

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

**Annual Report**

**01 April 2015 - 31 March 2016**



## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	London - City & East Research Ethics Committee
<b>Type of REC:</b>	RECs recognised to review CTIMPS in patients - type iii
<b>Type of Flag:</b>	IRB Phase 1 in patients Paediatric
<b>Chair:</b>	Dr John Keen
<b>Vice-Chair:</b>	Ms Alison Eden
<b>Alternate Vice-Chair:</b>	Dr Ayse Baxter
<b>REC Manager:</b>	Mr Rajat Khullar
<b>REC Assistant:</b>	Mr Wai Yeung
<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 Chandan Alam	Experimental Pathology	Expert	01/06/2005	31/05/2015
Dr Marie E Bardsley	Director -Medical 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	
Mr James Batchelor	Director of Clinical Informatics Research Unit	Lay	01/07/2014	31/05/2015
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	
Mrs Lisa Johnson	CRO	Lay Plus	01/05/2014	
Dr John Keen	GP	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	
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	01/05/2014	
Professor Kim Piper	Consultant Histopathologist/Professor of Oral Pathology	Expert	01/03/2008	01/06/2015
Mr Roy Sinclair	Pharmacist	Lay	01/11/2014	03/09/2015
Ms Anna (Renqian) Song	Pharmacist	Expert	01/01/2016	
Dr Ariel Zosmer	Honorary Senior Clinical Lecturer	Expert	17/09/2008	01/06/2015

## 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

<b>Name</b>	<b>Profession</b>	<b>Status</b>	<b>Meeting date attended</b>
Mr Ron Driver	Retired Statistician	Lay	02/04/2015
Professor Anthony Fox	Pharmaceutical Medicine	Expert	02/04/2015
Ms Stephanie Ellis	Retired Civil Servant	Lay Plus	02/04/2015
Professor David Caplin	Physicist	Lay	02/04/2015

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

Name	Declaration of Interest	Date
Ms Clare Barron	None	04/06/2015
Dr Ayse Baxter	Shares in AstraZeneca and Glaxo Smith Kline	07/06/2015
Mrs Lisa Johnson	None	08/01/2016
Dr John Keen	None	07/01/2016
Mr John Lynch	None	07/01/2016
Dr Kieran McCafferty	None	07/01/2016
Dr Wolfgang Meyer	None	04/02/2016
Dr Dylan Morrissey	None	04/06/2015
Mr Roy Sinclair	None	04/06/2015
Ms Anna (Renqian) Song	None	07/01/2016
Ms Alison Eden	100% owner of Alison Brand. Employee of ICON. Contract Research Organisation. Sometimes writes patient information/interviews sites, advises on recruitment/retention strategy	04/06/2015
Mr Roger Maran	Shares in GlaxoSmithKline as part of a professionally managed share portfolio.	04/06/2015
Dr Marie Bardsley	Director, E-Med Ltd. Data Manager Data Sharing Initiative Royal London Hospital Whitechapel Commission on Publishing Ethics (COPE) Member of Labour Party	07/01/2016
Mr Frank Cross	None	07/01/2016
Dr Luis Beltran	Collaborative work with the Orchid charity on male specific cancer. Work with Trans-Atlantic prostate group	07/01/2016
Ms Jane Batchelor	None	07/01/2016

### Meetings for Full Ethical Review 01 April 2015 - 31 March 2016:

Month	Date	Number of Members Present at Meeting
April	02/04/2015	9
May	07/05/2015	10
June	04/06/2015	10
July	02/07/2015	10
September	03/09/2015	11
October	01/10/2015	11
December	03/12/2015	12
January	07/01/2016	11
February	04/02/2016	12
March	03/03/2016	11

10 full committee meetings were held during the reporting period.

### Proportionate Review Sub-Committee Meetings held during 01 April 2015 - 31 March 2016:

Month	Date	Number of Members Present at Meeting
April	16/04/2015	4
May	21/05/2015	3
June	18/06/2015	3
July	16/07/2015	3
August	20/08/2015	3
September	17/09/2015	3
October	15/10/2015	3
November	19/11/2015	3
December	17/12/2015	3
January	21/01/2016	3
February	18/02/2016	3
March	17/03/2016	4

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

### Sub-Committee Meetings held during 01 April 2015 - 31 March 2016:

Month	Date	Number of Members Present at Meeting
April	14/04/2015	3
April	24/04/2015	5
May	08/05/2015	4
May	18/05/2015	4
June	01/06/2015	2
June	16/06/2015	3
June	29/06/2015	2
July	20/07/2015	4
July	28/07/2015	6

July	31/07/2015	3
August	01/08/2015	1
August	14/08/2015	3
August	25/08/2015	3
September	08/09/2015	4
September	21/09/2015	5
October	09/10/2015	5
October	20/10/2015	3
November	02/11/2015	5
November	20/11/2015	4
December	07/12/2015	3
January	05/01/2016	2
January	18/01/2016	4
January	29/01/2016	5
February	12/02/2016	4
February	15/02/2016	3
February	22/02/2016	4
March	11/03/2016	3
March	25/03/2016	5

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

#### Details of inquorate meeting held:01 April 2015 - 31 March 2016

None



**Attendance of Members at full committee meetings:01 April 2015 - 31 March 2016**

<b>Name</b>	<b>Number of Meetings Attended</b>
Dr Chandan Alam	1
Dr Marie E Bardsley	7
Ms Clare Barron	6
Ms Jane Batchelor	9
Dr Ayse Baxter	9
Dr Luis Beltran	7
Mr Frank Cross	7
Ms Alison Eden	4
Mrs Lisa Johnson	8
Dr John Keen	10
Mr John Lynch	9
Mr Roger Maran	9
Dr Kieran McCafferty	4
Dr Wolfgang Meyer	2
Dr Dylan Morrissey	5
Mr Roy Sinclair	4
Ms Anna (Rengian) Song	3

**Attendance of Members at proportionate review sub-committee meetings: 01 April 2015 - 31 March 2016**

<b>Name</b>	<b>Number of Meetings Attended</b>
Dr Marie E Bardsley	1
Ms Clare Barron	1
Ms Jane Batchelor	2
Mr James Batchelor	1
Dr Luis Beltran	2
Mr Frank Cross	1
Ms Alison Eden	3
Ms Lisa Johnson	7
Dr John Keen	10
Mr John Lynch	3
Mr Roger Maran	5
Professor Kim Piper	1
Mr Roy Sinclair	1

**Attendance of Members at sub-committee meetings: 01 April 2015 - 31 March 2016**

<b>Name</b>	<b>Number of Meetings Attended</b>
Dr Marie E Bardsley	3
Ms Clare Barron	2
Dr Ayse Baxter	16
Dr Luis Beltran	2
Mr Frank Cross	1
Ms Alison Eden	11
Ms Lisa Johnson	5
Dr John Keen	28
Mr John Lynch	2
Mr Roger Maran	9
Dr Kieran McCafferty	6
Dr Dylan Morrissey	6
Mr Roy Sinclair	9
Ms Anna (Renqian) Song	2

**Training 01 April 2015 - 31 March 2016**

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Dr Marie E Bardsley	02/11/2015	Equality & Diversity
Ms Jane Batchelor	26/11/2015	Local Training Day for London RECs
Dr Ayse Baxter	26/11/2015	Local training day
Dr Luis Beltran	07/12/2015	Equality & Diversity
Dr Luis Beltran	10/03/2016	New Members Induction
Professor David Caplin	23/07/2015	Research Involving the Disadvantaged and Vulnerable: a Workshop for Researchers and Reviewers
Mr Frank Cross	26/11/2015	Local training day
Professor Anthony Fox	10/06/2015	Equality & Diversity
Professor Anthony Fox	23/07/2015	Research Involving the Disadvantaged and Vulnerable: a Workshop for Researchers and Reviewers
Mrs Lisa Johnson	26/11/2015	Local training day 26.11.15
Mr Roger Maran	14/10/2015	Local training day - 14.10.15
Dr John Keen	09/12/2015	National Chairs Training Day for REC Chairs
Dr Kieran McCafferty	17/11/2015	New Members Induction
Dr Kieran McCafferty	26/11/2015	Local training day 26.11.15
Dr Dylan Morrissey	16/11/2015	International Clinical Trial Methodology Conference, Glasgow
Ms Anna (Renqian) Song	10/03/2016	New Members Induction
Dr Wolfgang Meyer	17/03/2016	London – Bromley Training Day 17 <sup>th</sup> March 2016

## PART 2: REC WORKLOAD AND ACTIVITY DURING THE REPORTING PERIOD

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

<b>Applications for full ethical review – Study Type</b>	<b>Number</b>	<b>%</b>
Clinical Trial of Investigational Medicinal Product	20	33.90
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	39	66.10
<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	1
Number of student applications reviewed	14
Number of paediatric applications reviewed	11
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	5

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

<b>Decisions taken at meetings following review of applications</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	2	3.39
Favourable Opinion with Additional Conditions	9	15.25
Unfavourable Opinion	3	5.08
Provisional Opinion	44	74.58
Provisional Opinion Pending Consultation with Referee	1	1.69
<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**

<b>Status of applications at date of generation of report</b>	<b>Number</b>	<b>%</b>
Further Information Favourable Opinion with Standard Conditions	42	71.19
Further Information Favourable Opinion with Additional Conditions	3	5.08
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	2	3.39
Favourable Opinion with Additional Conditions	9	15.25
Unfavourable Opinion	3	5.08
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
<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>44</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	3
Number of studies withdrawn prior to the meeting	4
Number of student applications reviewed	21
Number of paediatric applications reviewed	7
Number of device applications reviewed	1
Number of qualitative applications reviewed	9

**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	12	27.27
Favourable Opinion with Additional Conditions	8	18.18
No Opinion transfer to full committee for review	3	6.82
Provisional Opinion	21	47.73
Unfavourable Opinion	0	0.00
<b>Total</b>	<b>44</b>	<b>100</b>

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

<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>	8
<b>Number of completed applications over 40 days as a % of total</b>	13.56%
<b>Number of days taken to final decision – average (mean)</b>	34
<b>Number of completed proportionate review applications for ethical review</b>	41
<b>Number of completed proportionate review applications for ethical review over 14 days</b>	0
<b>Number of completed proportionate review applications over 14 days as a % of total</b>	0.00%
<b>Number of SSAs (non-Phase 1) reviewed</b>	10
<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>	199
<b>Number of completed substantial amendments over 35 days</b>	1
<b>Number of completed substantial amendments over 35 days as a % of total substantial amendments</b>	0.50%
<b>Number of completed substantial amendments over 28 days</b>	28
<b>Number of completed substantial amendments over 28 days as a % of total substantial amendments</b>	14.07%
<b>Number of modified amendments reviewed</b>	5
<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 minor amendments received</b>	32
<b>Number of substantial amendments received for information</b>	0
<b>Number of substantial amendments received for new sites/PIs</b>	56
<b>Number of annual progress reports received</b>	70

<b>Number of safety reports received</b>	21
<b>Number of Serious Adverse Events received</b>	0
<b>Number of final reports received</b>	5



**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>
15/LO/0485	SuPPoRT: Stitch, Progesterone or Pessary: a randomised controlled trial	44
15/LO/0521	Open-label Extension Study to Assess the Safety and Efficacy of AMG334	37
15/LO/0524	Telecare asthma reviews: comparison with standard care	40
15/LO/0525	Self-management after traumatic brain injury: a narrative inquiry	39
15/LO/0528	Wearable technology to monitor paediatric diseases	40
15/LO/0609	CapaCiTY Study 3- Chronic Constipation Treatment Pathway	34
15/LO/0722	GWEP1414 - GWP42003-P for seizures in Lennox-Gastaut Syndrome	31
15/LO/0732	CapaCiTY Study 2- Chronic Constipation Treatment Pathway	34
15/LO/0890	BETTER	32
15/LO/0894	LY2951742 in Chronic Cluster Headaches (CGAM)	35
15/LO/0954	INNOVATION (EORTC 1203)	47
15/LO/0967	iINNOVATE Study: A study of ibrutinib or placebo with rituximab	41
15/LO/0973	Sensorimotor integration in primary cervical dystonia	29
15/LO/1057	Feasibility study: RCT of Bracing of shoulder fractures (N-Brace Trial)	37
15/LO/1082	The effect of oxytocin on conduct disorder & Autism Spectrum Disorder	38
15/LO/1083	The effect of oxytocin on psychopathy and Autism Spectrum Disorder	38
15/LO/1089	X-82 in Age-Related Macular Degeneration	38
15/LO/1091	MARINAC Study	33
15/LO/1367	Retro-Mapping of transient & planar wavefronts in atrial fibrillation	36
15/LO/1390	Cardiac and respiratory function with non-invasive ventilation	28
15/LO/1524	Biomet nSTRIDE	34
15/LO/1594	In vitro evaluation of a novel pan JAK/STAT inhibitor in asthma	34
15/LO/1602	Engaging new migrants in infectious diseases screening at A&Es	27
15/LO/1610	V1.0 Extravasation: Clinical practice, patient experience & outcome	36
15/LO/1612	1st line treatment with MEDI4736 in urothelial bladder cancer (DANUBE)	46
15/LO/1879	CML study comparing 2 different doses of ponatinib versus nilotinib	33
15/LO/1897	VISUALISATION OF CORTICAL SPREADING DEPRESSION IN MIGRAINE AURA. V01	38
15/LO/1963	Development of the 'Sensing ET Tube'	40
15/LO/1979	Use of Betashot in children and adults with epilepsy.	28
16/LO/0003	Trauma Organ Protection - Artesunate (TOP-ART)	56
16/LO/0019	BESTT Women's Study	45
16/LO/0020	EE-ASI-1	35

16/LO/0034	BH29884 - Prophylactic RO5534262 vs no prophylaxis in Haemophilia A.	39
16/LO/0092	EVALUATING OBINUTUZUMAB, POLATUZUMAB VEDOTIN & LENALIDOMIDE THERAPY	28
16/LO/0122	Study of Pembrolizumab in Previously Treated Oesophageal Cancer	32
16/LO/0146	Experiences of MBT psycho-educational groups for PD in Secondary Care	28
16/LO/0152	Evaluate the Effect of a Digital Disease Management Tool in DM Patient	29
16/LO/0160	Influence of dietary nitrate on skin inflammation	50
16/LO/0163	PED-MERMAIDS	29
16/LO/0282	Shunt versus stent in idiopathic intracranial hypertension	31
16/LO/0368	Exploring elevated psychosis rates in the Black and Ethnic Minorities	37
16/LO/0374	PSYSCAN: Ultra High Risk	37

#### Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/LO/0703	LY2951742 in Episodic Cluster Headaches (CGAL)	35
15/LO/2010	Evaluation of Purified Poloxamer 188 in Subjects in Crisis (EPIC)	31
16/LO/0376	PSYSCAN: First Episode Psychosis	38

#### 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
15/LO/0669	Do all HEART scores beat the same?	15
16/LO/0016	Biomarkers for beta cell destruction	30

#### Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/LO/0500	Facet-joint feasibility study	28
15/LO/0724	Experiences of rehabilitation of adults undergoing limb reconstruction	28
15/LO/0725	Transmission of hepatitis C virus in men who have sex with men	28
15/LO/1076	Hepatitis C in an isolated UK community	31
15/LO/1334	Comparison of MRI with Colonoscopy for CGD-associated colitis	29

15/LO/1342	ProSpare, a rectal obturator in post-prostatectomy radiotherapy v1.0	28
15/LO/1376	Effort test performance in an NHS acquired brain injury sample	29
15/LO/1591	Comparison of two corticosteroids on macrophage function	27
16/LO/0022	Phase 1 BAX 826 Dose-Escalation Safety Study, Protocol 291501	48

#### Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
15/LO/1613	Brain Structure and function of children at risk for eating disorders.	28
16/LO/0143	Wave VI Feasibility Study	28
16/LO/0392	Long term Safety TOPAMAX monotherapy in paediatric patients	25

#### Provisional Opinion

REC Reference	Title	Number of Days on Clock
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#### 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
15/LO/0966	Acceptability of alternate-day in-centre haemodialysis: an evaluation	11

15/LO/0986	E-learning for African Caribbean Families affected by schizophrenia	10
15/LO/1297	Planning and Evaluation Methodologies for Mental Healthcare Buildings	13
15/LO/1508	Brain Pulsation in Acute Stroke	10
15/LO/1661	Physiotherapy in Mental Health: Barriers and Facilitators to Care	8
15/LO/1664	Influenza Clinical Investigation for Children (ICICLE)	7
15/LO/2052	Explant model	10
15/LO/2055	Effects of hospitalisation on acute exacerbations of airways disease	10
15/LO/2065	The role of lipids in immune cell function in SLE patients	8
15/LO/2200	IAPT outcome feedback trial	5
15/LO/2201	Medicine Reconciliation	4
15/LO/2202	The BOSS Study	3
16/LO/0224	An evaluation of an adapted ACT group for stroke survivors	12
16/LO/0233	Is a "spot check" of the ankle Doppler waveform comparable to ABPI?	14
16/LO/0389	Assessment of newly developed observational tool.	11
16/LO/0398	The Impact of Geographic Atrophy on Daily Behaviors of Individuals	9
16/LO/0410	Sustained attention in the acute stages post stroke	11
16/LO/0417	Processes of change in Cognitive Analytic Therapy (version 1)	9
16/LO/0533	Transition in Oesophageal Atresia	14
16/LO/0546	Families' Experiences of Paediatric ICC Diagnosis	14

#### Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/LO/1489	Tinnitus patients identifying key elements of a tinnitus service.	9

#### 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
15/LO/0727	EMPIRE miRNA	11
15/LO/0736	Principal Component Analysis in Medical Image Processing	5
15/LO/0739	Observer performance and image quality in low-dose CT.	11
15/LO/0748	Epilepsy patient care plans, an evaluation and pilot study	13

15/LO/0994	How do Adolescents with Cystic Fibrosis Experience Segregation?	11
15/LO/1169	B7 family proteins in diabetic nephropathy - version 1	8
15/LO/1305	Taking pART: How people decide to consent for fertility research	7
15/LO/1871	Case Register Assessment and Evaluation (CReAtE Study)	10
15/LO/1874	The Predictive Validity of the HCR20v3 to Forensic Inpatient Violence	6
15/LO/1878	A Stronger Voice	7
15/LO/2070	'Weighing as part of your care': a feasibility study	7
16/LO/0230	Families experiences of participating in cancer trials. Version 2.1	8

### Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/LO/1168	Dissociation: experience and change. Version n1	0
15/LO/1172	Mobile application (Apps) and Treatment Adherence in Dual Diagnosis	7
15/LO/1469	Intervention timing and outcome for TOF	11
15/LO/1663	A pilot study on the value of orthodontic treatment within society	4
15/LO/1864	BRAVO Study 1: beliefs about bladder cancer treatments	10
15/LO/2199	Assessment of free vitamin D in the acute phase response (VDA)	3
16/LO/0225	Blood pressure and personal-level environmental temperature	8
16/LO/0536	CRIMSON-Considering Risks and Benefits in MS Treatment Selection	10

### 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**

<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/AM56	ASPECT	SA122	26/01/2016	29
05/Q0603/108/AM03	National Gestational Age Statistics for England & Wales	SA3 December 2015	21/12/2015	28
05/Q0603/9/AM03	Skin cancer and epidermolysis bullosa Version 1	Substantial amendment dated 6	06/01/2016	28
06/Q1603/7/AM13	Chemoprevention of Premalignant Intestinal Neoplasia		30/04/2015	30
06/Q1603/7/AM14	Chemoprevention of Premalignant Intestinal Neoplasia		25/01/2016	26
07/Q0603/8/AM15	Phase III, placebo-controlled study in subjects with multiple myeloma			20
08/H0704/128+5/AM02	Brains for Dementia Research	1	26/06/2015	28
09/H0703/101/AM12	INSIGHT H1N1v Outpatient Study (FLU 002)		19/08/2015	25
09/H0703/102/AM11	INSIGHT H1N1v Hospitalization Study (FLU 003)		19/08/2015	25
09/H0703/27/AM07	Disease biomarkers in amyotrophic lateral sclerosis			22
09/H0703/75/AM15	Bortezomib consolidation trial	Substantial Amendment 12: Prot	21/08/2015	4
10/H0703/107/AM19	A3921061 Long Term Safety&Tolerability of 2 oral doses of CP-690,550			26
10/H0703/45/AM07	CAR-PET	SA 6	01/07/2015	24
10/H0703/56/AM15	Phase Ib/II Eribulin Mesylate Bladder Cancer		12/01/2016	27
10/H0703/98/AM01	Inorganic nitrate in resistant hypertension		30/03/2016	1
10/H0704/65/AM02	Molecular Investigation of Haematopoietic Malignancy		28/04/2015	17
10/H0704/74/AM04	T cell and macrophage function in the inflamed human gut	05¼ 09/06/2015	09/06/2015	30
11/H0703/10/AM06	An Exploratory Clinical and Genetic Study of Cone Disorders	Substantial Amendment 8 16 Jan	16/03/2015	1
11/H0703/10/AM07	An Exploratory Clinical and Genetic Study of Cone Disorders		10/11/2015	27
11/LO/0241/AM12	Parkinson's Progression Markers Initiative	9	04/06/2015	31

11/LO/0250/AM12	An evaluation study of Dynamic Interpersonal Therapy (DIT).	Substantial Amendment 11.0 (08	11/05/2015	26
11/LO/0326/AM03	FIT for Follow-up Study	4.0	24/12/2015	15
11/LO/0328/AM06	TRICREST	Substantial amendment dated 1	01/12/2015	24
11/LO/1303/AM08	Panobinostat and ruxolitinib in patients with myelofibrosis.		28/05/2015	28
11/LO/1303/AM09	Panobinostat and ruxolitinib in patients with myelofibrosis.		10/08/2015	12
11/LO/1595/AM06	FGFR		09/04/2015	25
11/LO/1595/AM07	FGFR	SUB AMENDMENT 9 (TO RE OPEN ON	18/08/2015	26
11/LO/1595/AM09	FGFR		05/01/2016	28
11/LO/1595/AM10	FGFR	Substantial amendment dated 7	07/03/2016	17
12/LO/0008/AM05	GAMMA	Substantial amendment dated 27	27/10/2015	26
12/LO/0315/AM08	Phase 2 Study of Anti-CCR4 MBA KW-0761 in subjects with PTCL	CTA Amendment 6, Dec 2014	14/05/2015	25
12/LO/0593/AM09	Daratumumab with lenalidomide and dexamethasone in multiple myeloma		23/07/2015	20
12/LO/0593/AM10	Daratumumab with lenalidomide and dexamethasone in multiple myeloma	Protocol Amendment 7 + Updated	20/11/2015	21
12/LO/0794/AM06	CHR258 in HCC	Substantial Amendment 7	23/12/2015	17
12/LO/0949/AM15	C16010: Phase 3 study of MLN9708 in Multiple Myeloma	Risk Language updated in ICF f	01/05/2015	27
12/LO/0949/AM16	C16010: Phase 3 study of MLN9708 in Multiple Myeloma		28/01/2016	27
12/LO/1138/AM05	MELCAP	Substantial Amendment no 5.0	26/10/2015	28
12/LO/1168/AM14	R2W: Randomised phase 2 trial in Waldenström macroglobulinaemia			23

12/LO/1313/AM03	ROX CONTROL HTN STUDY: Protocol RH-02 Version 1.0, June 20, 2012			28
12/LO/1492/AM09	Life Study	8.0	30/03/2015	21
12/LO/1492/AM10	Life Study		22/05/2015	11
12/LO/1492/AM11	Life Study		29/06/2015	21
12/LO/1492/AM12	Life Study	11.0, dated 12th October 2015	11/10/2015	4
12/LO/1492/AM13	Life Study	12.0, dated 23rd October 2015	23/10/2015	28
12/LO/1492/AM14	Life Study	13.0	07/12/2015	28
12/LO/1492/AM16	Life Study	14	22/01/2016	25
12/LO/1516/AM01	Testing for tuberculosis in a UK HIV infected population		14/04/2015	35
12/LO/1731/AM03	EnlighTN II		06/05/2015	28
12/LO/1949/AM05	Withdrawal of life sustaining treatment in newborn babies		22/05/2015	21
12/LO/1949/AM06	Withdrawal of life sustaining treatment in newborn babies		18/01/2016	27
13/LO/0033/AM17	GO28509 PEGGY - Phase 2 study of GDC-0941 in metastatic breast cancer	Substantial Amendment 14 – Pro	09/03/2015	28
13/LO/0033/AM20	GO28509 PEGGY - Phase 2 study of GDC-0941 in metastatic breast cancer		02/07/2015	33
13/LO/0033/AM21	GO28509 PEGGY - Phase 2 study of GDC-0941 in metastatic breast cancer		11/09/2015	25
13/LO/0049/AM06	REPARO NGF0212 Phase I/II Neurotrophic Keratitis Trial	Substantial Amendment 4 Update	10/04/2015	25
13/LO/0049/AM08	REPARO NGF0212 Phase I/II Neurotrophic Keratitis Trial	substantial amendment 5 Closur	10/06/2015	28
13/LO/0049/AM09	REPARO NGF0212 Phase I/II Neurotrophic Keratitis Trial		24/06/2015	21
13/LO/0150/AM05	The regorafenib in patients with hepatocellular carcinoma.		12/01/2016	71
13/LO/0315/AM04	BAMI		16/12/2015	28
13/LO/0393/AM04	INSIGHT: Investigation into biomarkers to predict preterm birth		14/03/2016	9
13/LO/0548/AM01	Bisphosphonate-related osteonecrosis of the jaw and the Immune system	Substantial amendment dated 3	03/11/2015	28
13/LO/0549/AM07	FG-4592 in the Treatment of Anemia in Chronic Kidney			34



	Disease Patients			
13/LO/0555/AM05	Brain in Pain IV (FM,NCCP)	5	12/10/2015	27
13/LO/0582/AM07	Abiraterone with Different Steroid Regimens in Prostate Cancer		14/01/2016	21
13/LO/0727/AM04	LDK378 in children with malignancies that have ALK alteration		09/07/2015	24
13/LO/0926/AM06	Phase 1 study to evaluate safety and efficacy of BMN 190	Substantial amendment dated 29	29/10/2015	28
13/LO/1207/AM02	Stereotactic radiotherapy for wet AMD (STAR)	2	31/07/2015	24
13/LO/1399/AM04	Brain in Pain III (CFS)	4	07/09/2015	27
13/LO/1399/AM05	Brain in Pain III (CFS)		12/02/2016	17
13/LO/1437/AM04	Phase I/II study of [124I]mIBG PET/CT in neuroblastoma.	Substantial amendment dated 7	07/05/2015	25
13/LO/1437/AM05	Phase I/II study of [124I]mIBG PET/CT in neuroblastoma.		15/07/2015	25
13/LO/1572/AM02	Host & Viral factors associated with HIV-1 control v1	2	01/10/2015	20
13/LO/1685/AM03	A study of the mechanisms that give rise to vascular disease		09/03/2016	9
13/LO/1720/AM04	Enzalutamide in Combination with Exemestane in Advanced Breast Cancer		20/07/2015	25
13/LO/1760/AM02	BAMI Platelet Sub-study	Substantial amendment dated 03	03/03/2016	21
13/LO/1943/AM04	PDOPPS	AM03	16/03/2016	8
13/LO/1948/AM01	The use of susceptibility weighted MR imaging(SWI)in neonates with HIE	1	23/07/2015	9
14/LO/0021/AM02	CE Mark Home Self-Test finger blood Total WBC, HGB, GRN, + Temperature	Substantial amendment dated 28	28/09/2015	24
14/LO/0044/AM03	EZH117208: Phase I Dose Escalation Study of GSK2816126		19/05/2015	18
14/LO/0122/AM06	Safety, tolerability & pharmacokinetics of regorafenib in paediatrics			29
14/LO/0122/AM08	Safety, tolerability & pharmacokinetics of regorafenib in paediatrics		25/03/2015	17
14/LO/0132/AM02	Robotic Surgery After Focal Ablation Therapy (RAFT)		16/04/2015	18
14/LO/0132/AM03	Robotic Surgery After Focal Ablation Therapy (RAFT)	Substantial amendment dated	02/02/2016	27

		2		
14/LO/0141/AM05	iMAP2		15/07/2015	23
14/LO/0141/AM06	iMAP2	Amendment to Protocol V7 dated	11/01/2016	26
14/LO/0418/AM07	CEDAR		18/08/2015	30
14/LO/0418/AM12	CEDAR	Substantial amendmndent 10	15/03/2016	9
14/LO/0465/AM02	PATRIOT		24/06/2015	27
14/LO/0527/AM08	GO28754 Anti-PDL1 in locally advanced or metastatic NSCLC		29/04/2015	18
14/LO/0527/AM09	GO28754 Anti-PDL1 in locally advanced or metastatic NSCLC		19/10/2015	22
14/LO/0527/AM11	GO28754 Anti-PDL1 in locally advanced or metastatic NSCLC	SA 6	29/10/2015	28
14/LO/0680/AM06	MEDI4736 in NSCLC (D4191C00003, ATLANTIC Study)		04/06/2015	25
14/LO/0680/AM07	MEDI4736 in NSCLC (D4191C00003, ATLANTIC Study)		11/11/2015	25
14/LO/0680/AM08	MEDI4736 in NSCLC (D4191C00003, ATLANTIC Study)		04/02/2016	22
14/LO/0855/AM02	673-201 Study of BMN 673 in patients with Germline BRCA mutation		08/04/2015	32
14/LO/0855/AM04	673-201 Study of BMN 673 in patients with Germline BRCA mutation	Substantial amendment dated 22	22/09/2015	28
14/LO/0855/AM05	673-201 Study of BMN 673 in patients with Germline BRCA mutation	Substantial amendment dated 1	01/03/2016	17
14/LO/1139/AM02	A Phase 2 Study to Evaluate AMG 334 in Chronic Migraine Prevention	2	27/03/2015	1
14/LO/1178/AM01	Assessment of Multiple Sclerosis in Routine Clinical Practice v1	1	05/08/2015	22
14/LO/1182/AM03	Iloprost in patients with Eisenmenger Syndrome	3	12/05/2015	21
14/LO/1184/AM05	Masitinib/Placebo + Gemcitabine + FOLFIRI.3 in Pancreatic Cancer V1		28/04/2015	32
14/LO/1184/AM06	Masitinib/Placebo + Gemcitabine + FOLFIRI.3 in Pancreatic Cancer V1		04/08/2015	14
14/LO/1184/AM07	Masitinib/Placebo + Gemcitabine + FOLFIRI.3 in Pancreatic Cancer V1		19/01/2016	21
14/LO/1184/AM08	Masitinib/Placebo + Gemcitabine + FOLFIRI.3 in Pancreatic Cancer V1	Substantial amendment date 11	11/02/2016	27

14/LO/1189/AM01	Pfizer B3281006-Ph 3 PF-05280586 vs Rituximab in low tumour burden FL		04/03/2015	33
14/LO/1189/AM02	Pfizer B3281006-Ph 3 PF-05280586 vs Rituximab in low tumour burden FL	AM02 Substantial Amendment 2 -	09/06/2015	29
14/LO/1193/AM06	Epanova in High Cardiovascular Risk Patients with Hypertriglyceridemia	3	05/08/2015	12
14/LO/1193/AM08	Epanova in High Cardiovascular Risk Patients with Hypertriglyceridemia		04/01/2016	26
14/LO/1193/AM10	Epanova in High Cardiovascular Risk Patients with Hypertriglyceridemia	Substantial Amendment - IBv6	22/03/2016	32
14/LO/1350/AM01	GARFIELD-VTE		02/04/2015	31
14/LO/1350/AM02	GARFIELD-VTE		06/07/2015	30
14/LO/1350/AM03	GARFIELD-VTE	3	05/01/2016	28
14/LO/1443/AM03	Pyrenees		13/05/2015	32
14/LO/1514/AM03	An Open Label Study of CORâ€™003 on the treatment of Cushing's syndrome	COR201201 Protocol amendment P	29/04/2015	21
14/LO/1514/AM05	An Open Label Study of CORâ€™003 on the treatment of Cushing's syndrome		13/07/2015	27
14/LO/1578/AM01	DMID 11-0069 Valgan Toddler, Version 2.0 Dated 30 May 2014		11/06/2015	24
14/LO/1737/AM02	U31287-A-U106	2	16/04/2015	29
14/LO/1737/AM03	U31287-A-U106		10/11/2015	27
14/LO/1786/AM01	CapaCiTY Study 1- Chronic Constipation Treatment Pathway	Amendmemnt 1	22/01/2016	21
14/LO/1939/AM05	Octreotide as prophylaxis for lapatinib-capecitabine related diarrhoea		18/09/2015	25
14/LO/1939/AM06	Octreotide as prophylaxis for lapatinib-capecitabine related diarrhoea	03	18/09/2015	27
14/LO/2036/AM01	WP29158-MPDL3280A & Erlotinib in advanced Non-Small Cell Lung Cancer		23/06/2015	28
14/LO/2036/AM02	WP29158-MPDL3280A & Erlotinib in advanced Non-Small Cell Lung Cancer		26/01/2016	25
14/LO/2101/AM02	GWEP1330 - A Study of GWP42006 in people with focal seizures		07/07/2015	28
14/LO/2101/AM03	GWEP1330 - A Study of GWP42006 in people with focal seizures	5	30/11/2015	29

14/LO/2101/AM04	GWEP1330 - A Study of GWP42006 in people with focal seizures	Substantial amendment dated 17	17/02/2016	26
14/LO/2125/AM01	Simeprevir and Daclatasvir in Hep-C Advanced Liver Disease - COMMIT		02/04/2015	30
14/LO/2125/AM02	Simeprevir and Daclatasvir in Hep-C Advanced Liver Disease - COMMIT	Substantial Amend 2 TMC435	21/05/2015	31
14/LO/2125/AM03	Simeprevir and Daclatasvir in Hep-C Advanced Liver Disease - COMMIT		18/06/2015	29
14/LO/2125/AM04	Simeprevir and Daclatasvir in Hep-C Advanced Liver Disease - COMMIT		02/06/2015	28
14/LO/2125/AM05	Simeprevir and Daclatasvir in Hep-C Advanced Liver Disease - COMMIT		18/06/2015	28
14/LO/2125/AM06	Simeprevir and Daclatasvir in Hep-C Advanced Liver Disease - COMMIT	SA5- IBs TMC9-DCV10	10/11/2015	28
14/LO/2137/AM01	(INSIGHT 006: FLU-IVIG)		12/10/2015	35
14/LO/2167/AM02	Adalimumab (HUMIRA®) use in patients with Ulcerative Colitis	2 21 May 2015	22/05/2015	14
14/LO/2167/AM03	Adalimumab (HUMIRA®) use in patients with Ulcerative Colitis	Substantial amendment dated 16	16/11/2015	28
14/LO/2184/AM03	Impact of Physical activity and Vitamin D on osteoarthritic knee pain	Substantial amendment dated 27	27/01/2016	27
14/LO/2290/AM01	Neurophysiology of fatigue in people with multiple sclerosis	Substantial Amendment 1 14 May	20/05/2015	21
14/LO/2290/AM02	Neurophysiology of fatigue in people with multiple sclerosis	2.0 11/06/2015	11/06/2015	27
15/LO/0005/AM01	TASMA: Targets of Bronchial Thermoplasty in Severe Asthma	Amendment 1	11/12/2015	27
15/LO/0023/AM03	Cardamon trial		01/05/2015	28
15/LO/0023/AM04	Cardamon trial		23/06/2015	28
15/LO/0023/AM05	Cardamon trial		01/06/2015	11
15/LO/0023/AM07	Cardamon trial	Cardamon substantial amendment	18/05/2015	26
15/LO/0023/AM08	Cardamon trial		17/12/2015	28

		CardamonÂ subst ntialÂ amendm ent		
15/LO/0024/AM01	Abbreviated Mentalization Based Therapy in Borderline Crises(AMBIC)		28/07/2015	15
15/LO/0159/AM02	SelPac Version 1	Substantial amendment dated 07	07/01/2016	28
15/LO/0159/AM03	SelPac Version 1		26/02/2016	21
15/LO/0182/AM03	TIGER-3	3	06/07/2015	27
15/LO/0182/AM05	TIGER-3		10/09/2015	22
15/LO/0182/AM06	TIGER-3	Investigator's Brochure (Editi Amendment 1 08 Oct 2015	16/10/2015	25
15/LO/0189/AM01	TAC Registry (Study Name: CHORUS)		08/10/2015	25
15/LO/0193/AM01	Efficacy of First Aid Treatment of Acute Apical Abscess (AAA)		18/09/2015	24
15/LO/0205/AM01	Auditory Verbal Hallucinations in Bipolar Disorder		11/08/2015	23
15/LO/0210/AM01	CR-AIR-007	3	15/07/2015	25
15/LO/0302/AM01	First-in-Human Study of TAK-659 in Advanced Solid Tumor and Lymphoma	Substantial Amendment 1	10/11/2015	27
15/LO/0355/AM01	Immune signatures associated with rapid beta cell loss in T1D	Substantial amendment dated 24	24/09/2015	22
15/LO/0367/AM01	Improving auditory outcomes	Amendment 1	28/09/2015	13
15/LO/0367/AM02	Improving auditory outcomes	Substantial amendment 2	17/03/2016	10
15/LO/0485/AM01	SuPPoRT: Stitch, Progesterone or Pessary: a randomised controlled trial		02/12/2015	16
15/LO/0500/AM01	Facet-joint feasibility study	Substantial amendment dated 08	08/01/2016	11
15/LO/0521/AM02	Open-label Extension Study to Assess the Safety and Efficacy of AMG334		28/08/2015	4
15/LO/0521/AM03	Open-label Extension Study to Assess the Safety and Efficacy of AMG334	Substantial amendment dated 17	17/11/2015	27
15/LO/0528/AM01	Wearable technology to monitor paediatric diseases		12/08/2015	10

15/LO/0545/AM01	CARAT - RTSY03	Substantial Amendment 1 dated	29/04/2015	19
15/LO/0609/AM01	CapaCiTY Study 3- Chronic Constipation Treatment Pathway	Substantial amendment 1 dated	02/02/2016	27
15/LO/0703/AM01	LY2951742 in Episodic Cluster Headaches (CGAL)		11/12/2015	27
15/LO/0703/AM02	LY2951742 in Episodic Cluster Headaches (CGAL)	Substantial amendment dated 22	26/01/2016	26
15/LO/0722/AM01	GWEP1414 - GWP42003-P for seizures in Lennox-Gastaut Syndrome		05/08/2015	26
15/LO/0725/AM01	Transmission of hepatitis C virus in men who have sex with men	Substantial amendment dated 14	14/10/2015	26
15/LO/0725/AM02	Transmission of hepatitis C virus in men who have sex with men		02/12/2015	18
15/LO/0725/AM03	Transmission of hepatitis C virus in men who have sex with men		29/02/2016	17
15/LO/0725/AM04	Transmission of hepatitis C virus in men who have sex with men	Substantial amendment dated 22	22/03/2016	8
15/LO/0732/AM01	CapaCiTY Study 2- Chronic Constipation Treatment Pathway	1	28/01/2016	27
15/LO/0736/AM02	Principal Component Analysis in Medical Image Processing	Substantial amendment dated 09	09/12/2015	20
15/LO/0739/AM01	Observer performance and image quality in low-dose CT.	Substantial amendment dated 5	05/11/2015	27
15/LO/0894/AM01	LY2951742 in Chronic Cluster Headaches (CGAM)		11/12/2015	27
15/LO/0894/AM02	LY2951742 in Chronic Cluster Headaches (CGAM)	Substantial amendment dated 25	25/01/2016	26
15/LO/0954/AM01	INNOVATION (EORTC 1203)	1	16/02/2016	27
15/LO/0967/AM01	iNOVATE Study: A study of ibrutinib or placebo with rituximab		25/11/2015	25
15/LO/1076/AM01	Hepatitis C in an isolated UK community	Substantial	08/12/2015	29

		amendment 1 dated		
15/LO/1076/AM02	Hepatitis C in an isolated UK community	Substantial amendment 2	18/03/2016	6
15/LO/1168/AM01	Dissociation: experience and change. Version n1		21/10/2015	31
15/LO/1169/AM01	B7 family proteins in diabetic nephropathy - version 1	Amendment 1	26/06/2015	21
15/LO/1612/AM01	1st line treatment with MEDI4736 in urothelial bladder cancer (DANUBE)	Substantial amendment 1 - 22 O	22/10/2015	7
15/LO/1612/AM02	1st line treatment with MEDI4736 in urothelial bladder cancer (DANUBE)	3	26/11/2015	29
15/LO/1612/AM10	1st line treatment with MEDI4736 in urothelial bladder cancer (DANUBE)		10/03/2016	9
15/LO/1664/AM01	Influenza Clinical Investigation for Children (ICICLE)		16/12/2015	22
15/LO/2070/AM01	'Weighing as part of your care': a feasibility study	Substantial amendment 1	09/03/2016	15
16/LO/0034/AM01	BH29884 - Prophylactic RO5534262 vs no prophylaxis in Haemophilia A.		08/02/2016	18
16/LO/0224/AM01	An evaluation of an adapted ACT group for stroke survivors		24/03/2016	7
MSA RETRO 11 1 SB/AM09	rotocol to identify suitable volunteers for inclusion Retroscreen Pane		11/08/2015	11
MSA RETRO 11 1 SB/AM10	rotocol to identify suitable volunteers for inclusion Retroscreen Pane			0

### Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
09/H0703/72/AM05	Hypoglycaemia and brain injury VN1	Amendment 4 02/04/2015	02/04/2015	28
14/LO/0855/AM01	673-201 Study of BMN 673 in patients with Germline BRCA mutation		15/04/2015	30
14/LO/1139/AM03	A Phase 2 Study to Evaluate AMG 334 in Chronic Migraine Prevention		29/07/2015	28
14/LO/1139/AM04	A Phase 2 Study to Evaluate AMG 334 in Chronic Migraine Prevention	Substantial amendment dated 02	02/10/2015	28

14/LO/2184/AM02	Impact of Physical activity and Vitamin D on osteoarthritic knee pain		13/08/2015	19
15/LO/0521/AM01	Open-label Extension Study to Assess the Safety and Efficacy of AMG334	SA1	29/07/2015	28
15/LO/0722/AM02	GWEP1414 - GWP42003-P for seizures in Lennox-Gastaut Syndrome	Substantial amendment 2	27/11/2015	28
P/03/122/AM13	Immunoregulation at the Mucosal Barrier		28/09/2015	25

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

<b>Favourable opinion timeline</b>				
<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>
07/Q0603/29/AM09/1	ACIT II: Version 1.3	Modified Amendment to Substant	19/05/2015	13
14/LO/1139/AM03/1	A Phase 2 Study to Evaluate AMG 334 in Chronic Migraine Prevention	Modified Amendment to SA3	28/08/2015	4
14/LO/1139/AM04/1	A Phase 2 Study to Evaluate AMG 334 in Chronic Migraine Prevention	Modified Amendmnet to Substant	02/11/2015	2
14/LO/2184/AM02/1	Impact of Physical activity and Vitamin D on osteoarthritic knee pain	Substantial amendment dated 2	21/10/2015	13
15/LO/0722/AM02/1	GWEP1414 - GWP42003-P for seizures in Lennox-Gastaut Syndrome	Modified amendment to Sub Amen	26/01/2016	8

<b>Unfavourable opinion timeline</b>				
<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>



**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 14 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
13/LO/0150/AM05	The regorafenib in patients with hepatocellular carcinoma.		12/01/2016	71

**Modified Amendments over 14 day timeline**

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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