

**London - Riverside Research Ethics Committee**

**Annual Report**

**01 April 2016 - 31 March 2017**



## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	London - Riverside Research Ethics Committee
<b>Type of REC:</b>	RECs recognised to review CTIMPS in healthy volunteers - type i, RECs recognised to review CTIMPS in patients - type iii
<b>Type of Flag:</b>	Phase 1 In healthy volunteers Paediatric
<b>Chair:</b>	Dr Margaret Jones
<b>Vice-Chair:</b>	Dr Matthew Hyde
<b>Alternate Vice-Chair:</b>	Mrs Dinah Smith
<b>REC Manager:</b>	Miss Tina Cavaliere
<b>REC Assistant:</b>	Helen Sivey (until 31/12/2016) Vacant (01/01/2017 to 19/03/2017) Miss Charlotte Ferris (from 20/3/2017)
<b>Committee Address:</b>	Level 3 Block B Whitefriars Lewins Mead Bristol BS1 2NT
<b>Telephone:</b>	02071048044
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## Chair's overview of the past year:

During the year, the Riverside committee has continued to review varied and interesting studies. Our committee has enjoyed meeting researchers from drug trial units as well as NHS organisations.

Our committee members are enthusiastic and keen to contribute their expertise. We are fortunate to have members who come from a variety of disciplines. They are all committed to the objective of supporting high quality research and at the same time protecting and promoting the interests of patients and the public.

This year we have been particularly aware of the need to involve patients and lay people in both the overall design and also the participant information sheets in all studies and have stressed this to our researchers. We are fortunate to have on our committee members who have a special interest in this area.

Once again, we are most grateful for the support which we receive from the administrative staff and in particular from our Manager, Tina Cavaliere who combines practical advice with good humour, a friendly manner and excellent efficiency.

## London - Riverside Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Dr Marina Cecelja	Centre Career Establishment Fellow	Expert	03/12/2015	
Dr Irina Chis Ster	Senior Lecturer In Biostatistics	Expert	02/12/2015	
Dr Julian Collinson	Consultant Cardiologist	Expert	01/03/2011	31/12/2016
Ms Stephanie Ellis	Former Civil Servant	Lay Plus	01/09/2012	
Dr Linda Feighery	Strategic Publication Lead	Lay	16/11/2015	01/10/2016
Dr Nuria Gonzalez-Cinca	Clinical Study Manager	Lay	14/03/2016	
Ms Alison Higgs	Lecturer in Social Work	Lay	31/03/2011	
Dr Matthew Hyde	Research Scientist	Lay	01/09/2009	
Dr Margaret Jones	Retired General Practitioner	Expert	26/09/2007	
Ms Alexandra Mancini	Pan London Lead for Neonatal/Palliative Care	Expert	06/04/2009	
Ms Fanny Mitchell	Retired NHS Manager	Lay Plus	01/10/2009	
Dr Lorraine Murphy	Pharmaceutical Consultant	Expert	13/07/2016	
Mr Kamen Shoylev	Lawyer	Lay Plus	01/12/2011	
Mrs Dinah Smith	Retired Head Teacher	Lay Plus	11/06/2013	
Ms Julia Williams	Senior Producer	Lay Plus	13/06/2013	

## London - Riverside Research Ethics Committee: Deputy Members

Name	Profession	Status	Meeting date attended
None			

## London - Riverside Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended
Mr David Burbidge	Communications/Marketing Development Officer (Retired)	Lay Plus	01/08/2016

## London - Riverside Research Ethics Committee: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Dr Marina Cecelja	Research Fellow at King's college London, associate editor at the JRSM cardiovascular disease journal, committee member at the London cardiovascular society. Associate editor at the JRSM cardiovascular disease journal, committee member at the London cardiovascular society	03/01/2017
Dr Irina Chis Ster	I am a member of the local ethical research committee at St George's university of London. i also act as statistical expert. We only review student local projects applications which are not submitted for further review.	03/03/2017
Ms Stephanie Ellis	None	03/01/2017
Dr Nuria Gonzalez-Cinca	Senior Project Manager at MAPI Group	15/12/2016
Dr Matthew Hyde	Employee of Imperial College London and Chelsea & Westminster NHS Trust	09/01/2017
Dr Margaret Jones	A few shares in Smith and Nephew	21/12/2016
Ms Alexandra Mancini	None	31/03/2017
Ms Fanny Mitchell	None	03/01/2017
Dr Lorraine Murphy	Self-employed consultant working for pharmaceutical companies. Pharmaceutical consultant working with numerous companies on a contract basis. Shareholdings in Novartis and small bio-tech/diagnostic companies e.g. Verona Medical Companies.	07/02/2017
Mr Kamen Shoylev	None	14/12/2016
Mrs Dinah Smith	None	09/01/2017
Ms Julia Williams	None	09/01/2017

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

Month	Date	Number of Members Present at Meeting
April	04/04/2016	12
June	06/06/2016	9
July	04/07/2016	9
August	01/08/2016	9
October	03/10/2016	8
November	07/11/2016	9
December	05/12/2016	9
January	09/01/2017	7
March	06/03/2017	9

9 full committee meetings were held during the reporting period.

### Proportionate Review Sub-Committee Meetings held during 01 April 2016 - 31 March 2017:

Month	Date	Number of Members Present at Meeting
July	20/07/2016	3
November	16/11/2016	3
December	15/12/2016	3
January	18/01/2017	4
March	20/03/2017	4

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

### Sub-Committee Meetings held during 01 April 2016 - 31 March 2017:

Month	Date	Number of Members Present at Meeting
April	01/04/2016	2
April	08/04/2016	2
April	15/04/2016	2
April	22/04/2016	2
April	29/04/2016	2
May	06/05/2016	2
May	13/05/2016	2
May	20/05/2016	2
June	03/06/2016	2
June	10/06/2016	2
June	17/06/2016	2
June	24/06/2016	2
July	01/07/2016	2
July	08/07/2016	2
July	15/07/2016	2
July	22/07/2016	2
July	29/07/2016	2

August	05/08/2016	2
August	12/08/2016	3
August	26/08/2016	2
September	02/09/2016	2
September	09/09/2016	3
September	16/09/2016	3
September	23/09/2016	2
October	07/10/2016	4
October	14/10/2016	3
October	28/10/2016	2
November	04/11/2016	2
November	11/11/2016	2
November	18/11/2016	2
November	25/11/2016	2
December	02/12/2016	2
December	09/12/2016	3
December	09/12/2016	3
December	16/12/2016	2
December	23/12/2016	4
December	30/12/2016	2
January	12/01/2017	2
January	20/01/2017	2
January	27/01/2017	3
February	03/02/2017	3
February	10/02/2017	2
February	17/02/2017	2
March	03/03/2017	2
March	10/03/2017	4
March	17/03/2017	2
March	24/03/2017	2
March	31/03/2017	2

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

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

None

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

Name	Number of Meetings Attended
Dr Marina Cecelja	7
Dr Irina Chis Ster	6
Dr Julian Collinson	3
Ms Stephanie Ellis	9
Dr Linda Feighery	2
Dr Nuria Gonzalez-Cinca	4
Dr Matthew Hyde	6
Dr Margaret Jones	9
Ms Fanny Mitchell	7
Dr Lorraine Murphy	6
Mr Kamen Shoylev	5
Mrs Dinah Smith	8
Ms Julia Williams	8

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

Name	Number of Meetings Attended
Dr Irina Chis Ster	1
Ms Stephanie Ellis	4
Dr Matthew Hyde	3
Dr Margaret Jones	4
Ms Fanny Mitchell	1
Mrs Dinah Smith	2
Ms Julia Williams	2

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

Name	Number of Meetings Attended
Dr Marina Cecelja	7
Dr Irina Chis Ster	6
Dr Julian Collinson	3
Ms Stephanie Ellis	8
Dr Linda Feighery	3
Dr Matthew Hyde	14
Dr Margaret Jones	44
Ms Fanny Mitchell	5
Dr Lorraine Murphy	3
Mr Kamen Shoylev	2



Mrs Dinah Smith	10
Ms Julia Williams	4

**Training 01 April 2016 - 31 March 2017**

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Dr Marina Cecelja	15/04/2016	Equality and Diversity
Dr Marina Cecelja	05/09/2016	Local Training Day - Riverside REC
Dr Marina Cecelja	14/11/2016	NIH Web-based training course "Protecting Human Research Participants"
Dr Marina Cecelja	05/12/2016	Local Training on reviewing Substantial amendments and PR applications
Dr Irina Chis Ster	21/04/2016	Fair research review A (possible) framework for reviewing research Handling disagreements
Dr Irina Chis Ster	05/09/2016	Local Training Day - Riverside REC
Dr Irina Chis Ster	09/02/2017	Equality and Diversity
Dr Irina Chis Ster	14/03/2017	HRA Committee Members Induction
Ms Stephanie Ellis	05/09/2016	Local Training Day - Riverside REC
Ms Stephanie Ellis	05/12/2016	Local Training on reviewing Substantial amendments and PR applications
Dr Nuria Gonzalez-Cinca	05/09/2016	Local Training Day - Riverside REC
Dr Nuria Gonzalez-Cinca	14/03/2017	HRA Committee Members Induction Course
Dr Matthew Hyde	30/06/2016	Training for new REC Chairs
Dr Matthew Hyde	06/07/2016	Local Training Day - York
Dr Matthew Hyde	05/09/2016	Local Training Day - Riverside REC
Dr Matthew Hyde	05/12/2016	Local Training on reviewing Substantial amendments and PR applications
Dr Matthew Hyde	14/02/2017	Equality and Diversity
Dr Matthew Hyde	27/03/2017	Chair's Review meeting
Dr Margaret Jones	05/09/2016	Local Training Day - Riverside REC
Dr Margaret Jones	01/12/2016	National Chairs Training Day
Dr Margaret Jones	05/12/2016	Local Training on reviewing Substantial amendments and PR applications
Dr Margaret Jones	02/02/2017	Equality and Diversity
Dr Margaret Jones	27/03/2017	Chair's Review meeting
Ms Fanny Mitchell	05/09/2016	Local Training Day - Riverside REC
Ms Fanny Mitchell	05/12/2016	Local Training on reviewing Substantial amendments and PR applications

Ms Fanny Mitchell	04/03/2017	E&D online
Dr Lorraine Murphy	20/07/2016	Induction for RES members
Dr Lorraine Murphy	04/08/2016	Equality and Diversity
Dr Lorraine Murphy	31/10/2016	Reviewing research design of trials
Dr Lorraine Murphy	31/10/2016	Training for commercial studies
Dr Lorraine Murphy	05/12/2016	Local Training on reviewing Substantial amendments and PR applications
Dr Lorraine Murphy	06/12/2016	Committee Members Induction
Dr Lorraine Murphy	16/02/2017	National Members Training Day
Mr Kamen Shoylev	05/12/2016	Local Training on reviewing Substantial amendments and PR applications
Mrs Dinah Smith	14/07/2016	Training - Personal Data in Research - A Workshop
Mrs Dinah Smith	05/09/2016	Local Training Day - Riverside REC
Mrs Dinah Smith	05/12/2016	Local Training on reviewing Substantial amendments and PR applications
Ms Julia Williams	05/09/2016	Local Training Day - Riverside REC
Ms Julia Williams	05/12/2016	Local Training on reviewing Substantial amendments and PR applications
Ms Julia Williams	15/03/2017	Adults Lacking Capacity to consent

## 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	17	38.64
Phase 1	1	2.27
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	0	0.00
Others	26	59.09
<b>Total Applications Reviewed</b>	<b>44</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	1
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	10
Number of paediatric applications reviewed	12
Number of device applications reviewed	0
Number of prisoner applications reviewed	1
Number of applications involving adults unable consent reviewed	0
Number of applications reviewed that are funded by the US DHHS	0
Number of qualitative applications reviewed	3

**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	11	25.00
Favourable Opinion with Additional Conditions	2	4.55
Unfavourable Opinion	2	4.55
Provisional Opinion	29	65.91
Provisional Opinion Pending Consultation with Referee	0	0.00
<b>Total</b>	<b>44</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	29	65.91
Further Information Favourable Opinion with Additional Conditions	0	0.00
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	11	25.00
Favourable Opinion with Additional Conditions	2	4.55
Unfavourable Opinion	2	4.55
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>44</b>	<b>100</b>

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

<b>Total Applications Reviewed</b>	<b>11</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	0
Number of student applications reviewed	4
Number of paediatric applications reviewed	3
Number of device applications reviewed	0
Number of qualitative applications reviewed	0

**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	7	63.64
Favourable Opinion with Additional Conditions	0	0.00
No Opinion transfer to full committee for review	3	27.27
Provisional Opinion	1	9.09
Unfavourable Opinion	0	0.00
<b>Total</b>	<b>11</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>	4.89
<b>Number of completed applications for full ethical review</b>	44
<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>	6
<b>Number of completed applications over 40 days as a % of total</b>	13.64%
<b>Number of days taken to final decision – average (mean)</b>	32
<b>Number of completed proportionate review applications for ethical review</b>	8
<b>Number of completed proportionate review applications for ethical review over 14 days (Please note, the timeline for the review of applications was extended from 14 to 21 calendar days in December 2016)</b>	0
<b>Number of completed proportionate review applications for ethical review over 21 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>	1
<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>	2
<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>	150
<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>	0.67%
<b>Number of completed substantial amendments over 28 days</b>	5
<b>Number of completed substantial amendments over 28 days as a % of total substantial amendments</b>	3.33%
<b>Number of modified amendments reviewed</b>	5
<b>Number of completed modified amendments over 14 days</b>	1
<b>Number of completed modified amendments over 14 days as a % of total modified amendments</b>	20.00%
<b>Number of non substantial amendments received</b>	99

<b>Number of substantial amendments received for information</b>	3
<b>Number of substantial amendments received for new sites/PIs</b>	39
<b>Number of annual progress reports received</b>	2
<b>Number of safety reports received</b>	36
<b>Number of Serious Adverse Events received</b>	5
<b>Number of final reports received</b>	9



**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>
16/LO/0541	CYNAPSUS CTH-300	36
16/LO/0542	CYNAPSUS CTH-301	36
16/LO/0545	iMYC	31
16/LO/0550	Human Retinal Leukogram	58
16/LO/0952	TARGET3D	31
16/LO/0961	An investigation into person recognition across different modalities	35
16/LO/1081	Electron microscopy to detect cellular apoptosis in mesothelioma	43
16/LO/1159	Guided online self-help for young people with cancer and depression	35
16/LO/1334	Placebo-Controlled Study–Systemic Lupus Erythematosus	60
16/LO/1342	Mephedrone administration study	29
16/LO/1354	LY2951742 in Patients with Episodic or Chronic Cluster Headache	25
16/LO/1355	InPACT	39
16/LO/1624	An Open-Label Extension Trial to Assess the Long-Term Safety of ZX008	55
16/LO/1718	Neonatal Resuscitation - Sustained Inflations	29
16/LO/1724	Computational model of SNS using tractography	26
16/LO/1879	Network dysfunction following paediatric traumatic brain injury	34
16/LO/1915	Mental Health and Psychological Wellbeing Drop-In Centre	25
16/LO/1919	Sarizotan in Patients with Rett Syndrome with Respiratory Symptoms	24
16/LO/1922	Can vibration therapy increase bone length?	31
16/LO/1954	LCZ696 vs Enalapril in Paediatric Patients with Heart Failure	24
16/LO/2038	Millendo - MLE4901-101 - Polycystic Ovary Syndrome - Phase 2b	31
16/LO/2041	THE BLF EARLY COPD DEVELOPMENT PARTNERSHIP GRANT	29
16/LO/2093	mitoPK	26
16/LO/2121	Participation of service users and carers in ICD11	27
16/LO/2227	Supporting Mental Wellbeing (SMW), v1	47
17/LO/0057	WELCOME project	49
17/LO/0385	Work of breathing in preterm infants: SNIPPV v HHHFNC	31
17/LO/0405	Systematic Genetic Testing For Personalised Ovarian Cancer Therapy	31
17/LO/0436	Development of an MCM5 ELISA test for oesophageal cancer	36

**Further Information Favourable Opinion with Additional Conditions**

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

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

REC Reference	Title	Number of Days on Clock
16/LO/0989	[14C]-CORT125134 in Healthy Subjects QCL117667	28
16/LO/1161	COBALT: Coversin in patients with PNH	28
16/LO/1175	The PEACH Study	28
16/LO/1367	Paediatric ARDS Incidence and Epidemiology(PARDIE) study	25
16/LO/1709	4296: NASH-Semaglutide in subjects with non-alcoholic steatohepatitis	24
16/LO/1853	Objective Assessment of Dynamic Bracing after PCL Injury	23
17/LO/0013	Breathing Together- Cross-sectional validation study	29
17/LO/0019	How service users experience formulations in therapy for psychosis v1	29
17/LO/0028	An evaluation of R&R2ADHD in Young Offenders: A mixed methods study	29
17/LO/0401	M15-942 DAA Re-Treatment for Virologic Failures in AbbVie HCV Studies	25
17/LO/0409	E7080-G000-307 CLEAR	25

#### Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/LO/1106	A Phase III Study of Pembrolizumab + Chemotherapy in 1L TNBC	28
16/LO/1390	APAChe	24

#### Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
16/LO/1204	The Effects of Modafanil on Surgical Error Rate	19
17/LO/0159	Patient-centred interpreting in medical settings	25

#### Provisional Opinion

REC Reference	Title	Number of Days on Clock
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<b>Provisional Opinion Pending Consultation with Referee</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>

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

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

**Table 9.2: Breakdown of current status of all PRS 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>
16/LO/1383	Spotted	14

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

<b>Further Information Unfavourable Opinion</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>

<b>Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
16/LO/1373	Biomolecular analysis of penile cancer, Version 1	2
16/LO/1374	Post-operative monitoring of tissue blood flow in plastic surgery V1.0	2
16/LO/2080	Illness perceptions, defence styles, alexithymia and QOL in IBD - v.1	4

16/LO/2083	High Resolution Retinal Imaging	3
16/LO/2088	Validation of the Paediatric Anaesthesia Behaviour Score in PACU	5
17/LO/0153	PTSD after traumatic brain injury	9
17/LO/0512	Cost of Autism Diagnostic Assessment Study	9

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

<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
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#### **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/Q0401/40/AM24	BRAINS	5.0	08/08/2016	18
09/H0706/62/AM03	Aetiopathogenesis of penile in-situ cancer and invasive penis cancer-2	3	29/03/2016	13
10/H0706/35/AM16	Pain In Neuropathy Study (PINS)	8	06/04/2016	14
10/H0706/92/AM04	STAPLED MESH STOMA REINFORCEMENT TO PREVENT PARASTOMAL HERNIAS	Protocol version 4.0, dated 20	20/12/2016	14
11/LO/0935/AM10	Personalised Medicine for Morbid Obesity	11	14/03/2016	1
11/LO/0935/AM12	Personalised Medicine for Morbid Obesity	Version 12, 20/10/2016	20/10/2016	8
11/LO/1162/AM02	Non-Hodgkin's Lymphoma in Young Adults	Amendment 2 - June 20th 2016	20/06/2016	23
11/LO/1570/AM29	CHEMO-T	7.0	08/06/2016	5
11/LO/1570/AM30	CHEMO-T	Amendment 21- Urgent safety me	06/12/2016	11
11/LO/1570/AM31	CHEMO-T	Amendment 21b- Urgent safety m	16/12/2016	7
12/LO/0081/AM13	008: Oral CP-690,550 as Maintenance Therapy for Ulcerative Colitis	A3921096	29/04/2016	19
12/LO/0082/AM14	009: Open-label Oral CP-690,550 for Treatment of Ulcerative Colitis	A3921139	22/04/2016	21
12/LO/0082/AM15	009: Open-label Oral CP-690,550 for Treatment of Ulcerative Colitis	A3921139 Substantial Amendment	09/02/2017	17
12/LO/1506/AM12	HGS1006-C1121 Phase 3 study of belimumab plus SoC in Lupus Nephritis	1.0	05/04/2016	9
12/LO/2019/AM07	Breast Screening and Monitoring Study	6	26/04/2016	12
12/LO/2019/AM10	Breast Screening and Monitoring Study	Amendment 7, 26/09/2016	09/01/2017	18
13/LO/0002/AM21	Efficacy & safety of GS-1101 with Ofatumumab in previously treated CLL	SA13	11/04/2016	7
13/LO/0002/AM22	Efficacy & safety of GS-1101 with Ofatumumab in previously	14.0	13/06/2016	3

	treated CLL			
13/LO/0002/AM25	Efficacy & safety of GS-1101 with Ofatumumab in previously treated CLL	SA15 - 06.09.2016	06/09/2016	23
13/LO/0002/AM26	Efficacy & safety of GS-1101 with Ofatumumab in previously treated CLL	SA #16	30/11/2016	6
13/LO/0242/AM08	GE180 and microglial activation in AD and MCI subjects	6.0	07/09/2016	32
13/LO/0699/AM19	ELAD study	SA13	09/03/2017	13
13/LO/0822/AM11	VinCaP	MREC11MHRA5	16/09/2016	14
13/LO/0822/AM12	VinCaP	MREC12MHRA6	21/10/2016	14
13/LO/1152/AM06	An exploratory breast lead interval study (EBLIS)	6	29/04/2016	9
13/LO/1152/AM07	An exploratory breast lead interval study (EBLIS)	7.0	11/11/2016	6
13/LO/1198/AM02	Exacerbations in severe asthma patients: mechanisms and biomarkers	3.0	18/08/2016	10
13/LO/1463/AM16	InterAACT A Multicentre Randomised Phase II Advanced Anal Cancer Trial	V6	15/02/2016	16
13/LO/1463/AM21	InterAACT A Multicentre Randomised Phase II Advanced Anal Cancer Trial	Amendment 11 - Change Protocol	13/03/2017	8
13/LO/1473/AM09	Telaprevir in genotype 3 HCV	Amendment 6	06/06/2016	16
13/LO/1787/AM03	PROFILE Study Version 1.1	5	25/05/2016	11
14/LO/0022/AM08	Randomised Phase II study in untreated advanced renal cell carcinoma	7.0	08/09/2016	22
14/LO/0324/AM14	Pulmaquin <sup>®</sup> with Non-Cystic Fibrosis Bronchiectasis (ORBIT 3)	SA#7	21/04/2016	4
14/LO/0339/AM06	The ACORN study: Coping and Relaxation in Pregnancy	5.0	24/05/2016	21
14/LO/0339/AM07	The ACORN study: Coping and Relaxation in Pregnancy	Amendment 6 07-11-2016	07/11/2016	6
14/LO/0343/AM05	PET monitoring for MS therapy	1	14/03/2016	25
14/LO/0471/AM13	Pulmaquin <sup>®</sup> with Non-Cystic Fibrosis Bronchiectasis (Orbit 4)	SA#7	21/04/2016	5
14/LO/0528/AM18	SAD Safety, PK&PD of IV GSK2831781 in HV & patients with psoriasis	8.0	15/07/2016	11
14/LO/0528/AM19	SAD Safety, PK&PD of IV GSK2831781 in HV & patients with psoriasis	9.0	12/08/2016	28
14/LO/0528/AM20	SAD Safety, PK&PD of IV GSK2831781 in HV & patients with psoriasis	10	04/11/2016	17
14/LO/0528/AM21	SAD Safety, PK&PD of IV GSK2831781 in HV & patients with psoriasis	Substantial Amendment 11	06/12/2016	7

14/LO/0813/AM05	CanACT feasibility	Substantial Amendment No. 3 [1]	02/12/2016	6
14/LO/0818/AM13	MK-3475 versus SOC in 1L Subjects with PD-L1 Strong Metastatic NSCLC	MK-3475-024-03	22/04/2016	16
14/LO/0818/AM15	MK-3475 versus SOC in 1L Subjects with PD-L1 Strong Metastatic NSCLC	6.0	15/08/2016	1
14/LO/1102/AM05	Helping Urgent Care Users Cope with Distress about Physical Complaints	Substantial amendment 31, Janu	21/02/2017	11
14/LO/1169/AM08	dHCP	5.0	23/03/2016	13
14/LO/1169/AM12	dHCP	6.0	27/09/2016	12
14/LO/1169/AM13	dHCP	7.0	27/10/2016	1
14/LO/1169/AM15	dHCP	Amendment 9.0, 07 February 201	07/02/2017	33
14/LO/1192/AM07	Bosutinib vs Imatinib in Newly Diagnosed CML	1.0	04/07/2016	23
14/LO/1192/AM09	Bosutinib vs Imatinib in Newly Diagnosed CML	AV0001_SA#05_C hange of Sponsor	21/02/2017	7
14/LO/1194/AM03	Neurophysiology in disorders of glycinergic neurotransmission	2nd Amendment	30/11/2016	17
14/LO/1293/AM08	Study of Effectiveness and Safety of SD-101 in Subjects with Epidermolysis Bullosa	3.0	09/11/2016	9
14/LO/1464/AM05	Natural History of Acute Hepatic Porphyria (AHP)	2.0	20/10/2016	11
14/LO/1490/AM14	Study of Nivolumab in patients with Melanoma	7	11/03/2016	21
14/LO/1490/AM15	Study of Nivolumab in patients with Melanoma	2.0	23/05/2016	10
14/LO/1490/AM16	Study of Nivolumab in patients with Melanoma	Nivolumab IB v15, IB15 erratum	12/10/2016	14
14/LO/1532/AM04	Copanlisib pharmacodynamic study	Substantial Amendment 4	22/04/2016	17
14/LO/1532/AM05	Copanlisib pharmacodynamic study	5	01/06/2016	6
14/LO/1532/AM07	Copanlisib pharmacodynamic study	6.0	19/08/2016	8
14/LO/1532/AM08	Copanlisib pharmacodynamic study	IB version 9	29/11/2016	7
14/LO/1918/AM07	Next Generation Tests for Latent Tuberculosis Infection	5	03/06/2016	5
14/LO/1948/AM03	Native T1 Mapping in Rare Diseases	3.0	21/09/2016	12
14/LO/2071/AM04	Healthy Start, Happy Start: Helping parents with children's behaviour	3.0	27/05/2016	24

14/LO/2071/AM06	Healthy Start, Happy Start: Helping parents with children's behaviour	4	13/01/2017	13/01/2017	19
14/LO/2119/AM08	Boston Biomedical: The BRIGHTER Study	9		22/03/2016	14
14/LO/2119/AM09	Boston Biomedical: The BRIGHTER Study	216525 GBR IEC Amendment Submi		25/01/2017	9
15/LO/0009/AM03	ProRAFT - Radiofrequency Ablation Focal Treatment	1		31/03/2016	20
15/LO/0010/AM01	3D surface imaging and breast conservation	1		06/04/2016	8
15/LO/0015/AM01	The predictive ability of 4MGS in IPF	1		14/04/2016	2
15/LO/0121/AM08	A Phase I/II trial of MK-3475 (pembrolizumab) in children's solid tumors and lymphoma	MK3475-051-04		18/08/2016	15
15/LO/0151/AM02	Immune cells in Inflammatory Bowel Disease	Amendment 1 (AM02)		09/11/2016	8
15/LO/0173/AM04	Structure/function relationship in glaucoma with 3D perimetric stimuli	3.0		01/09/2016	7
15/LO/0571/AM01	ALERT	1		27/04/2016	9
15/LO/0719/AM02	Paediatric Tumour Profiling	Amt 02 (SA01) 11.10.16		18/10/2016	7
15/LO/0815/AM01	Development of a lifestyle service pathway in NAFLD	1.0		09/08/2016	6
15/LO/0886/AM02	232SM201 - Spinal Muscular Atrophy Study	5.1		21/04/2016	9
15/LO/0924/AM02	A Phase 3 Double Blind Randomised Study of Orally Administered PLX3397	2.0		23/05/2016	12
15/LO/0924/AM03	A Phase 3 Double Blind Randomised Study of Orally Administered PLX3397	Sponsor change to Daiichi sank		08/08/2016	8
15/LO/0924/AM04	A Phase 3 Double Blind Randomised Study of Orally Administered PLX3397	5.0		13/10/2016	20
15/LO/0924/AM05	A Phase 3 Double Blind Randomised Study of Orally Administered PLX3397	Substantial Amendment #6		30/11/2016	15
15/LO/1119/AM04	ARTESiA: Apixaban in patients with device-detected sub-clinical AF	6.0		18/04/2016	17
15/LO/1120/AM01	ODYSSEY (Once daily DTG-based ART in young people vs standard therapy)	01		28/03/2016	9
15/LO/1138/AM03	SVR SOF Cirrhosis Registry Study	SA3: Eplusa (SOF/VEL) Investi		08/07/2016	2
15/LO/1238/AM06	CUTHIVAC002	1.0		27/09/2016	18
15/LO/1246/AM03	MM-141-07-02-02 (CARRIE) Pancreatic Cancer Phase 2	3.0		15/06/2016	15
15/LO/1399/AM01	ILD Controls V1.0	1		08/02/2016	21



15/LO/1419/AM08	PEARLS (pembrolizumab as adjuvant treatment for lung cancer)	16th Jan 2017	16/01/2017	9
15/LO/1432/AM02	RIM4DMD	2.1	30/06/2016	14
15/LO/1432/AM05	RIM4DMD	3.0	15/12/2016	6
15/LO/1653/AM10	CAM2038 in Adult Outpatients with Opioid Use Disorder	3.0	09/08/2016	17
15/LO/1653/AM12	CAM2038 in Adult Outpatients with Opioid Use Disorder	Amendment 7	30/09/2016	28
15/LO/1653/AM13	CAM2038 in Adult Outpatients with Opioid Use Disorder	Substantial Amendment 8	22/11/2016	6
15/LO/1665/AM03	Safetxt: a randomised controlled trial of a safer sex intervention	3.0	01/06/2016	6
15/LO/1729/AM04	VX15-770-123 - Cystic Fibrosis study for 3-5 year olds	SA03 Protocol Amend	03/01/2017	2
15/LO/1808/AM02	Vitamin K and folate status of breast fed preterm infants	2.0	19/05/2016	13
15/LO/1808/AM03	Vitamin K and folate status of breast fed preterm infants	version 3.0, 14th December 201	16/12/2016	5
15/LO/2008/AM03	MK1439A in treatment naïve HIV1 infected subjects with NNRTI transmitt	4.0	21/09/2016	12
15/LO/2008/AM04	MK1439A in treatment naïve HIV1 infected subjects with NNRTI transmitt	SA 03 (IB v.8)	17/06/2016	22
15/LO/2034/AM01	A Phase Ib study of pembrolizumab plus chemotherapy in TNBC	1	18/03/2016	8
15/LO/2034/AM02	A Phase Ib study of pembrolizumab plus chemotherapy in TNBC	MK-3475-173-03	12/07/2016	12
15/LO/2034/AM03	A Phase Ib study of pembrolizumab plus chemotherapy in TNBC	SA03	09/11/2016	12
15/LO/2073/AM02	KEYNOTE-158	SA02	11/05/2016	8
15/LO/2073/AM03	KEYNOTE-158	MK-3475-158-06	17/06/2016	14
15/LO/2073/AM05	KEYNOTE-158	SA05- PIS CF & FBR Update	13/12/2016	7
16/LO/0006/AM02	Safety and Biomarker Study with EPI-589 in Parkinson's Disease	1	14/03/2016	14
16/LO/0006/AM03	Safety and Biomarker Study with EPI-589 in Parkinson's Disease	2.0	07/11/2016	3
16/LO/0006/AM08	Safety and Biomarker Study with EPI-589 in Parkinson's Disease	3	13/02/2017	16
16/LO/0021/AM01	NEOD001 versus placebo in AL Amyloidosis with cardiac dysfunction	1	16/03/2016	19

16/LO/0021/AM07	NEOD001 versus placebo in AL Amyloidosis with cardiac dysfunction	2.0	31/08/2016	6
16/LO/0021/AM08	NEOD001 versus placebo in AL Amyloidosis with cardiac dysfunction	3.0	14/10/2016	12
16/LO/0024/AM01	STATIN (version 1.0)	1.0	20/06/2016	22
16/LO/0024/AM02	STATIN (version 1.0)	1.0	23/09/2016	11
16/LO/0025/AM04	simplify	1	15/09/2016	2
16/LO/0333/AM03	Phase II Study of Pembrolizumab in Advanced Recurrent Ovarian Cancer	2.0	27/05/2016	13
16/LO/0443/AM02	A multicentre, open-label, randomised ITP study	1.0	13/06/2016	3
16/LO/0443/AM03	A multicentre, open-label, randomised ITP study	3.0	28/07/2016	11
16/LO/0443/AM05	A multicentre, open-label, randomised ITP study	4.0	28/09/2016	2
16/LO/0443/AM07	A multicentre, open-label, randomised ITP study	Substantial Amendment 5.0	12/12/2016	7
16/LO/0443/AM08	A multicentre, open-label, randomised ITP study	Substantial Amendment 6.0	13/03/2017	8
16/LO/0542/AM01	CYNAPSUS CTH-301	1.0	31/05/2016	19
16/LO/0542/AM05	CYNAPSUS CTH-301	1.0	05/07/2016	7
16/LO/0542/AM08	CYNAPSUS CTH-301	1.0	02/09/2016	6
16/LO/0952/AM01	TARGET3D	4.0	19/10/2016	9
16/LO/1106/AM01	A Phase III Study of Pembrolizumab + Chemotherapy in 1L TNBC	MK-3475-355-00	19/08/2016	14
16/LO/1106/AM04	A Phase III Study of Pembrolizumab + Chemotherapy in 1L TNBC	MK-3475-355-00	04/11/2016	10
16/LO/1106/AM05	A Phase III Study of Pembrolizumab + Chemotherapy in 1L TNBC	SA03 REC (Protocol amendment 0)	20/01/2017	10
16/LO/1159/AM01	Guided online self-help for young people with cancer and depression	Amendment on Letter to GP v2.0	06/12/2016	6
16/LO/1161/AM01	COBALT: Coversin in patients with PNH	1.0	19/08/2016	14
16/LO/1161/AM02	COBALT: Coversin in patients with PNH	2.0	26/09/2016	2
16/LO/1161/AM05	COBALT: Coversin in patients with PNH	Substantial Amendment 3	16/02/2017	33
16/LO/1354/AM02	LY2951742 in Patients with Episodic or Chronic Cluster Headache	I5Q-MC-CGAR_PISCIF V4 update	20/02/2017	19

16/LO/1355/AM01	InPACT	MREC1	28/09/2016	9
16/LO/1624/AM01	An Open-Label Extension Trial to Assess the Long-Term Safety of ZX008	ICF Adaptation	15/11/2016	7
16/LO/1709/AM02	4296: NASH-Semaglutide in subjects with non-alcoholic steatohepatitis	UK Substantial Amendment 1, 13	13/01/2017	15
16/LO/1915/AM01	Mental Health and Psychological Wellbeing Drop-In Centre	1	07/02/2017	36
16/LO/1919/AM01	Sarizotan in Patients with Rett Syndrome with Respiratory Symptoms	Protocol Amend 3, v4.0, ICF v2	29/11/2016	7
16/LO/1919/AM02	Sarizotan in Patients with Rett Syndrome with Respiratory Symptoms	Substantial Amendment 2	14/12/2016	5
16/LO/2038/AM01	Millendo - MLE4901-101 - Polycystic Ovary Syndrome - Phase 2b	Urgent Safety Measure – Remova	09/03/2017	18

<b>Unfavourable opinion</b>				
<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>
07/H0706/81/AM19	Molecular basis of chronic inflammatory and degenerative diseases	19	07/07/2016	14
12/LO/2019/AM08	Breast Screening and Monitoring Study	Amendment 7, 26/09/2016	17/11/2016	10
12/LO/2019/AM09	Breast Screening and Monitoring Study	Amendment 7, 26/09/2016	26/09/2016	10
13/LO/0699/AM10	ELAD study		28/08/2015	12
14/LO/0818/AM18	MK-3475 versus SOC in 1L Subjects with PD-L1 Strong Metastatic NSCLC	SA10	20/03/2017	12
15/LO/1236/AM05	NEOD001 versus placebo in AL Amyloidosis	4.0	30/08/2016	16
15/LO/1665/AM05	Safetxt: a randomised controlled trial of a safer sex intervention	5.0	21/10/2016	14
15/LO/1665/AM08	Safetxt: a randomised controlled trial of a safer sex intervention	8	17/02/2017	29
15/LO/1987/AM05	A Trial to Evaluate Terguride in Subjects with CYP2D6 Genotypes.		08/04/2016	26
15/LO/2034/AM05	A Phase Ib study of pembrolizumab plus chemotherapy in TNBC	SA04	20/07/2016	18
16/LO/1106/AM09	A Phase III Study of Pembrolizumab + Chemotherapy in 1L TNBC	SA06 (IB Edition 13 and PIS/CF	20/03/2017	10

**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/H0706/81/AM19/1	Molecular basis of chronic inflammatory and degenerative diseases	19	04/08/2016	4
07/Q0401/25/AM08/1	Analysis of specimens from patients with orthopaedic implants	1	23/03/2016	15
13/LO/0699/AM10/1	ELAD study	1.0	28/06/2016	6
15/LO/1236/AM05/1	NEOD001 versus placebo in AL Amyloidosis			5
15/LO/1665/AM05/1	Safetxt: a randomised controlled trial of a safer sex intervention	5 (modified amendment)	05/12/2016	1

<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 21 0day 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
16/LO/1915/AM01	Mental Health and Psychological Wellbeing Drop-In Centre	1	07/02/2017	36

**Modified Amendments over 14 day timeline**

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
07/Q0401/25/AM08/1	Analysis of specimens from patients with orthopaedic implants	1	23/03/2016	15

