostatic PRX302 injection to treat localised prostate cancer /2b	38
16/LO/2150	OCTOVA	39
16/LO/2157	An efficacy,safety and tolerability study of Fosmetpantotenate in PKAN	27
17/LO/0017	Open-label Extension Study for Participants with Prostate Cancer	47
17/LO/0047	Enhanced, Personalized, and Integrated Care for Infection Management	46
17/LO/0049	Research using the National Chronic Kidney Disease Audit data	50
17/LO/0050	Feasibility study to support medication adherence following ACS	42
17/LO/0064	Study of Mirvetuximab Soravtansine vs standard cancer treatments	44
17/LO/0145	A Study of CA-170 in participants with Advanced Tumours and Lymphomas	40
17/LO/0270	GP/patient conversation	41
17/LO/0272	Extension Study of UTX-TGR-304	32

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

16/LO/1083	QuANTUM-First	35
16/LO/1560	Is arterial stiffness a consequence of respiratory failure?	28
16/LO/1735	The Mini Linguistic State Examination (MLSE)	38
16/LO/1782	Phase Ib/II Trial of Pembrolizumab (MK-3475) in Combination Therapies	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
16/LO/1753	Education delivery for the low FODMAP diet	21
17/LO/0273	The Nuclear Community Charity Fund Chromosomal study	25

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/LO/0575	Fatigue intervention co-design study	29
16/LO/0585	NeoART version 1.0	29
16/LO/0682	The Reproductive Life Course Project V1.0	22
16/LO/0717	Clinical trial of chlamydia vaccine CTH522 in healthy women; v1	24
16/LO/0995	Improving Outcome Measures For Adult CF ACT Trials	28
16/LO/1133	MK-3475 in the Treatment of Recurrent/Metastatic Head and Neck Cancer	28
16/LO/1169	Determining the effects of gut content on satiety	28
16/LO/1209	Peer Support for Late Presenters	28
16/LO/1272	Intello2 vs Manual Control for Optimizing Oxygenation in Infants	28
16/LO/1514	Phase III Study of MK-3475 + Best Supportive Care in Subjects with HCC	25
16/LO/1566	KORTUC	25
16/LO/2155	The Value of Health-Justice Partnerships	24
17/LO/0005	The PAPAYA Study	28
17/LO/0011	VEROnA	28
17/LO/0277	PTNS for the treatment of Premature Ejaculation- A Feasibility Study	32

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
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Provisional Opinion

REC Reference	Title	Number of Days on Clock
16/LO/1553	Comparison of water-perfused and air-charged urodynamic catheters	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
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Withdrawn after the meeting

REC Reference	Title	Number of Days on Clock
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Table 9.2: Breakdown of current status of all PRS applications reviewed within the reporting period

Further Information Favourable Opinion with Standard Conditions

REC Reference	Title	Number of Days on Clock
16/LO/0808	Diffusion Tensor Imaging of Levator ani injury	14
16/LO/1191	Designing HEAL-D	18
16/LO/1751	Medication Compliance in young people with ADHD; could the Qb help?	25
16/LO/1783	Oximetry in children with severe obstructive sleep apnoea	26
16/LO/1982	BVAC	10
16/LO/2125	The evaluation of pre, intra, and post-operative coagulation	8
16/LO/2128	PANORAMA V1.0 15Aug2016	10
16/LO/2130	Role of non-canonical NF kappa B in T cell independent IgA production	21
17/LO/0384	Dysphagia, Freezing and balance in Parkinson's patients	28

Further Information Favourable Opinion with Additional Conditions

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

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

REC Reference	Title	Number of Days on Clock
16/LO/0997	Characterisation of human intracellular immunity to viral infection	9
16/LO/1000	Design Practice in Health: PhD	9
16/LO/1194	SNOFLAC-MS	8
16/LO/2242	Hear and Treat Safety, Appropriateness and Acceptability	8
16/LO/2261	Platelet-rich plasma and fat graft for diabetic ulcer	6

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/LO/1358	Duration of viral shedding in children with cystic fibrosis	15
16/LO/1363	Is there a difference between short and long operating list waiters?	13
17/LO/0561	The effect of retrieval practice in AD and MCI	4

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
04/Q0801/60/AM11	Molecular characterisation of hormone refractory prostate cancer	Substantial Amendment 13	23/05/2016	16
04/Q0801/60/AM12	Molecular characterisation of hormone refractory prostate cancer	Substantial Amendment 14 - 23	23/09/2016	16
07/H0801/132/AM04	Erythrocyte encapsulated thymidine phosphorylase therapy	4	02/02/2017	4
09/H0801/19/AM07	The PROFILE study	7	05/02/2016	10
09/H0801/24/AM10	DDU screening protocol	Substantial Amendment 5 dated	16/09/2016	30
09/H0801/27/AM08	Analysis of immune responses in atherosclerosis-associated conditions	Substantial Amendment 9 dated	11/01/2017	33
09/H0801/75/AM18	Oral MDV3100 for progressive castration-resistant prostate cancer	Substantial Amendment 9 dated	01/06/2016	16
11/LO/0003/AM03	Exploratory Analysis of Genomic Signatures of Progression in Melanoma	Substantial Amendment 3	29/06/2016	12
11/LO/0043/AM37	ICON8: Weekly Chemotherapy in Ovarian Cancer v1.0	ICON8_SA_19Apr2016I 19/04/16	21/04/2016	21
11/LO/0153/AM17	BMN 673 in Patients with Advanced or Recurrent Solid Tumours A1 9DEC10	Substantial Amendment 12	09/02/2016	19
11/LO/0153/AM18	BMN 673 in Patients with Advanced or Recurrent Solid Tumours A1 9DEC10	13	26/04/2016	9
11/LO/0153/AM19	BMN 673 in Patients with Advanced or Recurrent Solid Tumours A1 9DEC10	Substantial Amendment 14	04/08/2016	24
11/LO/0954/AM19	1200.131 LUX-Head & Neck 2; Afatinib in Squamous Cell Carcinoma	Substantial Amendment 14 Dated	06/07/2016	19
11/LO/1619/AM18	Comparing safety & efficacy of AI/lapatinib/trastuzumab in HR+HER2 MBC	Substantial Amendment 5	18/03/2016	20
11/LO/1915/AM15	Phase III prostate cancer trial: surgery, radiotherapy,	Substantial	16/11/2016	21

	stereotactic	Amendment 9 dated		
11/LO/1974/AM05	Extension Study with AMG 145 in Subjects With Hypercholesterolemia	Amendment 5 - Protocol Amendment	12/11/2015	18
11/LO/1974/AM06	Extension Study with AMG 145 in Subjects With Hypercholesterolemia	6	04/05/2016	23
11/LO/1974/AM07	Extension Study with AMG 145 in Subjects With Hypercholesterolemia	7	04/07/2016	15
12/LO/0565/AM17	A phase I/II study of GDC-0068 or GDC-0980 in patients with CRPC	8	01/09/2016	22
12/LO/1540/AM16	BKM120 + fulvestrant in patients with HR+ HER2- after mTOR	Substantial Amendment [CBKM120	07/06/2016	13
12/LO/1915/AM03	SU2C Molecular Profiling	Substantial Amendment 3 - 26 S	26/09/2016	15
13/LO/0027/AM02	Multiparametric MRI for Oesophageal Cancer (MIMOSA)	AMD2	08/03/2016	24
13/LO/0108/AM12	LEGEND	Substantial Amendment 11	14/12/2016	28
13/LO/0264/AM04	Advanced Bolus Calculator for Type 1 Diabetes (ABC4D) v1.0	SA 1.4 - 12.08.16	12/08/2016	21
13/LO/0565/AM01	Non-Invasive Ventilation For Airway Clearance in Adult Cystic Fibrosis	Substantial Amendment 1 dated	20/02/2017	24
13/LO/0668/AM11	Onyx: Study of Carfilzomib in Newly Diagnosed Multiple Myeloma Patients	Substantial Amendment dated 20	20/06/2016	16
13/LO/0883/AM01	Histological correlation of textural features of PET & ceCT in NSCLC	Substantial Amendment 1	09/03/2016	17
13/LO/1252/AM12	The MILO Study (MEK Inhibitor in Low-grade Serous Ovarian Cancer)	SA09	18/05/2016	15
13/LO/1252/AM13	The MILO Study (MEK Inhibitor in Low-grade Serous Ovarian Cancer)	SA10	24/01/2017	28
13/LO/1265/AM15	First in Human, Dose-Escalating Study of HuMaX [®] -TF-ADC in solid Tumour	SA#9	29/03/2016	24
13/LO/1265/AM17	First in Human, Dose-Escalating Study of HuMaX [®] -TF-ADC	SA #10	13/05/2016	20

	in solid Tumour			
13/LO/1265/AM22	First in Human, Dose-Escalating Study of HuMaX ^Â ®-TF-ADC in solid Tumour	Substantial Amendment 13	20/07/2016	20
13/LO/1265/AM24	First in Human, Dose-Escalating Study of HuMaX ^Â ®-TF-ADC in solid Tumour	Substantial Amendment 14	11/08/2016	17
13/LO/1265/AM25	First in Human, Dose-Escalating Study of HuMaX ^Â ®-TF-ADC in solid Tumour	Substantial Amendment 15 dated	02/11/2016	20
13/LO/1265/AM26	First in Human, Dose-Escalating Study of HuMaX ^Â ®-TF-ADC in solid Tumour	Substantial Amendment 16 dated	05/01/2017	29
13/LO/1417/AM09	FINESSE	Substantial Amendment 8 [Notif	25/05/2016	8
13/LO/1417/AM12	FINESSE	Substantial Amendment dated 05	05/08/2016	15
13/LO/1417/AM14	FINESSE	Substantial Amendment dated 04	04/10/2016	15
13/LO/1579/AM06	SPOT Trial v 1.0 (13th June 2013)	Substantial Amendment 5	09/12/2016	28
14/LO/0231/AM01	Patients with axial spondyloarthritis: Five year observation study	amendment 1	24/01/2017	28
14/LO/0292/AM02	ABC-BIO: Biological Sample Collection Protocol	Protocol v3	18/01/2016	22
14/LO/0298/AM08	Single Arm Study of Enzalutamide in Patients with Prostate Cancer	7	15/04/2016	19
14/LO/0298/AM09	Single Arm Study of Enzalutamide in Patients with Prostate Cancer	Substantial Amendment 8 dated	08/09/2016	22
14/LO/0372/AM09	Vertex VX13-970-002	Substantial Amendment 5	12/05/2016	6
14/LO/0650/AM01	THE BIOLOGICAL BASIS OF REPRODUCTIVE DEPRESSION	SA1 - 01.08.16	01/08/2016	42
14/LO/0673/AM09	MLN9708 in Multiple Myeloma after Autologous Stem Cell Transplant	Global Amendment	29/06/2016	17

		Package 6		
14/LO/0673/AM10	MLN9708 in Multiple Myeloma after Autologous Stem Cell Transplant	Substantial Amendment 7 dated	05/12/2016	31
14/LO/0673/AM12	MLN9708 in Multiple Myeloma after Autologous Stem Cell Transplant	Substantial Amendment 8 dated	26/01/2017	27
14/LO/0712/AM04	Phase 1 Study of GSK2857916 in Subjects with Haematologic Malignancies	Substantial Amendment 3	01/06/2016	24
14/LO/0712/AM05	Phase 1 Study of GSK2857916 in Subjects with Haematologic Malignancies	Substantial Amendment 4	15/09/2016	27
14/LO/0712/AM10	Phase 1 Study of GSK2857916 in Subjects with Haematologic Malignancies	SA05 Exit Interviews	27/03/2017	30
14/LO/1034/AM16	BAY63-2521 in adult DeltaF508 homozygous Cystic Fibrosis patients. 1	Substantial Amendment dated 03	03/06/2016	14
14/LO/1034/AM17	BAY63-2521 in adult DeltaF508 homozygous Cystic Fibrosis patients. 1	Substantial Amendment 8 dated	18/08/2016	21
14/LO/1053/AM06	(duplicate) Momelotinib vs. Ruxolitinib in subjects with Myelofibrosis	5	04/05/2016	30
14/LO/1053/AM08	(duplicate) Momelotinib vs. Ruxolitinib in subjects with Myelofibrosis	Substantial Amendment 28 Septe	28/09/2016	21
14/LO/1068/AM05	Randomised study of Adalimumab in subjects with Ulcerative Colitis.	Substantial Amendment 4 - 16.0	16/06/2016	28
14/LO/1151/AM10	1280.8 - BI 836845 in metastatic castration resistant prostate cancer	Substantial Amendment 7 Dated	05/07/2016	20
14/LO/1151/AM11	1280.8 - BI 836845 in metastatic castration resistant prostate cancer	Substantial Amendment 8 dated	15/11/2016	23
14/LO/1163/AM07	Drug-Drug interaction study with ARN509 and abiraterone	Amendment 4	27/02/2017	22
14/LO/1539/AM12	CANDLE (Noctura400 for DMO)	Substantial Amendment 5 dated	16/12/2016	28

14/LO/1568/AM07	TIER	Substantial Amendment 6	17/03/2016	15
14/LO/1574/AM04	Clinical Phenotyping and Genotyping of HIV-Associated Neuropathy	Amendment 4 23/02/17	23/02/2017	13
14/LO/1598/AM09	Phase 1 - study of GSK2636771 plus Enzalutamide in mCRProstate Cancer	Substantial Amendment 5	25/07/2016	17
14/LO/1598/AM12	Phase 1 - study of GSK2636771 plus Enzalutamide in mCRProstate Cancer	Substantial Amendment 8 dated	20/12/2016	2
14/LO/1598/AM13	Phase 1 - study of GSK2636771 plus Enzalutamide in mCRProstate Cancer	Substantial Amendment 9 dated	15/02/2017	22
14/LO/1598/AM14	Phase 1 - study of GSK2636771 plus Enzalutamide in mCRProstate Cancer	SA10 -ICF v9 and v5	23/03/2017	34
14/LO/1994/AM24	The AMARANTH Study	Substantial Amendment dated 28	28/04/2016	10
14/LO/1994/AM25	The AMARANTH Study	Substantial Amendment dated 19	19/09/2016	21
14/LO/1994/AM27	The AMARANTH Study	Substantial Amendment 3	03/01/2017	27
14/LO/2151/AM04	Re-contact in mainstreaming genetics V1	Substantial Amendment 4	17/03/2016	18
14/LO/2169/AM03	The functional annotation of psoriasis susceptibility alleles (V1)	2	25/04/2016	13
14/LO/2186/AM03	AUX-CC-810: Long-term Follow-up Study in Men with Peyronie's Disease	2	02/11/2016	21
15/LO/0016/AM07	Monarch 3: Breast Cancer in Postmenopausal Women (JPBM Study)	Substantial Amendment 5 - date	12/12/2016	24
15/LO/0029/AM02	Intraoperative GE-137 fluorescence imaging in breast and oral cancer	2	05/05/2016	15
15/LO/0165/AM08	56021927PCR3001 - Prostate Cancer Study	Substantial Amendment 5	31/08/2016	28
15/LO/0165/AM10	56021927PCR3001 - Prostate Cancer Study	Substantial Amendment 6	20/02/2017	23

		dated		
15/LO/0304/AM03	Bubble	Substantial Amendment 3 dated	02/09/2016	22
15/LO/0344/AM05	VX14-803-001 in Subjects With Advanced Solid Tumours or Lymphoma	Substantial Amendment 4 dated	12/09/2016	14
15/LO/0344/AM06	VX14-803-001 in Subjects With Advanced Solid Tumours or Lymphoma	SA05	26/01/2017	28
15/LO/0538/AM02	SPRAINED Study - Version 1.0	Substantial Amendment 3	05/08/2016	16
15/LO/0548/AM01	The role of Home packs of HIV PEPSE in High Risk Individuals	1	06/04/2016	9
15/LO/0548/AM04	The role of Home packs of HIV PEPSE in High Risk Individuals	Substantial Amendment [HOME PE	20/12/2016	28
15/LO/0551/AM01	FDHT - version 1, 9 March 2015	Substantial Amendment - 18.08.	18/08/2016	23
15/LO/0564/AM06	ARMOR3-SV	Substantial Amendment 2 dated	16/03/2016	24
15/LO/0564/AM07	ARMOR3-SV	SA 3 - 16.03.16	16/03/2016	31
15/LO/0638/AM03	PAVE trial v1.0	Substantial Amendment 4	08/03/2016	21
15/LO/0638/AM04	PAVE trial v1.0	Substantial Amendment 5	07/07/2016	23
15/LO/0638/AM09	PAVE trial v1.0	Substantial Amendment 10 26/01	26/01/2017	22
15/LO/0834/AM07	WO29522 - A Study of MPDL3280A and Nab-paclitaxel in Breast Cancer	SA#7	05/04/2016	19
15/LO/0834/AM10	WO29522 - A Study of MPDL3280A and Nab-paclitaxel in Breast Cancer	SA 10 dated 5th October 2016	05/10/2016	20
15/LO/0834/AM12	WO29522 - A Study of MPDL3280A and Nab-paclitaxel in Breast Cancer	Amendment 12 - Updated re-imburement costs	24/11/2016	24

15/LO/0834/AM13	WO29522 - A Study of MPDL3280A and Nab-paclitaxel in Breast Cancer	Substantial Amendment 13 dated	26/01/2017	28
15/LO/0975/AM02	EDEN-OX the effect of dietary nitrate on exercise in hypoxia	2	31/03/2016	28
15/LO/1116/AM01	Effect of Remote Ischaemic Conditioning in Oncology Patients (ERICONC)	Substantial Amendment 1	17/02/2016	19
15/LO/1132/AM03	A Phase II Study of Pembrolizumab in Subjects with Triple-Negative Breast Cancer	Substantial Amendment 4	20/06/2016	12
15/LO/1132/AM06	A Phase II Study of Pembrolizumab in Subjects with Triple-Negative Breast Cancer	SA05- (IB Edition 13 and PIS u	15/03/2017	15
15/LO/1141/AM04	The PERM Study	Sub-Amendment 2	10/02/2017	28
15/LO/1174/AM04	Open label ISIS 420915-CS3	Protocol Supplement 3	12/04/2016	27
15/LO/1174/AM05	Open label ISIS 420915-CS3	Substantial Amendment 4	13/05/2016	26
15/LO/1174/AM06	Open label ISIS 420915-CS3	SA 12.04.16	12/04/2016	18
15/LO/1174/AM07	Open label ISIS 420915-CS3	Substantial Amendment 8 dated	23/09/2016	28
15/LO/1175/AM05	RPC01-3101 True North study	Substantial Amendment 1.2	28/07/2016	14
15/LO/1175/AM06	RPC01-3101 True North study	SA6 - 12.08.16	12/08/2016	15
15/LO/1502/AM02	Phase I study of IPH4102 treatment in patients with CTCL	Substantial Amendment 2	31/08/2016	21
15/LO/1502/AM03	Phase I study of IPH4102 treatment in patients with CTCL	Substantial Amendment 3 dated	19/01/2017	27
15/LO/1512/AM10	RPC01-3102 Open-label extension study	Substantial Amendment 1.3	07/06/2016	14
15/LO/1636/AM04	Effect of Serelaxin on cardiac troponin I release in patients with CHF	Substantial Amendment - Tempor	21/11/2016	21
15/LO/1636/AM06	Effect of Serelaxin on cardiac troponin I release in patients with CHF	CRLX030A2211-SA04-Restart of s	24/02/2017	17
15/LO/1648/AM02	Is a Virus Infection the Trigger That Leads to Type 1 Diabetes?	Substantial Amendment 2	05/10/2016	20

		dated		
15/LO/1670/AM02	U31287-A-U203: Double Blind Phase 2 Study of Patritumab (U31287).	Substantial Amendment 2	14/06/2016	14
15/LO/1670/AM03	U31287-A-U203: Double Blind Phase 2 Study of Patritumab (U31287).	Substantial Amendment 3 dated	03/11/2016	25
15/LO/1676/AM01	1269 - Phase 2/3 open label study of F/TAF in HIV-1 infected children	Substantial amendment 1	19/04/2016	24
15/LO/1676/AM03	1269 - Phase 2/3 open label study of F/TAF in HIV-1 infected children	SA - 25/08/16	25/08/2016	25
15/LO/1703/AM02	Point of care testing in the diagnosis and management of COPD	Substantial Amendment 1	19/08/2016	28
15/LO/1703/AM03	Point of care testing in the diagnosis and management of COPD	Substantial Amendment 2, 10th	10/01/2017	30
15/LO/1812/AM05	39039039STM4001: Rivaroxaban in Cancer Patients with high risk of VTE	Substantial Amendment 4	30/09/2016	19
15/LO/1816/AM02	ECLIPSE Study 2: Comparison of acceptability between CRT methods	Substantial Amendment 2	28/04/2016	14
15/LO/1924/AM01	Microbiome and Inflammation in Preterm Infants	1	01/06/2016	19
15/LO/1930/AM01	DNA damage response deficiency assay validation (version 1)	Substantial Amendment 2	01/08/2016	14
15/LO/1992/AM01	BARCODE 1 Pilot Study	Substantial Amendment 3	11/08/2016	14
15/LO/2208/AM01	Diabetic Foot and Retinopathy Screening feasibility study	1	10/05/2016	10
16/LO/0165/AM02	Evaluating support for carers of people with dementia	Substantial Amendment 2 dated	01/11/2016	21
16/LO/0396/AM01	PHysical activity Implementation Study In Community-dwelling AduLts	Amendment 2, SA0116	27/04/2016	17
16/LO/0396/AM07	PHysical activity Implementation Study In Community-dwelling AduLts	Substantial Amendment 5 dated	12/12/2016	39
16/LO/0586/AM01	Multiple Sclerosis Study Using Ocrelizumab	Substantial Amendment 1	16/06/2016	20
16/LO/0586/AM02	Multiple Sclerosis Study Using Ocrelizumab	Substantial Amendment 2 -	29/09/2016	18

		date		
16/LO/0586/AM07	Multiple Sclerosis Study Using Ocrelizumab		24/11/2016	15
16/LO/0586/AM08	Multiple Sclerosis Study Using Ocrelizumab	Amendment 5 (Substantial) - Pr	23/03/2017	29
16/LO/0595/AM01	monarchHER: Phase 2, 3-Arm, Study in Women with Advanced Breast Cancer	Amendment 1 28/06/2016	28/06/2016	11
16/LO/0595/AM02	monarchHER: Phase 2, 3-Arm, Study in Women with Advanced Breast Cancer	Substantial Amendment 2	05/08/2016	21
16/LO/0595/AM04	monarchHER: Phase 2, 3-Arm, Study in Women with Advanced Breast Cancer	Substantial Amendment 3	25/01/2017	28
16/LO/0595/AM05	monarchHER: Phase 2, 3-Arm, Study in Women with Advanced Breast Cancer	Substantial Amendment 4	16/03/2017	13
16/LO/0673/AM01	Pilot trial of targeted sexual risk reduction intervention package	Substantial Amendment 1	06/11/2016	21
16/LO/0682/AM02	The Reproductive Life Course Project V1.0	Substantial Amendment 1.3 date	16/08/2016	12
16/LO/0784/AM04	I2PETPG – Imidazoline2 Binding Site in patient group	Substantial Amendment 1	12/09/2016	23
16/LO/0886/AM02	101SK202 Acute Ischemic Stroke	SA2 - 18.08.16	18/08/2016	27
16/LO/0886/AM04	101SK202 Acute Ischemic Stroke			15
16/LO/0886/AM05	101SK202 Acute Ischemic Stroke		06/02/2017	29
16/LO/0995/AM01	Improving Outcome Measures For Adult CF ACT Trials	Substantial Amendment 1	12/07/2016	22
16/LO/0995/AM03	Improving Outcome Measures For Adult CF ACT Trials	Substantial Amendment 2, dated	15/02/2017	23
16/LO/1000/AM01	Design Practice in Health: PhD	SA1, dated 24th February 2017	24/02/2017	19
16/LO/1133/AM01	MK-3475 in the Treatment of Recurrent/Metastatic Head and Neck Cancer	Substantial Amendment 2 dated	12/10/2016	18
16/LO/1133/AM02	MK-3475 in the Treatment of Recurrent/Metastatic Head and Neck Cancer	SA03 - 16 January 2017	16/01/2017	29
16/LO/1169/AM01	Determining the effects of gut content on satiety	Substantial Amendment 1	27/10/2016	26

		dated		
16/LO/1272/AM01	Intello2 vs Manual Control for Optimizing Oxygenation in Infants	Amendment #1, 27 February 2017	27/02/2017	14
16/LO/1424/AM01	Clearing Lungs With ENaC Inhibition in Primary Ciliary Dyskinesia	Sub Am 001_Protocol 5.0	08/11/2016	29
16/LO/1424/AM02	Clearing Lungs With ENaC Inhibition in Primary Ciliary Dyskinesia	Substantial Amendment 2 dated	31/10/2016	29
16/LO/1514/AM01	Phase III Study of MK-3475 + Best Supportive Care in Subjects with HCC	SA1 dated 14th October 2016	14/10/2016	20
16/LO/1514/AM06	Phase III Study of MK-3475 + Best Supportive Care in Subjects with HCC	SA03	15/03/2017	13
16/LO/1566/AM01	KORTUC	Substantial Amdnment 1 dated	17/11/2016	22
16/LO/1566/AM02	KORTUC	AM1702/57 02/03/2017	03/03/2017	13
16/LO/1686/AM01	BARCODE 2	BARCODE 2 Substantial Amendmen	23/03/2017	29
16/LO/1735/AM01	The Mini Linguistic State Examination (MLSE)	Amendment 1.0 15/02/2017	15/02/2017	23
16/LO/1753/AM01	Education delivery for the low FODMAP diet	Substantial Amendment 1 - 12 D	12/12/2016	28
16/LO/1782/AM02	Phase Ib/II Trial of Pembrolizumab (MK-3475) in Combination Therapies	SA01 – Protocol amendment 01	02/02/2017	21
16/LO/1782/AM04	Phase Ib/II Trial of Pembrolizumab (MK-3475) in Combination Therapies	SA2	28/03/2017	48
16/LO/1982/AM01	BVAC	Substantial_Amend ment_1	14/03/2017	14
16/LO/2137/AM01	A Phase 1 Study of Durvalumab & IPH2201 in Adults with advance tumours	Substantial Amendment 1	14/03/2017	15
17/LO/0011/AM01	VEROnA	Substantial Amendment 1	10/03/2017	33

17/LO/0017/AM01	Open-label Extension Study for Participants with Prostate Cancer	AM01, substantial amendment 1	20/01/2017	30
CCR2075/AM04	Tissue Collection at Radical prostatectomy	Substantial Amendment 7 dated	19/07/2016	13

Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
11/LO/0971/AM03	Investigation of the maternal immune system	Substantial Amendment 3 dated	22/01/2016	28

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
11/LO/0971/AM03/1	Investigation of the maternal immune system	Modification of Amendment 3 da	31/07/2016	3

Unfavourable opinion timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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Table 11: Items exceeding timelines**Full applications for ethical review over 60 day timeline**

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

REC Reference	Title	Number of Days on Clock
16/LO/1751	Medication Compliance in young people with ADHD; could the Qb help?	25
16/LO/1783	Oximetry in children with severe obstructive sleep apnoea	26
17/LO/0384	Dysphagia, Freezing and balance in Parkinson's patients	28

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
14/LO/0650/AM01	THE BIOLOGICAL BASIS OF REPRODUCTIVE DEPRESSION	SA1 - 01.08.16	01/08/2016	42
16/LO/0396/AM07	PHysical activity Implementation Study In Community-dwelling AduLts	Substantial Amendment 5	12/12/2016	39
16/LO/1782/AM04	Phase Ib/II Trial of Pembrolizumab (MK-3475) in Combination Therapies	SA2	28/03/2017	48

Modified Amendments over 14 day timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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