



*Health Research Authority*

Research Ethics Service

**London - City & East Research Ethics Committee**

**Annual Report**

**01 April 2017 - 31 March 2018**



## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	London - City & East Research Ethics Committee
<b>Type of REC:</b>	Type III (CTIMP)
<b>Type of Flag:</b>	CTIMP, Phase 1 in Patients, IRB
<b>Chair:</b>	Dr John Keen
<b>Vice-Chair:</b>	Dr Kieran McCafferty
<b>Alternate Vice-Chair:</b>	Dr Ayse Baxter
<b>REC Manager:</b>	Mr Rajat Khullar
<b>REC Assistant:</b>	Ms Rebecca Howling
<b>Committee Address:</b>	Bristol Research Ethics Committee Centre Whitefriars Level 3, Block B Lewins Mead Bristol BS1 2NT
<b>Telephone:</b>	02071048033/53
<b>Email:</b>	nrescommittee.london-cityandeast@nhs.net

**Chair's overview of the past year:**

### 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	30/09/2017
Dr Ayse Baxter	Pharmaceutical Physician	Expert	30/06/2007	
Dr Luis Beltran	Consultant Histopathologist	Expert	01/05/2014	
Ms Ann Black	Health Economist/Psychosocial Researcher	Lay Plus	01/04/2018	
Mr Frank Cross	Consultant General and Vascular Surgeon	Expert	13/11/2008	
Ms Alison Eden	Manager Patient Recruitment	Lay Plus	06/01/2015	
Ms Elizabeth Hall	Vice Chair, Standards and Quality Assurance Committees	Lay Plus	01/04/2016	
Professor Joy Hinson	Independent Consultant/Retired Endocrine Scientist	Lay	01/03/2018	
Mr Fasahat Hussain	Solicitor	Lay Plus	21/09/2017	
Mrs Lisa Johnson	Head of Clinical Operations	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	
Dr Kieran McCafferty	Nephrologist Consultant/Hon Senior Lecturer	Expert	01/09/2015	
Dr Paul Metcalfe	Research Scientist - immunohaematology	Lay	01/07/2017	
Dr Wolfgang Meyer	Honorary senior clinical lecturer, Consultant psychiatrist and psychotherapist	Expert	21/01/2016	
Ms Anna (Rengqian) Song	Pharmacist	Expert	01/01/2016	

### London - City & East Research Ethics Committee: Deputy Members

Name	Profession	Status	Meeting date attended
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### London - City & East Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended
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**London - City & East Research Ethics Committee: Members' Declarations of Interest:**

<b>Name</b>	<b>Declaration of Interest</b>	<b>Date</b>
Dr Marie E Bardsley	Director E-Med - Unpaid publication of research	01/03/2018
Dr Ayse Baxter	ISA+SIPP Investments - Becton Dickenson, J&J, Novonordisk	01/03/2018
Dr Luis Beltran	Lead Clinician of Pathogenomics Ltd. Member of London Cancer Urology Pathway Board	01/03/2018
Ms Ann Black	None	01/03/2018
Professor Joy Hinson	None	01/03/2018
Mr Fasahat Hussain	None	01/03/2018
Dr John Keen	None	01/03/2018
Dr Kieran McCafferty	Deputy Director Barts Health R&D Divisional Director medicine Research Barts Health NHS Trust Peer Review Lead Renal Dept Barts Health NIHR Specialty Lead Renal	01/03/2018
Dr Paul Metcalfe	None	04/07/2017
Dr Wolfgang Meyer	None	01/06/2017
Mr Frank Cross	None	01/03/2018
Ms Lisa Johnson	Shares in AstraZeneca. Employee of Pharma	01/03/2018
Ms Elizabeth Hall	Queen Mary University of London fellow and Ex Vice Chair or Committee. Trustee of Tower Hamlets Friends and Neighbourhood Charity	05/10/2017

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

Month	Date	Number of Members Present at Meeting
April	06/04/2017	12
May	04/05/2017	11
June	01/06/2017	8
July	06/07/2017	9
September	07/09/2017	8
October	05/10/2017	12
December	07/12/2017	12
January	04/01/2018	11
February	01/02/2018	12
March	01/03/2018	10

10 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	20/04/2017	3
May	18/05/2017	3
June	15/06/2017	3
July	20/07/2017	3
September	21/09/2017	5
October	19/10/2017	6
November	16/11/2017	6
December	08/12/2017	3
January	12/01/2018	7
February	09/02/2018	6
March	09/03/2018	7

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	10/04/2017	3
April	26/04/2017	2
May	05/05/2017	2
May	19/05/2017	2
May	25/05/2017	3
June	02/06/2017	4
June	16/06/2017	6
July	03/07/2017	4
July	17/07/2017	4
July	28/07/2017	4

August	11/08/2017	4
August	25/08/2017	4
September	08/09/2017	5
September	22/09/2017	5
October	02/10/2017	4
October	16/10/2017	7
October	30/10/2017	6
November	10/11/2017	6
November	24/11/2017	2
November	27/11/2017	2
December	11/12/2017	5
December	28/12/2017	5
January	08/01/2018	3
January	26/01/2018	4
February	09/02/2018	5
February	16/02/2018	4
March	02/03/2018	5
March	19/03/2018	7
March	31/03/2018	4

29 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 Marie E Bardsley	9
Ms Clare Barron	6
Ms Jane Batchelor	4
Dr Ayse Baxter	8
Dr Luis Beltran	7
Mr Frank Cross	6
Ms Alison Eden	5
Ms Elizabeth Hall	8
Professor Joy Hinson	1
Mr Fasahat Hussain	5
Mrs Lisa Johnson	7
Dr John Keen	9
Mr John Lynch	8
Dr Kieran McCafferty	8
Dr Paul Metcalfe	6
Dr Wolfgang Meyer	1
Ms Anna (Renqian) Song	7

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

Name	Number of Meetings Attended
Ms Clare Barron	1
Ms Jane Batchelor	2
Dr Ayse Baxter	4
Ms Alison Eden	5
Ms Elizabeth Hall	2
Mrs Lisa Johnson	5
Dr John Keen	11
Mr John Lynch	9
Dr Kieran McCafferty	6
Dr Paul Metcalfe	3
Ms Anna (Renqian) Song	4

Commented [TL1]: can't find incorrect contact to merge so done manually.

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

Name	Number of Meetings Attended
Dr Marie E Bardsley	3
Dr Ayse Baxter	26



Dr Luis Beltran	1
Ms Alison Eden	4
Ms Elizabeth Hall	3
Mrs Lisa Johnson	7
Dr John Keen	29
Dr Kieran McCafferty	19
Dr Paul Metcalfe	9
Ms Anna (Renqian) Song	20

### Training 01 April 2017 - 31 March 2018

Name of Member	Date	Event(s) attended
Dr Marie E Bardsley	11/04/2017	Local Training Day - London - Harrow
Ms Clare Barron	11/04/2017	Local Training Day - London - Harrow
Ms Jane Batchelor	25/07/2017	from War Crime Trials to Clinical Trials
Dr Ayse Baxter	11/04/2017	Local Training Day - London - Harrow
Dr Ayse Baxter	17/10/2017	Training - Training for New REC Chairs
Dr Luis Beltran	30/11/2017	Digital Pathology Conference
Mr Frank Cross	11/04/2017	Local Training Day - London - Harrow
Mr Frank Cross	18/03/2018	Equality, Diversity & Human Rights
Ms Elizabeth Hall	11/04/2017	Local Training Day
Dr John Keen	11/04/2017	Local Training Day - London - Harrow
Dr Kieran McCafferty	17/10/2017	Training for New REC Chairs
Dr Paul Metcalfe	16/11/2017	Committee Members Induction
Ms Alison Eden	10/03/2017	E-Consent Workshop
Ms Anna (Renqian) Song	08/08/2017	Introduction to Good Clinical Practice eLearning (Secondary Care)
Ms Anna (Renqian) Song	09/08/2017	Introduction to GCP for IMP Management (Pharmacy)
Ms Anna (Renqian) Song	22/01/2018	Medical Devices Training

Commented [TL2]: Ms Ann Black – New member. Has booked for induction July 2018  
Mr Fasahat Hussain – New member. Has booked for induction July 2018

## 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	49.15
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	1	1.69
Others	29	49.15
<b>Total Applications Reviewed</b>	<b>59</b>	<b>100</b>

**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	16
Number of paediatric applications reviewed	16
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	1
Number of qualitative applications reviewed	2

Commented [TL3]:  
relates to 17/LQ/0893  
flagged with REC manager and investigating

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

Decisions taken at meetings following review of applications	Number	%
Favourable Opinion with Standard Conditions	4	6.78
Favourable Opinion with Additional Conditions	17	28.81
Unfavourable Opinion	6	10.17
Provisional Opinion	28	47.46
Provisional Opinion Pending Consultation with Referee	4	6.78
<b>Total</b>	<b>59</b>	<b>100</b>
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	47.46
Further Information Favourable Opinion with Additional Conditions	1	1.69
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	4	6.78
Favourable Opinion with Additional Conditions	17	28.81
Unfavourable Opinion	6	10.17
Provisional Opinion	1	1.69
Provisional Opinion Pending Consultation with Referee	0	0.00
Further Information response not complete	1	1.69
No decision entered on system	0	0.00
Number of studies withdrawn after the meeting	0	0.00
<b>Total</b>	<b>59</b>	<b>100</b>

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

<b>Total Applications Reviewed</b>	<b>42</b>
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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	4
Number of student applications reviewed	18
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**

<b>Decisions taken at proportionate review sub-committee meetings</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	27	64.29
Favourable Opinion with Additional Conditions	7	16.67
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	8	19.05
Unfavourable Opinion	0	0.00
<b>Total</b>	<b>42</b>	<b>100</b>

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

<b>Average number of applications reviewed per full meeting</b>	5.90
<b>Number of completed applications for full ethical review</b>	59
<b>Number of completed applications for full ethical review over 60 days</b>	0
<b>Number of completed applications over 60 days as a % of total</b>	0.00%
<b>Number of completed applications for full ethical review over 40 days</b>	9
<b>Number of completed applications over 40 days as a % of total</b>	15.25%
<b>Number of days taken to final decision – average (mean)</b>	34
<b>Number of completed proportionate review applications for ethical review</b>	42
<b>Number of completed proportionate review applications for ethical review over 21 days</b>	0
<b>Number of completed proportionate review applications over 21 days as a % of total</b>	0.00%
<b>Number of SSAs (non-Phase 1) reviewed</b>	8
<b>Number of completed applications for SSA review over 25 days</b>	0
<b>Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs</b>	0.00%
<b>Number of SSAs (Phase 1) reviewed</b>	0
<b>Number of completed applications for SSA review over 14 days</b>	0
<b>Number of completed applications for SSA review over 14 days as % of all Phase 1 SSAs</b>	0.00%
<b>Number of substantial amendments reviewed</b>	213
<b>Number of completed substantial amendments over 35 days</b>	3
<b>Number of completed substantial amendments over 35 days as a % of total substantial amendments</b>	1.41%
<b>Number of completed substantial amendments over 28 days</b>	87
<b>Number of completed substantial amendments over 28 days as a % of total substantial amendments</b>	40.85%
<b>Number of modified amendments reviewed</b>	4
<b>Number of completed modified amendments over 14 days</b>	0
<b>Number of completed modified amendments over 14 days as a % of total modified amendments</b>	0.00%
<b>Number of non substantial amendments received</b>	116
<b>Number of substantial amendments received for information</b>	1
<b>Number of substantial amendments received for new sites/PIs</b>	49
<b>Number of annual progress reports received</b>	81
<b>Number of safety reports received</b>	37
<b>Number of Serious Adverse Events received</b>	0

Number of final reports received	4
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**Table 9.1: Breakdown of current status of all full applications reviewed within the reporting period**

<b>Further Information Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
17/LO/0573	1368.10: BI655130 add-on in patients with UC during TNFi therapy	52
17/LO/0869	Understanding repetitive worries and responses in neonatal parents V1	40
17/LO/0882	CastleCreek - Diacerein Ointment - CCP-020-301	37
17/LO/0889	Double blind study of Axitinib in progressive advanced G1-G2 NETs	33
17/LO/0893	Hu5F9-G4 + Rituximab in Relapsed/Refractory B Cell NHL	45
17/LO/1018	STRONG Study	31
17/LO/1060	SUBsensory Sacral Neuromodulation for InContinence - SUBSoNIC	55
17/LO/1065	MK-8504 Single Dose Study in HIV-1 Infected Patients	33
17/LO/1086	Loxo15003 - Paediatric CNS	52
17/LO/1278	Fish Oil Supplementation On Maternal Health (FOSMAT)	44
17/LO/1429	CLR_15_03 Activity of K0706 Leukaemia	36
17/LO/1451	Sotagliflozin vs. Placebo added to insulin +/- other OADs in T2DM	31
17/LO/1622	Inotuzumab Ozogamicin for treatment of pediatric BCP-ALL	43
17/LO/1671	The genetic basis of heritable corneal disease	33
17/LO/1758	ECLIPSE: Preoperative immunotherapy combinations in breast cancer	21
17/LO/1989	Proof of Concept Study of ACH 0144471 in Untreated Patients With PNH	42
17/LO/2064	Phase 2 study of BGB-3111 and Obinutuzumab in Follicular Lymphoma	32
17/LO/2107	Cytokines in anorexia nervosa	33
18/LO/0021	EACH	37
18/LO/0050	Unique features of under-recognised eating disorder groups	39
18/LO/0052	A study to evaluate JNJ-64300535 DNA vaccine in chronic Hepatitis B	46
18/LO/0064	The Paediatric Intensive Care (PICU) adolescent experience study.	34
18/LO/0128	Digital Medicine System	38
18/LO/0133	MIAMI - Safe Surgery for multiple breast cancers	40
18/LO/0143	TARGET AF study	23
18/LO/0152	HepaVac-101 trial with IMA970A plus CV8102 in HCC patients	33
18/LO/0353	Exploring narratives of young people after the Tree of Life group	43
18/LO/0364	Nalu Medical NAL-02-2016-FS SCS Feasibility trial	29

<b>Further Information Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>



17/LO/0871	MePFAC	39
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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
17/LO/0556	Head or Heart Study - A dormant trial linkage feasibility study	30
17/LO/0979	Explorers' Participation and Well-being	28
17/LO/1676	COSMoS version 1.0, January 2017	28
17/LO/1711	Synbiotic Extensively Hydrolysed Feed Study	28

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
17/LO/0486	Esperion 1002-048 (Bempedoic Acid (ETC-1002)	32
17/LO/0571	Nutrient intake in UK paediatric intestinal transplant recipients	32
17/LO/0572	Readyfusor health economics study	27
17/LO/0741	MOVES-PD	30
17/LO/0747	Investigating Unexplained Sudden Cardiac Death	28
17/LO/0768	The Lived Experience of Patients following Primary Angioplasty	31
17/LO/0770	Postnatal Contraception - Views of women on a postnatal ward	28
17/LO/0891	DIOS Study	28
17/LO/1372	RAPID-1 Diabetic Foot Ulcer Study [Version 1.0]	28
17/LO/1447	Bedside ultrasound scan for screening of arterial disease in diabetes	28
17/LO/1624	Effect of dietary nitrate ingestion in Heart Failure (DiNOmo-HF)	28
17/LO/2004	SUMMIT Study	28
17/LO/2038	TRITON- Macitentan, Tadalafil and Selexipag Study in Patients with PAH	27
17/LO/2052	POLYP I – Chronic RhinoSinusitis with Nasal Polyps with Omalizumab	28
18/LO/0019	Emotional adjustment after ABI	28
18/LO/0141	OPINION, Olaparib Maintenance Monotherapy Ovarian Cancer.	28
18/LO/0149	MO39193 - Atezolizumab + Chemotherapy in early relapsing TNBC	28

Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock
17/LO/0557	CTMT212X2102 Study of Trametinib in female patients with solid tumours	32
17/LO/0651	Fish Oil Supplementation On Maternal Health (FOSMAT)	29
17/LO/1453	SPRINT study	28
17/LO/1665	TARGET AF study	29
17/LO/2063	CALIBRATION	27
18/LO/0360	CALIBRATION	36

Provisional Opinion		
REC Reference	Title	Number of Days on Clock
18/LO/0320	EMERGE	n/a

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

Further information response not complete		
REC Reference	Title	Number of Days on Clock
18/LO/0352	CA017-063: BMS-986205 and Nivolumab versus chemotherapy in SCCHN	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/0714	Molecular and cellular analysis of inflammatory arthritis	12
17/LO/0864	Benefit extraction & realisation & the diagnostic radiological image	20
17/LO/1277	GP and nurse communication study_220517	14

17/LO/1631	Debris extrusion from root canals during root canal shaping	13
18/LO/0118	Small molecules and activation of heart recovery after injury	20
18/LO/0262	Hallucinations and Modality-Specific Biases	19
18/LO/0415	Human samples in laboratory research	12
18/LO/0510	Investigating Health Literacy Differences in London	20

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

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
17/LO/0706	SPIRIT - Survey of Patients with Resistant Hypertension	12
17/LO/0707	Cardiac biomarkers in patients with chronic kidney disease	7
17/LO/0722	SleepSoundly v2	13
17/LO/1013	The Neurobiology of Post-Exertional Fatigue in Patients with ME/CFS	13
17/LO/1024	TICON Day -3	18
17/LO/1111	Investigation of TEG6 in Parturients Attending for Operative Delivery	11
17/LO/1275	Refining breast cancer risk materials and optimising care pathways	7
17/LO/1279	Nutritional Scoring Systems and Outcomes in Vascular Patients	12
17/LO/1639	Pediatric International Nutrition Study 2018	11
17/LO/1818	Ex-vivo evaluation of the Polymeric Heart Valve	1
17/LO/1822	Impact of neonatal inter-hospital transport	20
17/LO/1824	Caspase-8 availability in oral cancer	13
17/LO/1855	Spinal Cord Independence Measure, Version IV: Validity and Reliability	21
17/LO/1991	The effects of different popular diets on the metabolic profile	19
17/LO/1994	CMV infection in HSCT recipients	2
17/LO/2003	Spectra Retrospective Chart Review	15
17/LO/2089	Use of FGFRi assay to determine eligibility for trial enrolment	18
17/LO/2090	NeuroGait	10
17/LO/2092	Clinical Usefulness of Wideband Absorbance in Children	19

18/LO/0109	Does CPAP Treatment Reduce Depression in OSA?	19
18/LO/0110	Evaluating how lung cancer patient experiences affect outcomes	12
18/LO/0115	ACTIVATE V1	19
18/LO/0258	Critical Analysis of the Nocturnal Distribution of Light Exposure	18
18/LO/0260	RiskReductionInterventionWithMDOs	18
18/LO/0264	Body contouring surgery outcomes in the post-bariatric population	21
18/LO/0300	What influences paramedic's to administer analgesia.	19
18/LO/0428	Patient perceptions of physical activity in SLE	20

#### **Favourable Opinion with Additional Conditions**

<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
17/LO/0873	The Trauma Recovery Empowerment Model (TREM): A Qualitative Study	19
17/LO/0874	PREPS - Vaginal Preparation at caesarean section.	15
17/LO/1274	Predictors of depression in people with Ulcerative Colitis - Version 1	7
17/LO/1634	Fluorescent LN target in colorectal cancer	13
17/LO/1645	Hepcasus	15
17/LO/1998	SVP	14
18/LO/0436	The biomechanical assessment of balance and gait for stroke patients	21

#### **Unfavourable Opinion**

<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
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#### **Provisional Opinion**

<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
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#### **Further information response not complete**

<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
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#### **Withdrawn after the meeting**

<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
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**Table 10.1: Breakdown of current status of all substantial amendments reviewed within the reporting period**

<b>Favourable opinion</b>				
<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>
04/Q0603/1/AM65	ASPECT	SA 132	14/06/2017	28
05/Q0603/9/AM04	Skin cancer and epidermolysis bullosa Version 1	4	05/02/2018	17
06/Q1603/7/AM17	Chemoprevention of Premalignant Intestinal Neoplasia	13	26/04/2017	27
08/H0704/128+5/AM04	Brains for Dementia Research	08/H0704/128+5 Amendment 3 07/	07/03/2018	12
10/H0703/45/AM10	CAR-PET	SA08	04/07/2017	32
10/H0703/6/AM06	Assessment of Cough Intensity	5	31/05/2017	4
10/H0703/98/AM03	Inorganic nitrate in resistant hypertension	3	19/07/2017	11
11/LO/1595/AM14	FGFR	SUBSTANTIAL AMENDMENT 15 - STU	30/03/2017	28
11/LO/1595/AM15	FGFR	SUBSTANTIAL AMENDMENT 16 - RE	12/05/2017	3
11/LO/1921/AM16	MO27775 PERTAIN Study	Amendment #12 (substantial) -	23/03/2017	28
12/LO/0482/AM13	Peruse: Global safety study with pertuzumab in Her2+ advanced BC	Amendment 11 (substantial) - u	29/03/2017	28
12/LO/0498/AM01	The Genetics of Congenital Vascular Anomalies	AM1 Jan 2018	25/01/2018	7
12/LO/0593/AM15	Daratumumab with lenalidomide and dexamethasone in multiple myeloma	Substantial Amendment 2	14/02/2018	35
12/LO/0949/AM20	C16010: Phase 3 study of MLN9708 in Multiple Myeloma	IB Edition 11 dated 27 July 20	28/02/2018	15
13/LO/0549/AM15	FG-4592 in the Treatment of Anemia in Chronic Kidney Disease Patients	9.0	28/04/2017	-5
13/LO/0582/AM08	Abiraterone with Different Steroid Regimens in Prostate Cancer	Substantial Amendment 8 - 2120	12/12/2017	35
13/LO/0582/AM09	Abiraterone with Different Steroid Regimens in Prostate Cancer	AM7	31/10/2017	4
13/LO/0582/AM10	Abiraterone with Different Steroid Regimens in Prostate Cancer	212082PCR2023 SA-9 (CI Change)	29/01/2018	22

13/LO/1207/AM08	Stereotactic radiotherapy for wet AMD (STAR)	5	15/08/2017	28
13/LO/1401/AM11	FORECAST - Focal Recurrent Assessment and Salvage Treatment	6	01/08/2017	28
13/LO/1437/AM08	Phase I/II study of [124I]mIBG PET/CT in neuroblastoma.	11	26/06/2017	14
13/LO/1720/AM09	Enzalutamide in Combination with Exemestane in Advanced Breast Cancer	06	02/03/2018	21
13/LO/1943/AM10	PDOPPS	08	14/08/2017	35
14/LO/0044/AM11	EZH117208: Phase I Dose Escalation Study of GSK2816126	7	11/04/2017	33
14/LO/0044/AM12	EZH117208: Phase I Dose Escalation Study of GSK2816126	SA08	13/07/2017	19
14/LO/0122/AM09	Safety, tolerability & pharmacokinetics of regorafenib in paediatrics	Expansion Phase - Clinical Study Protocol V4.0	08/08/2017	30
14/LO/0122/AM11	Safety, tolerability & pharmacokinetics of regorafenib in paediatrics	Expansion Phase	29/05/2017	30
14/LO/0132/AM07	Robotic Surgery After Focal Ablation Therapy (RAFT)	SA5.0	05/05/2017	23
14/LO/0141/AM07	iMAP2	1	07/08/2017	26
14/LO/0141/AM08	iMAP2	SA 04 Jan 2018	04/01/2018	29
14/LO/0165/AM05	Sickle Cell Analgesia Protocol Evaluation (SCAPE)	5	19/10/2017	33
14/LO/0165/AM06	Sickle Cell Analgesia Protocol Evaluation (SCAPE)	9	15/02/2018	22
14/LO/0465/AM05	PATRIOT	AM05	04/09/2017	32
14/LO/0527/AM14	GO28754 Anti-PDL1 in locally advanced or metastatic NSCLC	Amendment 8( Substantial) UK P	16/05/2017	28
14/LO/0527/AM15	GO28754 Anti-PDL1 in locally advanced or metastatic NSCLC	9	31/07/2017	16
14/LO/0527/AM16	GO28754 Anti-PDL1 in locally advanced or metastatic NSCLC	SA 10 - Atezo IB and PIS/ICF U	19/12/2017	28
14/LO/0680/AM15	MEDI4736 in NSCLC (D4191C00003, ATLANTIC Study)	IB Ed11, updated Re-Treatment	02/08/2017	31
14/LO/0680/AM16	MEDI4736 in NSCLC (D4191C00003, ATLANTIC Study)	Protocol Amendment 5, updated	09/10/2017	35
14/LO/1182/AM07	Iloprost in patients with Eisenmenger Syndrome	5	27/04/2017	28
14/LO/1184/AM12	Masitinib/Placebo + Gemcitabine + FOLFIRI.3 in Pancreatic Cancer V1	13	04/07/2017	16
14/LO/1185/AM02	Testing a new stepwise strategy for the management of renal anaemia	2	03/07/2017	0
14/LO/1193/AM21	Epanova in High Cardiovascular Risk Patients with	SA - Appreciation	25/05/2017	11

	Hypertriglyceridemia	Items		
14/LO/1193/AM22	Epanova in High Cardiovascular Risk Patients with Hypertriglyceridemia	SA16 - Patient eNewsletter	28/07/2017	4
14/LO/1193/AM23	Epanova in High Cardiovascular Risk Patients with Hypertriglyceridemia	New legislation in the EU rega	19/01/2018	26
14/LO/1443/AM04	Pyrenees		31/03/2017	28
14/LO/1443/AM05	Pyrenees	Protocol v3.0	30/05/2017	31
14/LO/1443/AM07	Pyrenees	1517-CL-0613 – Substantial Ame	15/01/2018	28
14/LO/1736/AM01	Stress Echocardiography vs Exercise ECG in women with chest pain	1	14/08/2017	32
14/LO/1786/AM03	CapaCiTY Study 1- Chronic Constipation Treatment Pathway	SA2	22/03/2017	28
14/LO/2036/AM05	WP29158-MPDL3280A & Erlotinib in advanced Non-Small Cell Lung Cancer	SA4 - Alectinib IB v7.0, v7.0	20/12/2017	28
14/LO/2101/AM07	GWEP1330 - A Study of GWP42006 in people with focal seizures	7	26/04/2017	30
15/LO/0023/AM20	Cardamon trial	18 - Protocol v5 PET sub-study	05/04/2017	35
15/LO/0159/AM05	SelPac Version 1	Amendment 5	13/07/2017	14
15/LO/0159/AM06	SelPac Version 1	6	09/03/2018	10
15/LO/0182/AM12	TIGER-3	8	23/10/2017	10
15/LO/0187/AM02	Acoustic analysis of nasal airflow in normal and abnormal subjects(V2)	SA1	03/05/2017	8
15/LO/0302/AM04	First-in-Human Study of TAK-659 in Advanced Solid Tumor and Lymphoma	SA04 - Protocol Amendment 6, I	20/06/2017	31
15/LO/0363/AM01	The role of LLT1 in immune evasion and hepatocellular carcinoma	1	04/04/2017	43
15/LO/0367/AM03	Improving auditory outcomes	3	19/09/2017	24
15/LO/0545/AM06	CARAT - RTSY03	AM 4	29/06/2017	0
15/LO/0609/AM03	CapaCiTY Study 3- Chronic Constipation Treatment Pathway	2	30/03/2017	28
15/LO/0703/AM09	LY2951742 in Episodic Cluster Headaches (CGAL)	7	30/03/2017	34
15/LO/0725/AM08	Transmission of hepatitis C virus in men who have sex with men	Substantial Amend 06, 03Mar201	03/03/2017	35
15/LO/0732/AM04	CapaCiTY Study 2- Chronic Constipation Treatment Pathway	Amendment 2,dated 24 March 201	24/03/2017	28

15/LO/0736/AM03	Principal Component Analysis in Medical Image Processing	2	09/03/2017	7
15/LO/0894/AM11	LY2951742 in Chronic Cluster Headaches (CGAM)	7	30/03/2017	34
15/LO/0894/AM12	LY2951742 in Chronic Cluster Headaches (CGAM)	ICF V8 and IB2017 Substantial	04/12/2017	22
15/LO/0966/AM02	Acceptability of alternate-day in-centre haemodialysis: an evaluation	One1¼ 1st September 2017	01/09/2017	28
15/LO/0967/AM06	iNNOVATE Study: A study of ibrutinib or placebo with rituximab	05Feb2017	07/02/2018	31
15/LO/0986/AM03	E-learning for African Caribbean Families affected by schizophrenia	14/09/2017 V3	14/09/2017	28
15/LO/1305/AM05	Taking pART: How people decide to consent for fertility research	5	14/08/2017	35
15/LO/1342/AM03	ProSpare, a rectal obturator in post-prostatectomy radiotherapy v1.0	Amendment No. 3, Dated 7th Dec	07/12/2017	28
15/LO/1367/AM01	Retro-Mapping of transient & planar wavefronts in atrial fibrillation	1	20/09/2017	34
15/LO/1367/AM02	Retro-Mapping of transient & planar wavefronts in atrial fibrillation	2nd amendment	31/08/2017	28
15/LO/1524/AM02	Biomet nSTRIDE	Amendment 1, Version 3, 3 Augu	03/08/2017	27
15/LO/1612/AM19	1st line treatment with MEDI4736 in urothelial bladder cancer (DANUBE)	SA14	24/05/2017	28
15/LO/1612/AM20	1st line treatment with MEDI4736 in urothelial bladder cancer (DANUBE)	15	24/10/2017	26
15/LO/1612/AM21	1st line treatment with MEDI4736 in urothelial bladder cancer (DANUBE)	Substantial Amendment 16	20/12/2017	28
15/LO/1663/AM01	A pilot study on the value of orthodontic treatment within society	1	01/03/2018	18
15/LO/1979/AM02	Use of Betashot in children and adults with epilepsy.	2	30/03/2017	34
15/LO/1979/AM04	Use of Betashot in children and adults with epilepsy.	Substantial Amendment 3, 16/10	16/10/2017	33
15/LO/2055/AM01	Effects of hospitalisation on acute exacerbations of airways disease	2	09/08/2017	22
15/LO/2055/AM02	Effects of hospitalisation on acute exacerbations of airways disease	3 - 20.02.18	20/02/2018	28
15/LO/2065/AM01	The role of lipids in immune cell function in SLE patients	4	18/07/2017	21



15/LO/2202/AM09	The BOSS Study	9 (2nd substantial amendment)	20/04/2017	24
15/LO/2202/AM10	The BOSS Study	10 (3rd substantial amendment)	22/12/2017	27
16/LO/0003/AM02	Trauma Organ Protection - Artesunate (TOP-ART)	2.1	25/04/2017	30
16/LO/0003/AM03	Trauma Organ Protection - Artesunate (TOP-ART)	009531 - Substantial Amendmen	29/01/2018	24
16/LO/0019/AM07	BESTT Women's Study	SA 4 - Changes to Protocol and	14/12/2017	28
16/LO/0020/AM04	EE-ASI-1	5	16/05/2017	34
16/LO/0020/AM07	EE-ASI-1	SA8	20/11/2017	22
16/LO/0034/AM07	BH29884 - Prophylactic RO5534262 vs no prophylaxis in Haemophilia A.	7 (substantial) – PIS/ICF v5.0	14/12/2017	29
16/LO/0092/AM07	EVALUATING OBINUTUZUMAB, POLATUZUMAB VEDOTIN & LENALIDOMIDE THERAPY	SA5	20/04/2017	33
16/LO/0092/AM09	EVALUATING OBINUTUZUMAB, POLATUZUMAB VEDOTIN & LENALIDOMIDE THERAPY	6	25/08/2017	28
16/LO/0092/AM10	EVALUATING OBINUTUZUMAB, POLATUZUMAB VEDOTIN & LENALIDOMIDE THERAPY	Substantial Amendment 8 – Upda	29/09/2017	20
16/LO/0092/AM12	EVALUATING OBINUTUZUMAB, POLATUZUMAB VEDOTIN & LENALIDOMIDE THERAPY	Substantial Amendment 9	31/01/2018	28
16/LO/0122/AM04	Study of Pembrolizumab in Previously Treated Oesophagael Cancer	SA04 - IB15	09/11/2017	22
16/LO/0122/AM05	Study of Pembrolizumab in Previously Treated Oesophagael Cancer	SA05 - Change in length of stu	04/12/2017	25
16/LO/0160/AM01	Influence of dietary nitrate on skin inflammation	1	31/08/2017	24
16/LO/0374/AM03	PSYSCAN: Ultra High Risk	SA3	15/05/2017	6
16/LO/0374/AM04	PSYSCAN: Ultra High Risk	4	20/06/2017	13
16/LO/0376/AM03	PSYSCAN: First Episode Psychosis	3	15/05/2017	7
16/LO/0376/AM04	PSYSCAN: First Episode Psychosis	4	20/06/2017	13
16/LO/0498/AM03	NAVIGATE	2.0, 24-MAR-2017	24/03/2017	28
16/LO/0498/AM05	NAVIGATE	3.0, 25th Jan 2018	29/01/2018	30
16/LO/0581/AM08	C31004-A Phase 2, Randomised Study in Advanced Endometrial Cancer	Protocol C31004 Amendment 03	31/05/2017	28

16/LO/0581/AM10	C31004-A Phase 2, Randomised Study in Advanced Endometrial Cancer	05 - Change of CI	04/08/2017	32
16/LO/0581/AM12	C31004-A Phase 2, Randomised Study in Advanced Endometrial Cancer	SA06	16/10/2017	28
16/LO/0581/AM13	C31004-A Phase 2, Randomised Study in Advanced Endometrial Cancer	SA07	22/12/2017	31
16/LO/0581/AM14	C31004-A Phase 2, Randomised Study in Advanced Endometrial Cancer	SA 8 - Protocol C31004 Amendme	14/03/2018	14
16/LO/0582/AM08	C31005 MLN0128 and MLN0128+MLN1117 Compared With Everolimus in mcrRCC	4	06/06/2017	24
16/LO/0582/AM10	C31005 MLN0128 and MLN0128+MLN1117 Compared With Everolimus in mcrRCC	SA #06	13/12/2017	33
16/LO/0693/AM03	BANG-CH	Substantial amendment #3 - 23r	31/03/2017	28
16/LO/0735/AM08	BH29992 - Subcutaneous emicizumab in Haemophilia A paediatric patients	SA07	30/10/2017	21
16/LO/0735/AM09	BH29992 - Subcutaneous emicizumab in Haemophilia A paediatric patients	Amendment 8 (substantial) - em	20/12/2017	28
16/LO/0737/AM01	An Avatar Aid in the Memory Clinic (AAA-MC)	1	09/10/2017	30
16/LO/0769/AM03	EMR200647-001 MERCK TRAP	Protocol Amend 5, v6.0, PIS/IC	11/05/2017	28
16/LO/0769/AM05	EMR200647-001 MERCK TRAP	3	03/05/2017	23
16/LO/0769/AM06	EMR200647-001 MERCK TRAP	5	15/06/2017	28
16/LO/0769/AM07	EMR200647-001 MERCK TRAP	6	08/02/2018	34
16/LO/0793/AM02	1199.227 Effect of nintedanib on biomarkers	SA2	10/03/2017	29
16/LO/0964/AM04	Understanding Visual Snow Syndrome: A Functional Imaging Approach	1	01/07/2017	28
16/LO/0966/AM03	Physiological changes following MIE in NMD	SA1	17/04/2017	28
16/LO/0966/AM04	Physiological changes following MIE in NMD	2	06/07/2017	19
16/LO/0985/AM03	CHECKpoint pathway and nivolumab clinical Trial Evaluation 577	SA02	05/07/2017	14
16/LO/1007/AM04	SEM Glove study for spinal cord injury - v1	3	21/07/2017	29
16/LO/1173/AM04	SAFETY	2 - 29.06.17	28/09/2017	32
16/LO/1180/AM05	PHASE 3 STUDY OF AVELUMAB COMBINED WITH AXITINIB VS SUTINIB IN RCC	4	30/06/2017	14

16/LO/1180/AM06	PHASE 3 STUDY OF AVELUMAB COMBINED WITH AXITINIB VS SUTINIB IN RCC	Protocol Amendment 5 and ICF v	07/08/2017	28
16/LO/1180/AM09	PHASE 3 STUDY OF AVELUMAB COMBINED WITH AXITINIB VS SUTINIB IN RCC	ICDv7.0 dated 10Jan2018	18/01/2018	32
16/LO/1199/AM05	CA224-020 Anti-LAG-3 with Nivolumab in Advanced Solid Tumors	SA04	11/10/2017	34
16/LO/1210/AM02	A comparison of 3rd generation to 2nd generation airway devices	2	01/03/2018	13
16/LO/1301/AM01	Urban Environment & Early Psychosis: An EMA Study	NOSA1_20_12_2017	20/12/2017	34
16/LO/1495/AM02	SPACE	2	27/11/2017	35
16/LO/1505/AM03	Diabetes Stopwatch v1	3	03/07/2017	34
16/LO/1509/AM04	Use of extended release sodium oxybate for treatment of narcolepsy.	SA03 - Protocol Update - V4.3	16/05/2017	35
16/LO/1509/AM05	Use of extended release sodium oxybate for treatment of narcolepsy.	SA04	16/08/2017	23
16/LO/1509/AM07	Use of extended release sodium oxybate for treatment of narcolepsy.	Addition of IP kit v1.0[¼ link2	02/02/2018	29
16/LO/1518/AM01	Breathing Together	1	15/05/2017	28
16/LO/1675/AM03	M14-234 Phase 2b/3 study in Mod/Severe Ulcerative Colitis	SA03 IB ed7	11/08/2017	34
16/LO/1675/AM08	M14-234 Phase 2b/3 study in Mod/Severe Ulcerative Colitis	SA06	01/07/2016	34
16/LO/1675/AM09	M14-234 Phase 2b/3 study in Mod/Severe Ulcerative Colitis	M14-234 SA05 Addition of Scott	17/10/2017	27
16/LO/1675/AM10	M14-234 Phase 2b/3 study in Mod/Severe Ulcerative Colitis	M14-234 SA07 PIS v6	01/02/2018	28
16/LO/1676/AM03	M14-533 Ph 3 study in Mod/Severe Ulcerative Colitis Extension study	3	11/08/2017	34
16/LO/1676/AM08	M14-533 Ph 3 study in Mod/Severe Ulcerative Colitis Extension study	SA06 PIS/ICF v4 plus Site and	05/01/2018	17
16/LO/1726/AM01	RNAscope Pan-UK OPSCC Testing	1st proposed amendment (Amendm	09/08/2017	30
16/LO/1744/AM03	KIDES: safety and tolerability of ODM-203 in advanced solid tumours	SA2	20/07/2017	15
16/LO/1744/AM07	KIDES: safety and tolerability of ODM-203 in advanced solid	SA03	19/10/2017	28

	tumours			
16/LO/1754/AM01	LIFTD-PIN	3	30/03/2017	28
16/LO/1754/AM02	LIFTD-PIN	Substantial Amendment 2.0: 13-	13/12/2017	28
16/LO/1905/AM03	REACT	01	22/01/2018	34
16/LO/1983/AM01	EPOP 2- Peri -Operative Isometric Exercise Programme	1	07/04/2017	31
16/LO/1983/AM02	EPOP 2- Peri -Operative Isometric Exercise Programme	AM2	14/06/2017	32
16/LO/2076/AM02	IRMA	Substantial amendment 2 [30/01	30/01/2018	22
17/LO/0007/AM01	Calcium balance studies in children with kidney failure	1	11/08/2017	19
17/LO/0012/AM01	Cinnamon - Infant milk formula with two Human Milk Oligosaccharides	1	31/07/2017	34
17/LO/0012/AM02	Cinnamon - Infant milk formula with two Human Milk Oligosaccharides	2	06/02/2018	32
17/LO/0024/AM03	JPCJ: Abemaciclib in Metastatic Pancreatic Ductal Adenocarcinoma	SA2	19/05/2017	28
17/LO/0024/AM04	JPCJ: Abemaciclib in Metastatic Pancreatic Ductal Adenocarcinoma	SA03	24/07/2017	27
17/LO/0024/AM05	JPCJ: Abemaciclib in Metastatic Pancreatic Ductal Adenocarcinoma	4	14/08/2017	25
17/LO/0024/AM06	JPCJ: Abemaciclib in Metastatic Pancreatic Ductal Adenocarcinoma	SA5: Abemaciclib IB 15Sep2017[3/4	23/01/2018	35
17/LO/0026/AM01	Lymph node biopsy study in ANCA-associated vasculitis	SA1	05/05/2017	32
17/LO/0026/AM02	Lymph node biopsy study in ANCA-associated vasculitis	2	02/11/2017	28
17/LO/0101/AM01	Placebo controlled study with TEV-48125 for EC Headaches	SA01	30/05/2017	30
17/LO/0101/AM02	Placebo controlled study with TEV-48125 for EC Headaches	Substantial Amendment 2	12/06/2017	29
17/LO/0102/AM01	Placebo controlled study with TEV-48125 for Chronic Cluster Headaches	1	30/05/2017	28
17/LO/0102/AM02	Placebo controlled study with TEV-48125 for Chronic Cluster Headaches	SA#2	12/06/2017	29
17/LO/0103/AM01	Long-Term Safety Study with TEV-48125 for Cluster Headache Prevention	SA#1	01/06/2017	28
17/LO/0103/AM02	Long-Term Safety Study with TEV-48125 for Cluster Headache	SA2	12/06/2017	29

	Prevention			
17/LO/0113/AM02	GBT440-031 - GBT440 in Patients With Sickle Cell Disease (HOPE)	2 Recruitment Materials	27/04/2017	28
17/LO/0113/AM05	GBT440-031 - GBT440 in Patients With Sickle Cell Disease (HOPE)	SA3	07/11/2017	35
17/LO/0113/AM06	GBT440-031 - GBT440 in Patients With Sickle Cell Disease (HOPE)	6	19/12/2017	36
17/LO/0121/AM01	SHP633-303 Ext Study of Teduglutide in Paediatric Subjects with SBS	1	26/04/2017	40
17/LO/0121/AM02	SHP633-303 Ext Study of Teduglutide in Paediatric Subjects with SBS	2	22/08/2017	35
17/LO/0163/AM01	GO39374: GDC-0077 for PIK3CA-mutant solid tumours / breast cancer	AM1	28/03/2017	34
17/LO/0163/AM02	GO39374: GDC-0077 for PIK3CA-mutant solid tumours / breast cancer	2	28/06/2017	19
17/LO/0163/AM04	GO39374: GDC-0077 for PIK3CA-mutant solid tumours / breast cancer	SA3 --Updated IB V2 / Main Sta	02/11/2017	31
17/LO/0163/AM05	GO39374: GDC-0077 for PIK3CA-mutant solid tumours / breast cancer	SA 4 - Protocol V4 / Main Stag	22/12/2017	31
17/LO/0372/AM01	REACH 2	1	01/05/2017	23
17/LO/0374/AM01	EASE Study	1	04/08/2017	32
17/LO/0378/AM01	ICONIC	SUBSTANTIAL AMENDMENT 1 TO HAL	28/09/2017	30
17/LO/0378/AM02	ICONIC	2	23/11/2017	32
17/LO/0486/AM03	Esperion 1002-048 (Bempedoic Acid (ETC-1002)	4	15/02/2018	29
17/LO/0556/AM02	Head or Heart Study - A dormant trial linkage feasibility study	amendment 1, 28 February 2018	28/02/2018	23
17/LO/0573/AM02	1368.10: BI655130 add-on in patients with UC during TNFi therapy	2	11/07/2017	19
17/LO/0573/AM06	1368.10: BI655130 add-on in patients with UC during TNFi therapy	SA3	24/01/2018	1
17/LO/0741/AM01	MOVES-PD	SA001	23/08/2017	28
17/LO/0869/AM01	Understanding repetitive worries and responses in neonatal parents V1	1	16/11/2017	33
17/LO/0871/AM01	MePFAC	1	21/09/2017	34

17/LO/0871/AM02	MePFAC	2	26/02/2018	14
17/LO/0874/AM01	PREPS - Vaginal Preparation at caesarean section.	AM01	08/11/2017	33
17/LO/0874/AM02	PREPS - Vaginal Preparation at caesarean section.	SA02	16/01/2018	34
17/LO/0882/AM01	CastleCreek - Diacerein Ointment - CCP-020-301	Protocol Amendment 1.1	26/06/2017	30
17/LO/0882/AM02	CastleCreek - Diacerein Ointment - CCP-020-301		09/02/2018	32
17/LO/1018/AM04	STRONG Study	Protocol Amendment v4 dated 08	20/03/2018	8
17/LO/1065/AM01	MK-8504 Single Dose Study in HIV-1 Infected Patients	SA01 - Protocol Amendment 01 -	09/08/2017	33
17/LO/1274/AM01	Predictors of depression in people with Ulcerative Colitis - Version 1	1	11/10/2017	20
17/LO/1279/AM01	Nutritional Scoring Systems and Outcomes in Vascular Patients	1	07/08/2017	26
17/LO/1429/AM01	CLR_15_03 Activity of K0706 Leukaemia	1	09/03/2018	16
17/LO/1451/AM02	Sotagliflozin vs. Placebo added to insulin +/- other OADs in T2DM	SA02	23/11/2017	30
17/LO/1451/AM03	Sotagliflozin vs. Placebo added to insulin +/- other OADs in T2DM	EFC14868 SA3 - PAC	05/02/2018	26
17/LO/1989/AM01	Proof of Concept Study of ACH 0144471 in Untreated Patients With PNH	Protocol V6 (AMD5) dated 05 De	19/01/2018	26
17/LO/2064/AM02	Phase 2 study of BGB-3111 and Obinutuzumab in Follicular Lymphoma	SA02 Protocol amendment versio	01/03/2018	26
17/LO/2090/AM01	NeuroGait	Amendment 1	12/01/2018	5
MSA RETRO 11 1 SB/AM14	Panel Screening Protocol	SA24	26/05/2017	27
MSA RETRO 11 1 SB/AM15	Panel Screening Protocol	25	12/10/2017	35
MSA RETRO 11 1 SB/AM16	Panel Screening Protocol	26	07/03/2018	2

#### Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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11/LO/0328/AM08	TRICREST	8	09/09/2017	35
13/LO/1720/AM08	Enzalutamide in Combination with Exemestane in Advanced Breast Cancer	SA#05	22/08/2017	35
16/LO/0374/AM05	PSYSCAN: Ultra High Risk	5	16/08/2017	34
16/LO/0546/AM01	Families' Experiences of Paediatric ICC Diagnosis	1	04/05/2017	35
16/LO/1676/AM07	M14-533 Ph 3 study in Mod/Severe Ulcerative Colitis Extension study	SA05	02/11/2017	35
17/LO/0486/AM02	Esperion 1002-048 (Bempedoic Acid (ETC-1002)	2	02/10/2017	35

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

Favourable opinion timeline				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
11/LO/0328/AM08/1	TRICREST	Modified Amendment to SA08	27/11/2017	14
13/LO/1720/AM08/1	Enzalutamide in Combination with Exemestane in Advanced Breast Cancer	SA #05	30/11/2017	14
16/LO/0374/AM05/1	PSYSCAN: Ultra High Risk	Modified - PSYSCAN_UHR_N OSA-5	09/11/2017	11
17/LO/0486/AM02/1	Esperion 1002-048 (Bempedoic Acid (ETC-1002)	Modified Amendment to SA2	19/10/2017	7

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

**Table 11: Items exceeding timelines**

**Full applications for ethical review over 60 day timeline**

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

REC Reference	Title	Number of Days on Clock
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**SSAs (non Phase 1) over 25 day timeline**

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

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

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
15/LO/0363/AM01	The role of LLT1 in immune evasion and hepatocellular carcinoma	1	04/04/2017	43
17/LO/0113/AM06	GBT440-031 - GBT440 in Patients With Sickle Cell Disease (HOPE)	6	19/12/2017	36
17/LO/0121/AM01	SHP633-303 Ext Study of Teduglutide in Paediatric Subjects with SBS	1	26/04/2017	40

**Modified Amendments over 14 day timeline**

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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