Health Research Authority

Research Ethics Service

London - City & East Research Ethics Committee

Annual Report

01 April 2016 - 31 March 2017

Part 1 – Committee Membership and Training

Name of REC:	London - City & East Research Ethics Committee
Type of REC:	RECs recognised to review CTIMPS in patients - type iii
Type of Flag:	IRB Registered Phase 1 in patients Research involving Children
Chair:	Dr John Keen
Vice-Chair:	Ms Alison Eden
Alternate Vice-Chair:	Dr Ayse Baxter
REC Manager:	Mr Rajat Khullar
REC Assistant:	Mr Wai Yeung
Committee Address:	Bristol Research Ethics Committee Centre Whitefriars Level 3, Block B Lewins Mead Bristol BS1 2NT
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Chair's overview of the past year:

Thank you to everyone who contributed to another busy year for London - City & East Research Ethics Committee.

Dr John W Keen

London - City & East Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Dr Marie E Bardsley	Director (Pharmaceutical Publication)	Lay	01/10/2009	
Ms Clare Barron	Solicitor – in-house legal department	Lay Plus	27/02/2014	
Ms Jane Batchelor	Centre Administrator, Advanced Cardiovascular Imaging	Lay Plus	01/12/2011	
Dr Ayse Baxter	Pharmaceutical Physician	Expert	30/06/2007	
Dr Luis Beltran	Consultant Histopathologist	Expert	01/05/2014	
Mr Frank Cross	Consultant General and Vascular Surgeon	Expert	13/11/2008	
Ms Alison Eden	Manager Patient Recruitment	Lay Plus	07/01/2015	
Ms Elizabeth Hall	Vice Chair, Standards and Quality Assurance Committees	Lay Plus	01/04/2016	
Mrs Lisa Johnson	Clinical Manager	Lay Plus	01/12/2014	
Dr John Keen	GP (REC Chairman)	Expert	06/11/2014	
Mr John Lynch	Non - NHS & Voluntary Sector Activity	Lay	01/10/2007	
Mr Roger Maran	Barrister	Lay Plus	06/10/2011	06/10/2016
Dr Kieran McCafferty	Nephrologist Consultant/ Hon Senior Lecturer	Expert	01/09/2015	
Dr Wolfgang Meyer	Honorary senior clinical lecturer, Consultant psychiatrist and psychotherapist	Expert	21/01/2016	
Dr Dylan Morrissey	Senior Clinical Lecturer in Sports and Exercise Medicine	Expert	01/12/2014	31/03/2017
Ms Anna (Renqian) Song	Pharmacist	Expert	01/01/2016	

London - City & East Research Ethics Committee: Deputy Members

Name	Profession	Status	Meeting date attended

London - City & East Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended

London - City & East Research Ethics Committee: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Dr Marie E Bardsley	Director, E-Med Ltd. Data Manager Data Sharing Initiative Royal London Hospital Whitechapel Commission on Publishing Ethics (COPE)	05/01/2017
Ms Clare Barron	None	02/02/2017
Ms Jane Batchelor	Centre Administrator, Advanced Cardiovascular Imaging, William Harvey Research Institute, QMUL	05/01/2017
Dr Ayse Baxter	Shares in AstraZeneca Shares in Glaxo Smithkline	02/02/2017
Dr Luis Beltran	Collaborative work with the Orchid charity on male specific cancer. Work with Trans-Atlantic prostate group	02/02/2017
Mr Frank Cross	None	05/01/2017
Ms Alison Eden	100% owner of Alison Brand - sometimes writes patient information/interviews sites, advises on recruitment/retention strategy. Employee of ICON. Contract Research Organisation.	05/01/2017
Ms Elizabeth Hall	Tower Hamlets Friends & Neighbours – trustee (Vice-Chair) Bow Foodbank – trustee (Vice-Chair)	31/05/2016
Ms Elizabeth Hall	Queen Mary University of London – Vice-Chair of Council until 15.12.15; Chair of Ethics of Research Committee and other minor honorary appointments	03/04/2016
Mrs Lisa Johnson	None	05/01/2017
Dr John Keen	None	05/01/2017
Mr John Lynch	None	05/01/2017
Dr Kieran McCafferty	None	05/01/2017
Dr Wolfgang Meyer	None	01/06/2017
Ms Anna (Renqian) Song	None	05/01/2017

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

Month	Date	Number of Members Present at Meeting
April	07/04/2016	12
May	05/05/2016	12
June	02/06/2016	8
July	07/07/2016	10
September	01/09/2016	10
October	06/10/2016	11
December	01/12/2016	5
December	13/12/2016	7
January	05/01/2017	9
February	02/02/2017	12
March	02/03/2017	7

11 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	08/04/2016	4
May	19/05/2016	4
June	16/06/2016	5
July	21/07/2016	6
August	22/08/2016	4
September	15/09/2016	3
October	20/10/2016	3
November	17/11/2016	3
December	15/12/2016	4
January	19/01/2017	5
February	16/02/2017	4
March	28/03/2017	4

12 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	11/04/2016	2
April	22/04/2016	5
May	02/05/2016	4
May	16/05/2016	6
June	01/06/2016	4
June	17/06/2016	4
June	20/06/2016	5
July	01/07/2016	7

July	20/07/2016	3
August	01/08/2016	4
August	22/08/2016	5
September	09/09/2016	6
September	26/09/2016	4
October	07/10/2016	5
October	21/10/2016	2
November	03/11/2016	7
November	17/11/2016	5
November	30/11/2016	6
December	08/12/2016	2
December	12/12/2016	3
January	03/01/2017	4
January	18/01/2017	5
February	03/02/2017	2
February	10/02/2017	5
February	24/02/2017	5
March	13/03/2017	3
March	27/03/2017	4

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

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

Date	Reason	Action taken
01/12/2016	**Less than 7 members present**	**Applications discussed and decisions ratified at 13/12/2016 meeting**

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

Name	Number of Meetings Attended
Dr Marie E Bardsley	8
Ms Clare Barron	6
Ms Jane Batchelor	7
Dr Ayse Baxter	8
Dr Luis Beltran	5
Mr Frank Cross	4
Ms Alison Eden	5
Ms Elizabeth Hall	4
Mrs Lisa Johnson	7
Dr John Keen	9
Mr John Lynch	7
Mr Roger Maran	6
Dr Kieran McCafferty	6
Dr Wolfgang Meyer	2
Dr Dylan Morrissey	6
Ms Anna (Renqian) Song	8

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

Name	Number of Meetings Attended
Ms Clare Barron	1
Ms Jane Batchelor	7
Dr Ayse Baxter	3
Ms Alison Eden	4
Mrs Lisa Johnson	2
Ms Lisa Johnson	1
Dr John Keen	11
Mr John Lynch	5
Mr Roger Maran	4
Dr Kieran McCafferty	4
Dr Dylan Morrissey	3
Ms Anna (Renqian) Song	4

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

Name	Number of Meetings Attended
Dr Marie E Bardsley	5
Ms Clare Barron	1

Ms Jane Batchelor	1
Dr Ayse Baxter	24
Dr Luis Beltran	1
Ms Alison Eden	9
Ms Lisa Johnson	5
Dr John Keen	27
Mr John Lynch	1
Mr Roger Maran	7
Dr Kieran McCafferty	17
Dr Wolfgang Meyer	1
Dr Dylan Morrissey	5
Ms Anna (Renqian) Song	13

Training 01 April 2016 - 31 March 2017

Name of Member	Date	Event(s) attended
Dr Marie E Bardsley	01/02/2017	Medical Devices Training Day
Ms Clare Barron	05/09/2016	Local Training Day - 05 Sep 2016
Ms Clare Barron	17/10/2016	Equality & Diversity
Ms Jane Batchelor	15/09/2016	National roles and responsibilities in patient involvement & experience
Dr Ayse Baxter	04/09/2016	Equality & Diversity
Mr Frank Cross	17/04/2017	Local Training Day – London Harrow
Ms Alison Eden	04/07/2016	ICON training programme on conflict of interest and ethical decision-making
Ms Alison Eden	10/03/2017	HRA eConsent workshop
Ms Elizabeth Hall	14/03/2017	Committee Members Induction
Mrs Lisa Johnson	06/07/2016	Understanding Medical Devices Clinical Investigations
Mrs Lisa Johnson	17/10/2016	Equality & Diversity
Dr John Keen	13/05/2016	Equality & Diversity
Dr John Keen	01/12/2016	National Training Day for REC Chairs
Mr John Lynch	04/04/2016	Quantitative research
Mr John Lynch	26/10/2016	Equality & Diversity
Dr Kieran McCafferty	12/10/2016	Equality & Diversity
Dr Kieran McCafferty	30/11/2016	The World Congress on Clinical Trials in Diabetes
Ms Anna (Renqian) Song	13/10/2016	Equality & Diversity
Ms Anna (Renqian) Song	01/02/2017	Medical Devices 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	29	47.54
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	0	0.00
Others	32	52.46
Total Applications Reviewed	**61**	**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	12
Number of paediatric applications reviewed	15
Number of device applications reviewed	3
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	0
Number of applications reviewed that are funded by the US DHHS	1
Number of qualitative applications reviewed	3

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

Decisions taken at meetings following review of applications	Number	%
Favourable Opinion with Standard Conditions	3	4.92
Favourable Opinion with Additional Conditions	8	13.11
Unfavourable Opinion	1	1.64
Provisional Opinion	45	73.77
Provisional Opinion Pending Consultation with Referee	4	6.56
Total	**61**	**100**
Number of studies sent back to full committee meeting for final opinion	4	

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	44	72.13
Further Information Favourable Opinion with Additional Conditions	5	8.20
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	3	4.92
Favourable Opinion with Additional Conditions	8	13.11
Unfavourable Opinion	1	1.64
Provisional Opinion	0	0.00
Provisional Opinion Pending Consultation with Referee	0	0.00
Further Information response not complete	0	0.00
No decision entered on system	0	0.00
Number of studies withdrawn after the meeting	0	0.00
Total	**61**	**100**

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

Total Applications Reviewed	**43**

Table 6: **Breakdown of PRS applications and other activity during reporting period:**

Number of applications made invalid by the REC Manager	1
Number of studies withdrawn prior to the meeting	1
Number of student applications reviewed	19
Number of paediatric applications reviewed	1
Number of device applications reviewed	6
Number of qualitative applications reviewed	7

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	14	32.56
Favourable Opinion with Additional Conditions	8	18.60
No Opinion transfer to full committee for review	2	4.65
Provisional Opinion	19	44.19
Unfavourable Opinion	0	0.00
Total	**43**	**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	5.55
Number of completed applications for full ethical review	61
Number of completed applications for full ethical review over 60 days	1
Number of completed applications over 60 days as a % of total	1.64%
Number of completed applications for full ethical review over 40 days	7
Number of completed applications over 40 days as a % of total	11.48%
Number of days taken to final decision – average (mean)	34

Number of completed proportionate review applications for ethical review	41
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)	2
Number of completed proportionate review applications for ethical review over 21 days	0
Number of completed proportionate review applications over 14 days as a % of total	4.88%

Number of SSAs (non-Phase 1) reviewed	12
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	8.33%

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	210
Number of completed substantial amendments over 35 days	0
Number of completed substantial amendments over 35 days as a % of total substantial amendments	0.00%
Number of completed substantial amendments over 28 days	31
Number of completed substantial amendments over 28 days as a % of total substantial amendments	14.76%

Number of modified amendments reviewed	6
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	122

Number of substantial amendments received for information	3
Number of substantial amendments received for new sites/PIs	39
Number of annual progress reports received	92
Number of safety reports received	30
Number of Serious Adverse Events received	0
Number of final reports received	21

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/0498	NAVIGATE	32
16/LO/0554	Facial phenotyping in obstructive sleep apnoea-hypopnoea syndrome.	28
16/LO/0572	Before HIV, Version 0.3.11	28
16/LO/0578	MBCT for People with Memory Problems and Low Mood (Student Study) V1	28
16/LO/0581	C31004-A Phase 2, Randomised Study in Advanced Endometrial Cancer	31
16/LO/0582	C31005 MLN0128 and MLN0128+MLN1117 Compared With Everolimus in mccRCC	31
16/LO/0693	BANG-CH	36
16/LO/0769	EMR200647-001 MERCK TRAP	33
16/LO/0782	Assay development for cancer biomarkers	37
16/LO/0783	Pelvic Girdle Pain in Pregnancy (Student) Masters Research	31
16/LO/0793	1199.227 Effect of nintedanib on biomarkers	39
16/LO/0951	IDES IN ASYMPTOMATIC ANTIBODY-MEDIATED TTP PATIENTS WITH LOW ADAMTS13	30
16/LO/0966	Physiological changes following MIE in NMD	32
16/LO/0985	CHECKpoint pathway and nivoluMAb clinical Trial Evaluation 577	47
16/LO/1180	PHASE 3 STUDY OF AVELUMAB COMBINED WITH AXITINIB VS SUTINIB IN RCC	36
16/LO/1181	Phase 2 study of MHAA4549A for seasonal Influenza A infection	32
16/LO/1199	CA224-020 Anti-LAG-3 with Nivolumab in Advanced Soild Tumors	34
16/LO/1301	Urban Environment & Early Psychosis: An EMA Study	32
16/LO/1505	Diabetes Stopwatch v1	35
16/LO/1509	Use of extended release sodium oxybate for treatment of narcolepsy.	39
16/LO/1675	M14-234 Phase 2b/3 study in Mod/Severe Ulcerative Colitis	30
16/LO/1676	M14-533 Ph 3 study in Mod/Severe Ulcerative Colitis Extension study	31
16/LO/1744	KIDES: safety and tolerability of ODM-203 in advanced solid tumours	40
16/LO/1748	Acceptability of a Medication Adherence Intervention	30
16/LO/1750	INNODIA	31
16/LO/1754	LIFTD-PIN	29
16/LO/1905	REACT	29
16/LO/1983	EPOP 2- Peri -Operative Isometric Exercise Programme	33
16/LO/2039	Open label study of ATX-F8-17 in male subjects with Haemophilia A	33
16/LO/2072	Children's Views on the Usability of SISOM Version 2	34
16/LO/2084	VALIDATION OF A PREDICTIVE SCORE OF ACUTE CHEST SYNDROME (PRESEV-2)	27
17/LO/0007	Calcium balance studies in children with kidney failure	46

17/LO/0012	Cinnamon - Infant milk formula with two Human Milk Oligosaccharides	31
17/LO/0024	JPCJ: Abemaciclib in Metastatic Pancreatic Ductal Adenocarcinoma	53
17/LO/0026	Lymph node biopsy study in ANCA-associated vasculitis	40
17/LO/0101	Placebo controlled study with TEV-48125 for EC Headaches	39
17/LO/0102	Placebo controlled study with TEV-48125 for Chronic Cluster Headaches	40
17/LO/0103	Long-Term Safety Study with TEV-48125 for Cluster Headache Prevention	40
17/LO/0113	GBT440-031 - GBT440 in Patients With Sickle Cell Disease (HOPE)	41
17/LO/0121	SHP633-303 Ext Study of Teduglutide in Paediatric Subjects with SBS	39
17/LO/0337	Life experiences of individuals with Autism Spectrum Disorders	28
17/LO/0371	ODAK Phase 3 study 043SI V1.0	43
17/LO/0372	REACH 2	36
17/LO/0374	EASE Study	64

Further Information Favourable Opinion with Additional Conditions		
REC Reference	**Title**	**Number of Days on Clock**
16/LO/0735	BH29992 - Subcutaneous emicizumab in Haemophilia A paediatric patients	37
16/LO/1518	Breathing Together	36
17/LO/0010	Intraluminal optical monitoring of large bowel tissue perfusion (1)	35
17/LO/0025	Fertility Outcomes after Pregnancies of Unknown Location	32
17/LO/0163	GO39374: GDC-0077 for PIK3CA-mutant solid tumours / breast cancer	36

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/0990	Pilot study of contingency management for smoking cessation	28
16/LO/1210	A comparison of 3rd generation to 2nd generation airway devices	21
17/LO/0167	The deep phenotype of lamin A/C cardiomyopathy	28

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

16/LO/0964	Understanding Visual Snow Syndrome: A Functional Imaging Approach	28
16/LO/0973	The activity of the premature gut	52
16/LO/1206	Transcriptomic response to latent TB treatment	25
16/LO/1495	SPACE	29
16/LO/1506	Assessing frailty in older adults with functional mental illness.	25
16/LO/2076	IRMA	27
17/LO/0322	Examining HRQL and Health Behaviours in Paediatric SCD (Version 1)	28
17/LO/0378	ICONIC	28

Unfavourable Opinion		
REC Reference	**Title**	**Number of Days on Clock**
16/LO/1155	Long term Safety TOPAMAX monotherapy in paediatric patient	28

Provisional Opinion		
REC Reference	**Title**	**Number of Days on Clock**

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**

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/0778	Optimising secondary prevention medication post-ACS: version 1.7	13
16/LO/0787	The Molecular Mechanisms of Mastocytosis	12
16/LO/1007	SEM Glove study for spinal cord injury - v1	9
16/LO/1111	Biodosimetric assessment of radiation during endovascular procedures	11
16/LO/1173	SAFETY	12
16/LO/1182	Women's experiences of maternity bladder care	12
16/LO/1184	BOLD study (version 01)	13
16/LO/1395	Measuring and manipulating melanocyte/keratinocyte ratios	15
16/LO/1607	Immunological and genetic association with Cancer development- V1	6
16/LO/1608	Pain experience in older adults with chronic musculoskeletal pain	7
16/LO/1722	Use of opioids in the treatment of chronic non-cancer pain	6
16/LO/1729	Investigating the impact of Implementing exercise on Haemodialysis	8
16/LO/1738	Urine collection from non-pregnant peri- and post-menopausal women	15
16/LO/1956	Compliance aid patients' views	10
16/LO/2091	VERIFIE	9
16/LO/2184	Chair based exercise in patients with heart failure v1	10
16/LO/2255	SKIP-IT smoking cessation in pregnancy	10
17/LO/0187	Accuracy of non-contact thermometry	14

Further Information Favourable Opinion with Additional Conditions		
REC Reference	**Title**	**Number of Days on Clock**
16/LO/0737	An Avatar Aid in the Memory Clinic (AAA-MC)	14

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/0740	Facilitating informed decision making in haemato-oncology	6
16/LO/0972	Understanding participation and consent in CFAS (ERIC 1)	11

16/LO/0996	ASAS-FLARE	4
16/LO/1394	Development of Tests to Measure Medicines in Breast Milk	11
16/LO/1425	Ground Reaction Force Patterns in Total vs Uni Knee Replacement	12
16/LO/2098	Skin cancer	12
16/LO/2103	Evaluation of an assay to predict response to a PARP inhibitor: Ver 1	11
16/LO/2266	OBSERVATIONAL STUDY OF VISTABEL FOR THE TREATMENT OF CROW'S FEET	8
16/LO/2267	Facilitators and barriers to self-management in CCS	9
17/LO/0178	Evaluating the health burden of systemic vasculitis	12
17/LO/0358	ENABLE - Liverpool v1	10
17/LO/0514	Measurement of cortisol and haemoglobin from dried blood samples	14
17/LO/0530	Virtual Clinic Follow-up for Joint Replacement	13
17/LO/0534	Acceptance and Commitment Therapy in the treatment of obesity: pilot.	8

Favourable Opinion with Additional Conditions		
REC Reference	**Title**	**Number of Days on Clock**
16/LO/0976	Dietary Intake in IBD, IBS and healthy controls	5
16/LO/1429	BME Type 2 Diabetic patients understanding of Carbohydrates	13
16/LO/1726	RNAscope Pan-UK OPSCC Testing	8
16/LO/1966	Carrier Screening: Exploring the Experience in the Fertility Clinic	10
17/LO/0162	Transition of care from paediatric to adult asthma services	11
17/LO/0321	Quantitive assessment of hand function in Systemic Sclerosis	13
17/LO/0356	Acute physiological response to exercise in end stage renal disease	7
17/LO/0483	Paediatric Oximetry Algorithms	14

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**
04/Q0603/1/AM59	ASPECT	Substantial Amendment 127 Date	23/03/2016	22
06/Q1603/7/AM15	Chemoprevention of Premalignant Intestinal Neoplasia	Amendment 11 06 Dec 2016	07/06/2016	31
06/Q1603/7/AM16	Chemoprevention of Premalignant Intestinal Neoplasia	Amendment 12 Study Suspension	06/12/2016	31
08/H0704/128+5/AM03	Brains for Dementia Research	2	30/03/2016	25
09/H0703/104/AM13	1199.15: BIBF 1120 in ovarian cancer	15	23/06/2016	28
09/H0703/28/AM03	CASTLE-AF	Amendment 3 - 08 Dec 2016	20/12/2016	28
10/H0703/107/AM21	A3921061 Long Term Safety&Tolerability of 2 oral doses of CP-690,550	A3921061 Substantial Amendment	19/04/2016	26
10/H0703/98/AM02	Inorganic nitrate in resistant hypertension	2Í¾ 18-01-2017	25/01/2017	26
11/H0703/10/AM08	An Exploratory Clinical and Genetic Study of Cone Disorders	Amendment 9 - 14 September 201	20/09/2016	27
11/LO/0241/AM14	Parkinson's Progression Markers Initiative	Amendment 10, September 18 201	23/03/2016	28
11/LO/0241/AM15	Parkinson's Progression Markers Initiative	01/08/2016	26/08/2016	28
11/LO/1303/AM10	Panobinostat and ruxolitinib in patients with myelofibrosis.	Substantial amendment for CLBH	16/08/2016	27
11/LO/1595/AM13	FGFR	AMENDMENT 13 - PROTOCOL V7 PRO	12/09/2016	28
11/LO/1757/AM01	Pilot Pharmacological-fMRI Study	Amendment number 1Í¾ 18/04/2016	03/06/2016	27

11/LO/1921/AM11	MO27775 PERTAIN Study	SA. 08 Protocol Version 3.0	28/06/2016	27
11/LO/1921/AM12	MO27775 PERTAIN Study	SA09	26/09/2016	28
11/LO/1921/AM15	MO27775 PERTAIN Study	SA 11 - Addendum to Pertuzumab	24/02/2017	31
12/LO/0008/AM06	GAMMA	Substantial amendment dated 28	28/06/2016	27
12/LO/0482/AM05	Peruse: Global safety study with pertuzumab in Her2+ advanced BC	SA#5 dated 30 Mar 2015 - Proto	30/03/2016	23
12/LO/0482/AM08	Peruse: Global safety study with pertuzumab in Her2+ advanced BC	SA9	22/11/2016	26
12/LO/0482/AM12	Peruse: Global safety study with pertuzumab in Her2+ advanced BC	Substantial amendment 10 - 15t	12/01/2017	31
12/LO/0593/AM11	Daratumumab with lenalidomide and dexamethasone in multiple myeloma	IB version 13, Protocol amendment	15/11/2016	27
12/LO/0949/AM17	C16010: Phase 3 study of MLN9708 in Multiple Myeloma	NOSA 8.0 Patient Information &	09/08/2016	29
12/LO/0949/AM19	C16010: Phase 3 study of MLN9708 in Multiple Myeloma	Patient Facing Materials V 9.0	24/02/2017	27
12/LO/1138/AM06	MELCAP	Substantial Amendment No 6	26/07/2016	27
12/LO/1492/AM18	Life Study	V15.0 25 October 2016	16/11/2016	26
13/LO/0049/AM12	REPARO NGF0212 Phase I/II Neurotrophic Keratitis Trial	End of Trial PIS dated 19.12.1	31/08/2016	27
13/LO/0150/AM07	The regorafenib in patients with hepatocellular carcinoma.	Change to Sponsor - BHC to BAG	30/06/2016	25
13/LO/0150/AM08	The regorafenib in patients with hepatocellular carcinoma.	Substantial Amendment 7	05/01/2017	21
13/LO/0315/AM05	BAMI	Amendment 6.0-substantial-stud	01/12/2016	28
13/LO/0549/AM09	FG-4592 in the Treatment of Anemia in Chronic Kidney	Amendment 6 -	13/06/2016	28

	Disease Patients	13th June 2016		
13/LO/0549/AM10	FG-4592 in the Treatment of Anemia in Chronic Kidney Disease Patients	Amendment 7 - 2016/07/14	14/07/2016	25
13/LO/0549/AM12	FG-4592 in the Treatment of Anemia in Chronic Kidney Disease Patients	V4.1GBRv2.0 dated 14 Dec 2016	12/01/2017	27
13/LO/0727/AM05	LDK378 in children with malignancies that have ALK alteration	Substantial Amendment - Change	14/04/2016	24
13/LO/0727/AM06	LDK378 in children with malignancies that have ALK alteration	CLDK378X2103 Protocol amendment	25/04/2016	21
13/LO/0727/AM08	LDK378 in children with malignancies that have ALK alteration	CLDK378X2103 Protocol amendment	17/03/2017	13
13/LO/0908/AM10	Enzalutamide in Triple Negative Breast Cancer	IB Ed 9, dated 01Jun2016 - SA	26/08/2016	28
13/LO/0908/AM11	Enzalutamide in Triple Negative Breast Cancer	Protocol Am #2, v3.0, dated 09	02/02/2017	26
13/LO/1207/AM04	Stereotactic radiotherapy for wet AMD (STAR)	Substantial Amendment number 3	28/06/2016	27
13/LO/1207/AM05	Stereotactic radiotherapy for wet AMD (STAR)	Substantial Amendment number 4	24/11/2016	28
13/LO/1401/AM06	FORECAST - Focal Recurrent Assessment and Salvage Treatment	Version 5 07/12/2015	21/04/2016	25
13/LO/1437/AM07	Phase I/II study of [124I]mIBG PET/CT in neuroblastoma.	1	20/07/2016	28
13/LO/1720/AM06	Enzalutamide in Combination with Exemestane in Advanced Breast Cancer	IB Ed 9, Main ICF v4.0 SA #04	26/08/2016	28
13/LO/1943/AM08	PDOPPS	AM06 - V7.1 01-JUL-16	20/11/2016	26
14/LO/0044/AM06	EZH117208: Phase I Dose Escalation Study of GSK2816126	SA04	15/04/2016	22
14/LO/0044/AM07	EZH117208: Phase I Dose Escalation Study of GSK2816126	SA05: Updated ICF & Protocol C	01/09/2016	28
14/LO/0132/AM04	Robotic Surgery After Focal Ablation Therapy (RAFT)	Amendment 4-21Mar2016	02/08/2016	28

14/LO/0165/AM02	Sickle Cell Analgesia Protocol Evaluation (SCAPE)	Amendment 2 - 2016/05/01	03/06/2016	16
14/LO/0165/AM03	Sickle Cell Analgesia Protocol Evaluation (SCAPE)	Substantial amendment 3 dated	02/08/2016	29
14/LO/0165/AM04	Sickle Cell Analgesia Protocol Evaluation (SCAPE)	Substantial amendment 4 dated	02/08/2016	29
14/LO/0418/AM14	140470	Amendment 11.0	15/08/2016	28
14/LO/0418/AM17	140470	Substantial Amendment 13.0 Hal	09/01/2017	24
14/LO/0418/AM18	140470	SA14	21/02/2017	24
14/LO/0465/AM03	PATRIOT	Substantial amendment 03 15th	07/06/2016	26
14/LO/0465/AM04	PATRIOT	CCR4087 AM1612/39	13/02/2017	27
14/LO/0527/AM13	GO28754 Anti-PDL1 in locally advanced or metastatic NSCLC	Amendment 7 (substantial)	18/11/2016	13
14/LO/0680/AM09	MEDI4736 in NSCLC (D4191C00003, ATLANTIC Study)	Substantial Amendment	05/05/2016	26
14/LO/0680/AM14	MEDI4736 in NSCLC (D4191C00003, ATLANTIC Study)	IB ed10, Main PIS/ICF update	31/01/2017	27
14/LO/0855/AM06	673-201 Study of BMN 673 in patients with Germline BRCA mutation	Substantial Amendment	11/05/2016	20
14/LO/0855/AM07	673-201 Study of BMN 673 in patients with Germline BRCA mutation	Substantial Amendment - 29 June	01/07/2016	27
14/LO/0855/AM08	673-201 Study of BMN 673 in patients with Germline BRCA mutation	IB Update v8.0 Dated 08 July 2	18/08/2016	19
14/LO/1182/AM06	Iloprost in patients with Eisenmenger Syndrome	AM04	08/03/2017	20
14/LO/1184/AM09	Masitinib/Placebo + Gemcitabine + FOLFIRI.3 in Pancreatic Cancer V1	Substantial amendment 9	09/11/2016	25
14/LO/1184/AM10	Masitinib/Placebo + Gemcitabine + FOLFIRI.3 in Pancreatic Cancer V1	Substantial amendment 10	01/12/2016	28

14/LO/1189/AM05	Pfizer B3281006-Ph 3 PF-05280586 vs Rituximab in low tumour burden FL	Enrolment hold at trial site 2	27/05/2016	19
14/LO/1189/AM06	Pfizer B3281006-Ph 3 PF-05280586 vs Rituximab in low tumour burden FL	B3281006 Protocol Amendment 4	07/06/2016	27
14/LO/1189/AM07	Pfizer B3281006-Ph 3 PF-05280586 vs Rituximab in low tumour burden FL	Reopening of site to enrolment	27/09/2016	28
14/LO/1193/AM12	Epanova in High Cardiovascular Risk Patients with Hypertriglyceridemia	Substantial Amendment	20/06/2016	28
14/LO/1193/AM13	Epanova in High Cardiovascular Risk Patients with Hypertriglyceridemia	Substantial Amendment	28/06/2016	26
14/LO/1193/AM15	Epanova in High Cardiovascular Risk Patients with Hypertriglyceridemia	Substantial Amendment	21/12/2016	35
14/LO/1514/AM08	An Open Label Study of CORâ€”003 on the treatment of Cushing's syndrome	COR-2012-01 Patient and recruitment	13/04/2016	27
14/LO/1578/AM02	DMID 11-0069 Valgan Toddler, Version 2.0 Dated 30 May 2014	3	10/08/2016	28
14/LO/1578/AM03	DMID 11-0069 Valgan Toddler, Version 2.0 Dated 30 May 2014	4, Substantial Amendment	01/12/2016	30
14/LO/1740/AM01	VIRTUE	Amendment 1 - 29/07/2016	18/08/2016	28
14/LO/1939/AM07	Octreotide as prophylaxis for lapatinib-capecitabine related diarrhoea	Study stop communication,	09/12/2016	28
14/LO/2101/AM05	GWEP1330 - A Study of GWP42006 in people with focal seizures	Substantial amendment	03/06/2016	27
14/LO/2101/AM06	GWEP1330 - A Study of GWP42006 in people with focal seizures	Prot17_IB5_ICF7	07/12/2016	33
14/LO/2137/AM03	(INSIGHT 006: FLU-IVIG)	#4	29/06/2016	28
14/LO/2137/AM04	(INSIGHT 006: FLU-IVIG)	#5 dated 29 July 2016	29/07/2016	27
14/LO/2137/AM06	(INSIGHT 006: FLU-IVIG)	Substantial Amendment #6 27/09	27/09/2016	34
15/LO/0005/AM02	TASMA: Targets of Bronchial Thermoplasty in Severe Asthma	Amendment 2: 15th July 2016	15/07/2016	24
15/LO/0006/AM05	Open-Label Extension to the Odanacatib Fracture Trial	Substantial	11/05/2016	20

	(PN018)	Amendment Change o		
15/LO/0006/AM06	Open-Label Extension to the Odanacatib Fracture Trial (PN018)	SA09	16/08/2016	27
15/LO/0006/AM08	Open-Label Extension to the Odanacatib Fracture Trial (PN018)	SA11 Early Termination	16/09/2016	31
15/LO/0023/AM13	Cardamon trial	Cardamon substantial amendment	19/04/2016	27
15/LO/0023/AM14	Cardamon trial	Cardamon substantial amendment	17/05/2016	27
15/LO/0023/AM16	Cardamon trial	SA15	10/11/2016	27
15/LO/0023/AM17	Cardamon trial	17 - Urgent Safety Measure	20/01/2017	14
15/LO/0159/AM04	SelPac Version 1	SelPac Amendment - Amendment 0	15/11/2016	27
15/LO/0182/AM09	TIGER-3	Amendment 4 (version 5 , dated	19/10/2016	27
15/LO/0210/AM02	CR-AIR-007	AM002	07/03/2017	21
15/LO/0302/AM02	First-in-Human Study of TAK-659 in Advanced Solid Tumor and Lymphoma	C34001, Protocol Am 5.0, 04 Ma	24/06/2016	27
15/LO/0302/AM03	First-in-Human Study of TAK-659 in Advanced Solid Tumor and Lymphoma	SA3	10/11/2016	27
15/LO/0485/AM04	SuPPoRT: Stitch,Progesterone or Pessary: a randomised controlled trial	Substantial Amendment 3 – 08/	13/12/2016	29
15/LO/0500/AM02	Facet-joint feasibility study	SA2 dated 21 April 2016 - Chan	06/05/2016	18
15/LO/0500/AM03	Facet-joint feasibility study	SA3 dated 20.10.16	02/11/2016	27
15/LO/0521/AM05	Open-label Extension Study to Assess the Safety and Efficacy of AMG334	Amendment 4 dated May 2016 -	09/05/2016	23
15/LO/0521/AM06	Open-label Extension Study to Assess the Safety and Efficacy of AMG334	Substantial amendment 5	16/01/2017	26
15/LO/0703/AM03	LY2951742 in Episodic Cluster Headaches (CGAL)	Substantial	05/04/2016	16

		Amendment dated 05		
15/LO/0703/AM04	LY2951742 in Episodic Cluster Headaches (CGAL)	I5Q-MC-CGAL-IB and PISICF update	29/06/2016	33
15/LO/0703/AM07	LY2951742 in Episodic Cluster Headaches (CGAL)	Substantial Amendment - 2015/1	01/02/2017	5
15/LO/0703/AM08	LY2951742 in Episodic Cluster Headaches (CGAL)	I5Q-MC-CGAL-PISICF V6 update	14/02/2017	28
15/LO/0725/AM07	Transmission of hepatitis C virus in men who have sex with men	Substantial Amend 05 - 12 Sep	26/10/2016	14
15/LO/0894/AM03	LY2951742 in Chronic Cluster Headaches (CGAM)	Substantial Amendment dated 05	05/04/2016	16
15/LO/0894/AM05	LY2951742 in Chronic Cluster Headaches (CGAM)	I5Q-MC-CGAM-IB and PISICF update	29/06/2016	26
15/LO/0894/AM06	LY2951742 in Chronic Cluster Headaches (CGAM)	Substantial amendment dated 17	17/08/2016	26
15/LO/0894/AM09	LY2951742 in Chronic Cluster Headaches (CGAM)	Kings College Advert - Dec 2016	01/02/2017	5
15/LO/0894/AM10	LY2951742 in Chronic Cluster Headaches (CGAM)	I5Q-MC-CGAM-PISICF V6 update	14/02/2017	28
15/LO/0954/AM02	INNOVATION (EORTC 1203)	UK02 dated 10.11.16	10/11/2016	26
15/LO/0967/AM02	iNNOVATE Study: A study of ibrutinib or placebo with rituximab	Ibrutinib, Investigator's Broc	18/10/2016	24
15/LO/0967/AM03	iNNOVATE Study: A study of ibrutinib or placebo with rituximab	Ibrutinib, Investigator's Brochure, Edition 10.1 dated 08 Dec 2016	27/01/2017	28
15/LO/0986/AM02	E-learning for African Caribbean Families affected by schizophrenia	19-08-2016 V2	08/09/2016	27
15/LO/1082/AM01	The effect of oxytocin on conduct disorder & Autism Spectrum Disorder	Substantial 1	18/05/2016	25
15/LO/1082/AM03	The effect of oxytocin on conduct disorder & Autism Spectrum	Substantial 2	06/02/2017	18

	Disorder			
15/LO/1083/AM01	The effect of oxytocin on psychopathy and Autism Spectrum Disorder	Substantial Amendment 1 - May	18/05/2016	25
15/LO/1083/AM02	The effect of oxytocin on psychopathy and Autism Spectrum Disorder	Number 2. Date: 26/1/17	26/01/2017	19
15/LO/1091/AM01	MARINAC Study	1 (7/12/2016)	07/12/2016	28
15/LO/1305/AM01	Taking pART: How people decide to consent for fertility research	Substantial amendment dated 23	23/05/2016	27
15/LO/1342/AM01	ProSpare, a rectal obturator in post-prostatectomy radiotherapy v1.0	Substantial amendment 1	31/03/2016	28
15/LO/1342/AM02	ProSpare, a rectal obturator in post-prostatectomy radiotherapy v1.0	Substantial amendment 2 dated	09/02/2017	26
15/LO/1390/AM01	Cardiac and respiratory function with non-invasive ventilation	Substantial amendment 1	16/01/2017	27
15/LO/1612/AM13	1st line treatment with MEDI4736 in urothelial bladder cancer (DANUBE)	Substantial amendment 9	26/04/2016	26
15/LO/1612/AM14	1st line treatment with MEDI4736 in urothelial bladder cancer (DANUBE)	Substantial Amendment 10	28/07/2016	24
15/LO/1612/AM15	1st line treatment with MEDI4736 in urothelial bladder cancer (DANUBE)	Substantial Amendment 11	28/09/2016	34
15/LO/1612/AM17	1st line treatment with MEDI4736 in urothelial bladder cancer (DANUBE)	Substantial Amendment 12	05/01/2017	22
15/LO/1612/AM18	1st line treatment with MEDI4736 in urothelial bladder cancer (DANUBE)	Substantial Amendment 13 - CSP	02/02/2017	24
15/LO/1879/AM01	CML study comparing 2 different doses of ponatinib versus nilotinib	Substantial Amendment 1:	19/10/2016	28
15/LO/1897/AM01	VISUALISATION OF CORTICAL SPREADING DEPRESSION IN MIGRAINE AURA. V01	PROTOCOL VERSION 02.	28/06/2016	26
15/LO/1979/AM01	Use of Betashot in children and adults with epilepsy.	Substantial Amendment 1: 28/04	28/04/2016	25
15/LO/2202/AM04	The BOSS Study	Substantial	23/04/2016	27

		amendment 1.		
16/LO/0003/AM01	Trauma Organ Protection - Artesunate (TOP-ART)	Substantial Amendment July	26/07/2016	28
16/LO/0019/AM03	BESTT Women's Study	2.0 dated 21.12.16	17/01/2017	27
16/LO/0020/AM01	EE-ASI-1	EE-ASI-1 SA1b	22/04/2016	33
16/LO/0020/AM02	EE-ASI-1	EE-ASI-1 SA2	29/06/2016	26
16/LO/0020/AM03	EE-ASI-1	EE-ASI - Substantial Amendment	03/03/2017	23
16/LO/0022/AM02	Phase 1 BAX 826 Dose-Escalation Safety Study, Protocol 291501	Substantial Amendment 04 July	04/07/2016	24
16/LO/0034/AM02	BH29884 - Prophylactic RO5534262 vs no prophylaxis in Haemophilia A.	SA2 Protocol version 2, 21 Apr	11/05/2016	26
16/LO/0034/AM03	BH29884 - Prophylactic RO5534262 vs no prophylaxis in Haemophilia A.	Substantial amendment 3	02/08/2016	28
16/LO/0034/AM04	BH29884 - Prophylactic RO5534262 vs no prophylaxis in Haemophilia A.	Amendment 4 (substantial)	13/10/2016	30
16/LO/0034/AM05	BH29884 - Prophylactic RO5534262 vs no prophylaxis in Haemophilia A.	Amendment 5 (substantial)	12/01/2017	35
16/LO/0034/AM06	BH29884 - Prophylactic RO5534262 vs no prophylaxis in Haemophilia A.	6 (substantial) – Emicizumab I	16/03/2017	13
16/LO/0092/AM01	EVALUATING OBINUTUZUMAB, POLATUZUMAB VEDOTIN & LENALIDOMIDE THERAPY	Substantial Amendment 1 Addend	07/04/2016	28
16/LO/0092/AM02	EVALUATING OBINUTUZUMAB, POLATUZUMAB VEDOTIN & LENALIDOMIDE THERAPY		05/05/2016	21
16/LO/0092/AM06	EVALUATING OBINUTUZUMAB, POLATUZUMAB VEDOTIN & LENALIDOMIDE THERAPY	Substantial Amendment 4 - IB U	07/12/2016	34
16/LO/0122/AM02	Study of Pembrolizumab in Previously Treated Oesophagael Cancer	Substantial Amendment 20 March	20/03/2017	10
16/LO/0152/AM02	Evaluate the Effect of a Digital Disease Management Tool in DM Patient	Substantial Amendment 1:	04/07/2016	23
16/LO/0163/AM01	PED-MERMAIDS	Amendment	17/02/2017	6

		number 1 (17/02/17)		
16/LO/0374/AM01	PSYSCAN: Ultra High Risk	PSYSCAN_UHR_NOSA-1_20_June_201	30/06/2016	25
16/LO/0374/AM02	PSYSCAN: Ultra High Risk	PSYSCAN_UHR_NOSA-2_11 November	22/11/2016	28
16/LO/0376/AM01	PSYSCAN: First Episode Psychosis	PSYSCAN_FEP_NOSA-1_04_07_2016	18/07/2016	28
16/LO/0376/AM02	PSYSCAN: First Episode Psychosis	PSYSCAN_FEP_NOSA-2_10 November	16/10/2016	27
16/LO/0389/AM01	Assessment of newly developed observational tool.	Substantial amendment	31/05/2016	23
16/LO/0398/AM01	The Impact of Geographic Atrophy on Daily Behaviors of Individuals	1	21/05/2016	21
16/LO/0410/AM01	Sustained attention in the acute stages post stroke	Substantial amendment	08/04/2016	28
16/LO/0417/AM01	Processes of change in Cognitive Analytic Therapy (version 1)	Substantial Amendment 13.0	09/01/2017	28
16/LO/0498/AM01	NAVIGATE	Substantial Amendment 1.0,	22/12/2016	21
16/LO/0536/AM01	CRIMSON-Considering Risks and Benefits in MS Treatment Selection	Amendment number 1 dated 14 April	14/04/2016	25
16/LO/0572/AM01	Before HIV, Version 0.3.11	Substantial amendment 01	22/02/2017	26
16/LO/0581/AM01	C31004-A Phase 2, Randomised Study in Advanced Endometrial Cancer	SA#1: Protocol amendment 2 19	11/06/2016	35
16/LO/0581/AM02	C31004-A Phase 2, Randomised Study in Advanced Endometrial Cancer	SA02	10/11/2016	25
16/LO/0581/AM05	C31004-A Phase 2, Randomised Study in Advanced Endometrial Cancer	SA03 - MLN1117 IB (ed7)	10/02/2017	27
16/LO/0582/AM03	C31005 MLN0128 and MLN0128+MLN1117 Compared With	SA02	08/11/2016	27

	Everolimus in mccRCC			
16/LO/0693/AM01	BANG-CH	Substantial amendment #1 - 4th	07/11/2016	25
16/LO/0693/AM02	BANG-CH	Substantial amendment #2 -	20/12/2016	28
16/LO/0735/AM01	BH29992 - Subcutaneous emicizumab in Haemophilia A paediatric patients	Amendment 1 - Screenshots, IFU	06/07/2016	22
16/LO/0735/AM03	BH29992 - Subcutaneous emicizumab in Haemophilia A paediatric patients	SA3	14/09/2016	28
16/LO/0735/AM04	BH29992 - Subcutaneous emicizumab in Haemophilia A paediatric patients	Amendment 4 - Updated PIS	13/10/2016	28
16/LO/0735/AM05	BH29992 - Subcutaneous emicizumab in Haemophilia A paediatric patients	Amendment 5 - Protocol v3	22/12/2016	28
16/LO/0735/AM06	BH29992 - Subcutaneous emicizumab in Haemophilia A paediatric patients	SA6 dated 21.02.17	22/02/2017	27
16/LO/0769/AM01	EMR200647-001 MERCK TRAP	SA1 dated 21 Oct 2016	24/10/2016	16
16/LO/0769/AM02	EMR200647-001 MERCK TRAP	Substantial amendment 2	03/03/2017	24
16/LO/0793/AM01	1199.227 Effect of nintedanib on biomarkers	Substantial Amendment 1 dated	09/08/2016	28
16/LO/0985/AM01	CHECKpoint pathway and nivoluMAb clinical Trial Evaluation 577	SA01	11/01/2017	28
16/LO/0996/AM01	ASAS-FLARE	S.A #1, July 2016	05/07/2016	16
16/LO/1007/AM03	SEM Glove study for spinal cord injury - v1	1 dated 06.09.16	07/09/2016	28
16/LO/1173/AM01	SAFETY	1 dated 31.08.16	16/08/2016	27
16/LO/1173/AM03	SAFETY	Substantial amendment	22/02/2017	7
16/LO/1180/AM01	PHASE 3 STUDY OF AVELUMAB COMBINED WITH AXITINIB VS SUTINIB IN RCC	Protocol Amendment 3, IB,	19/10/2016	29
16/LO/1180/AM02	PHASE 3 STUDY OF AVELUMAB COMBINED WITH AXITINIB VS SUTINIB IN RCC	Substantial Amendment	19/12/2016	27
16/LO/1180/AM03	PHASE 3 STUDY OF AVELUMAB COMBINED WITH AXITINIB VS SUTINIB IN RCC	PA4, IB, ICF & Re-Start of Trial	25/01/2017	28

16/LO/1181/AM01	Phase 2 study of MHAA4549A for seasonal Influenza A infection	Substantial amendment 1	31/08/2016	27
16/LO/1181/AM03	Phase 2 study of MHAA4549A for seasonal Influenza A infection	ICF Version 3.3 dated 11.10.16	12/10/2016	28
16/LO/1181/AM04	Phase 2 study of MHAA4549A for seasonal Influenza A infection	ICF version 3.4 dated 16.11.16	17/11/2016	26
16/LO/1181/AM05	Phase 2 study of MHAA4549A for seasonal Influenza A infection	Substantial Amendment - Sites	21/12/2016	28
16/LO/1182/AM01	Women's experiences of maternity bladder care	1 dated 3 October 2016	12/10/2016	28
16/LO/1199/AM01	CA224-020 Anti-LAG-3 with Nivolumab in Advanced Soild Tumors	1	14/10/2016	26
16/LO/1199/AM02	CA224-020 Anti-LAG-3 with Nivolumab in Advanced Soild Tumors	CA224-020 GP Letter Version 1.	19/12/2016	33
16/LO/1199/AM03	CA224-020 Anti-LAG-3 with Nivolumab in Advanced Soild Tumors	Substantial Amendment 03	21/02/2017	26
16/LO/1495/AM01	SPACE	Substantial amendment	01/03/2017	2
16/LO/1505/AM01	Diabetes Stopwatch v1	Amendment 1. Dated 06.02.2017	09/02/2017	26
16/LO/1505/AM02	Diabetes Stopwatch v1	2	09/03/2017	15
16/LO/1506/AM01	Assessing frailty in older adults with functional mental illness.	Amendment number 1, date: 09/0	11/01/2017	28
16/LO/1509/AM03	Use of extended release sodium oxybate for treatment of narcolepsy.	CFLT218-1501-protocol and ICF	07/02/2017	25
16/LO/1675/AM01	M14-234 Phase 2b/3 study in Mod/Severe Ulcerative Colitis	Protocol Amendment 1	22/12/2016	27
16/LO/1676/AM01	M14-533 Ph 3 study in Mod/Severe Ulcerative Colitis Extension study	Substantial Amendment 1 (SA01)	22/12/2016	28
16/LO/1744/AM02	KIDES: safety and tolerability of ODM-203 in advanced solid tumours	Protocol Amendment #7,	17/02/2017	28
16/LO/2039/AM03	Open label study of ATX-F8-17 in male subjects with Haemophilia A	SA01 dated 30.01.17	31/01/2017	34
16/LO/2072/AM01	Children's Views on the Usability of SISOM Version 2	Amendment	07/03/2017	20

		number 1, 3/3/17		
16/LO/2076/AM01	IRMA	Substantial Amendment 1 27/02	27/02/2017	28
17/LO/0024/AM02	JPCJ: Abemaciclib in Metastatic Pancreatic Ductal Adenocarcinoma	SA1: Abemaciclib IB Ed Dec 201	09/03/2017	18
17/LO/0178/AM01	Evaluating the health burden of systemic vasculitis	AM1	06/03/2017	9
MSA RETRO 11 1 SB/AM12	Protocol to identify suitable volunteers for inclusion Retroscreen Pane	Substantial amendment number 2	25/05/2016	18
MSA RETRO 11 1 SB/AM13	Protocol to identify suitable volunteers for inclusion Retroscreen Pane	23 Dated 19OCT2016	19/10/2016	33

Unfavourable opinion				
Amendment REC Reference	**Title**	**Version**	**Date**	**Number of Days on Clock**
13/LO/0727/AM07	LDK378 in children with malignancies that have ALK alteration	6	08/11/2016	32
14/LO/1184/AM11	Masitinib/Placebo + Gemcitabine + FOLFIRI.3 in Pancreatic Cancer V1	Combined investigator's brochure	04/01/2017	33
14/LO/1514/AM09	An Open Label Study of CORâ€”003 on the treatment of Cushing's syndrome	COR-2012-01, PA6, 25Oct2016 an	01/12/2016	34
14/LO/2036/AM03	WP29158-MPDL3280A & Erlotinib in advanced Non-Small Cell Lung Cancer	3	24/08/2016	34
15/LO/0182/AM07	TIGER-3	Substantial Amendment - Protocol	15/04/2016	34
15/LO/0528/AM03	Wearable technology to monitor paediatric diseases	Amendment 2 18/3/2016	15/08/2016	29
16/LO/1509/AM01	Use of extended release sodium oxybate for treatment of narcolepsy.	Substantial Amendment 01	01/12/2016	34

Table 10.2: **Breakdown of current status of all modified amendments reviewed within the reporting period**

Favourable opinion timeline				
Amendment REC Reference	**Title**	**Version**	**Date**	**Number of Days on Clock**
13/LO/0727/AM07/1	LDK378 in children with malignancies that have ALK alteration	Modified amendment dated 9 Jan	09/01/2017	7
14/LO/1184/AM11/1	Masitinib/Placebo + Gemcitabine + FOLFIRI.3 in Pancreatic Cancer V1	Modified Amendment- AM12 -Comb	21/02/2017	10
14/LO/1514/AM09/1	An Open Label Study of CORâ€"003 on the treatment of Cushing's syndrome	Modified amendment dated 06.01	06/01/2017	6
14/LO/2036/AM03/1	WP29158-MPDL3280A & Erlotinib in advanced Non-Small Cell Lung Cancer	Substantial Amendment 3- Modified	16/02/2017	12
15/LO/0528/AM03/1	Wearable technology to monitor paediatric diseases	Modified amendment dated 19.09.16	19/09/2016	13
16/LO/1509/AM01/1	Use of extended release sodium oxybate for treatment of narcolepsy.	Modified Substantial Amendment	19/01/2017	13

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

Table 11: **Items exceeding timelines**

Full applications for ethical review over 60 day timeline		
REC Reference	**Title**	**Number of Days on Clock**
17/LO/0374	EASE Study	64

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

SSAs (non Phase 1) over 25 day timeline		
REC Reference	**Title**	**Number of Days on Clock**
16/LO/1813	Longitudinal Investigation of	40

SSAs (Phase 1) over 14 day timeline		
REC Reference	**Title**	**Number of Days on Clock**

Substantial Amendments over 35 day timeline				
Amendment REC Reference	**Title**	**Version**	**Date**	**Number of Days on Clock**

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