

London - Chelsea Research Ethics Committee

Annual Report

01 April 2015 - 31 March 2016



Part 1 – Committee Membership and Training

Name of REC:	London - Chelsea Research Ethics Committee
Type of REC:	REC recognised to review CTIMPs in Healthy Volunteers – Type I REC recognised to review CTIMPs in Patients - Type III
Type of Flag:	Phase 1 in patients and healthy volunteers
Chair:	Dr Shelley Dolan
Vice-Chair:	Mrs Patricia Pank
Alternate Vice-Chair:	Dr Michael Schachter
REC Manager:	Miss Gemma Oakes (until November 2015) Miss Aliko Sifostratoudaki (December 2015 – Present)
REC Assistant:	Aliko Sifostratoudaki (April 2015-November 2015) Vacant from (December 2015 - Present)
Committee Address:	Research Ethics Committee (REC) Bristol Centre Level 3, Block B Whitefriars Lewins Mead Bristol BS1 2NT
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Chair's overview of the past year:

We have seen some excellent studies and have enjoyed working together as a committee with everyone's different skills all essential in making the committee decisions clear and robust. We have welcomed some new members all of whom have added to the rigor and quality of debate. We have always been quorate and most of the committee have attained the required educational and training requirements. We have benefitted from the excellent coordination of Gemma Oakes and then a very smooth transition to our new substantive REC Manager Aliko Sifostatoudaki who has ensured timely access to papers and is a warm and excellent coordinator. There is a marked improvement in support and effective working with the Bristol office and this has been sustained throughout this year.

Dr Shelley Dolan

London - Chelsea Research Ethics Committee Membership

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

London - Chelsea Research Ethics Committee: Deputy Members

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

Name	Profession	Status	Meeting date attended
Ms Stephanie Ellis	Formal Civil Servant	Lay Plus	13/04/2015, 13/07/2015
Canon Ian Ainsworth Smith	Retired Hospital Chaplain	Lay Plus	PRSC- 27/10/2015

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

Name	Declaration of Interest	Date
Mr Roger A'Hern	Retired as ICRCBU Senior Statistician 30/09/2013 but still active in field part time.	08/02/2016
Dr Judy Allfrey	Lay member on King College London Research Ethics Committee sub-Committee.	15/02/2016
Dr. Sonya Babu-Narayan	British Heart Foundation funded awardee	15/02/2016
Dr Shelley Dolan	ED Royal Marsden NHS FtED Cancer Vanguard (NHS). Member of the RM & ICR Clinical Research Governance board	16/01/2016
Dr Adam Jacobs	1. Employed as a statistician at Premier Research, a CRO. 2. Holds shares in Dianthus Medical Limited.	13/10/2015
Ms Karen Lipworth	Clients include pharmaceutical companies and CROs who could potentially be involved in a study which is sent for review by the REC. Patient safety champion with Imperial College Health Partners.	11/05/2015
Mr Serge Miodragovic	Employed as Ophthalmology Research Co-ordinator based at Western Eye Hospital, Imperial College Healthcare NHS Trust.	15/10/2015
Mrs Patricia Pank	1. A Trustee of the Helen Bamber Foundation. 2. Patient Representative Clinical Governance for Emergency Services - UCLH	13/10/2015
Mrs Paula Rogers	Associate member for Foundation and Nursing studies. Received funding from the British Heart Foundation. Full time in roles such as assessing feasibility of new research studies, ethical research delivery. Regular contact with local R&D office, completion of REC applications and Site Specific Assessments. Involved with Local Clinical Research Network - Workforce Development Group. Change of role: From Senior Research Nurse to Research Nurse Manager - (MSc Qualification)	08/02/2016
Ms Cate Savidge	None	13/10/2015
Dr Michael Schachter	None	15/04/2015
Dr Elliot Shinebourne	None	14/12/2015
Dr Mary Taj	None	14/09/2015
Miss Isobel Vass	None	13/10/2015
Ms Mary Watkinson	None	13/10/2015
Mr Fraser Wilson	Member of the Imperial College Research Ethics Committee. It does not consider proposals for medical research within the NHS.	15/02/2016

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

Month	Date	Number of Members Present at Meeting
April	13/04/2015	15
May	11/05/2015	11
June	08/06/2015	11
July	13/07/2015	14
September	14/09/2015	9
October	12/10/2015	16
November	09/11/2015	13
December	14/12/2015	15
February	08/02/2016	14

9 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	22/04/2015	3
July	27/07/2015	3
September	22/09/2015	3
October	27/10/2015	3
December	22/12/2015	3
January	14/01/2016	3
February	18/02/2016	3
March	31/03/2016	3

8 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	03/04/2015	2
April	10/04/2015	2
April	17/04/2015	2
April	24/04/2015	2
May	01/05/2015	3
May	08/05/2015	2
May	15/05/2015	2
May	22/05/2015	2
May	29/05/2015	2
June	05/06/2015	3
June	12/06/2015	2
June	19/06/2015	2
June	26/06/2015	2
July	17/07/2015	2

July	17/07/2015	2
July	24/07/2015	3
July	24/07/2015	2
July	31/07/2015	2
August	10/08/2015	2
August	28/08/2015	3
August	28/08/2015	2
September	11/09/2015	2
September	18/09/2015	2
October	08/10/2015	2
October	15/10/2015	2
October	16/10/2015	2
October	23/10/2015	2
October	30/10/2015	2
November	06/11/2015	2
November	13/11/2015	2
November	16/11/2015	2
November	20/11/2015	2
November	27/11/2015	2
December	04/12/2015	2
December	11/12/2015	2
December	18/12/2015	3
December	25/12/2015	2
January	08/01/2016	2
January	15/01/2016	3
January	22/01/2016	2
January	29/01/2016	2
February	05/02/2016	2
February	12/02/2016	2
February	19/02/2016	2
February	26/02/2016	2
March	04/03/2016	2
March	11/03/2016	2
March	18/03/2016	2
March	25/03/2016	2

49 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

Name	Number of Meetings Attended
Mr Roger A'Hern	8
Dr Judy Allfrey	7
Dr. Sonya Babu-Narayan	5
Mr Jeremy Butler	4
Dr Shelley Dolan	6
Dr Adam Jacobs	7
Mr Philip Kimberley	1
Ms Karen Lipworth	5
Mr Serge Miodragovic	8
Mrs Patricia Pank	9
Mrs Paula Rogers	8
Ms Cate Savidge	7
Dr Michael Schachter	8
Dr Elliot Shinebourne	7
Dr Mary Taj	6
Miss Isobel Vass	8
Ms Mary Watkinson	5
Mr Fraser Wilson	7

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

Name	Number of Meetings Attended
Mr Roger A'Hern	3
Dr Judy Allfrey	3
Mr Serge Miodragovic	1
Mrs Paula Rogers	2
Ms Cate Savidge	1
Dr Michael Schachter	8
Dr Elliot Shinebourne	1
Dr Mary Taj	1
Miss Isobel Vass	2
Ms Mary Watkinson	1

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

Name	Number of Meetings Attended
Mr Roger A'Hern	9
Dr Judy Allfrey	1

Dr Adam Jacobs	7
Mr Philip Kimberley	2
Mr Serge Miodragovic	5
Mrs Patricia Pank	41
Mrs Paula Rogers	6
Ms Cate Savidge	10
Dr Michael Schachter	11
Dr Elliot Shinebourne	6
Dr Mary Taj	2
Miss Isobel Vass	4

Training 01 April 2015 - 31 March 2016

Name of Member	Date	Event(s) attended
Mr Roger A'Hern	11/01/2016	Chelsea Training day
Mr Roger A'Hern	03/02/2016	Research & Human Tissue Legislation course
Dr Judy Allfrey	09/11/2015	NMC Online E&D Training
Dr Judy Allfrey	18/12/2015	IRAS (Integrated Research Application System) training module
Dr Judy Allfrey	11/01/2016	Local Training Day
Dr. Sonya Babu-Narayan	11/01/2016	Local Training Day - London - Chelsea
Dr. Sonya Babu-Narayan	25/01/2016	Induction for new Research Ethics Service Committee members
Dr. Sonya Babu-Narayan	25/01/2016	Training on HRA guidance on Information Sheets and Consent forms
Mr Jeremy Butler	11/01/2016	Local Training Day
Dr Shelley Dolan	11/01/2016	Chelsea Training Day
Dr Adam Jacobs	22/10/2015	EU Data Protection Directive Module 3: 95/46/EC Sep 2015
Dr Adam Jacobs	28/10/2015	ICH GCP Training
Dr Adam Jacobs	29/10/2015	EU Directives and Clinical Trials Directive 2001/20/EC Module 1 Sep 2015
Dr Adam Jacobs	30/10/2015	EU Directives and Clinical Trials Module 2: Directive 2005/28/EC Sep 2015
Dr Adam Jacobs	11/01/2016	Local Training Day
Ms Karen Lipworth	07/05/2015	Introduction to Phase 1 Research - Trials & Regulation module
Ms Karen Lipworth	24/09/2015	Committee Member Induction Training Day
Ms Karen Lipworth	03/12/2015	HRA Workshop: Pragmatic or Point of Care trials.
Ms Karen Lipworth	10/12/2015	Online E&D Training
Ms Karen Lipworth	11/01/2016	Local Training Day
Mr Serge Miodragovic	12/10/2015	Complex Cases Training
Mr Serge Miodragovic	11/01/2016	Local Training Day
Mrs Patricia Pank	08/04/2015	Ethics & GCP Forum ICR
Mrs Patricia Pank	11/01/2016	Local Training Day
Mrs Paula Rogers	25/08/2015	Introduction to Good Clinical Practice eLearning (Secondary Care)
Mrs Paula Rogers	26/11/2015	Local Training Day - London REC Members' Training Day
Mrs Paula Rogers	11/01/2016	Local Training Day
Mrs Paula Rogers	13/01/2016	Training - Assessing the Consequences (benefits and

		harms) of Research: a Health Research Authority workshop
Ms Cate Savidge	03/12/2015	Training - HRA Workshop: Pragmatic or Point of Care trials
Ms Cate Savidge	11/01/2016	Local Training Day
Dr Michael Schachter	09/12/2015	Training - National Training Day for Committee Chairs
Dr Michael Schachter	11/01/2016	Local Training Day
Dr Elliot Shinebourne	19/10/2015	The Ethical Issues of Research Involving Children Training
Dr Elliot Shinebourne	26/11/2015	Local Training Day - London REC Members' Training Day
Dr Elliot Shinebourne	11/01/2016	Local Training Day
Dr Mary Taj	12/10/2015	Analysis and Decision making in safeguarding
Dr Mary Taj	02/02/2016	Good clinical practice update training course
Miss Isobel Vass	19/10/2015	The Ethical Issues of Research Involving Children
Miss Isobel Vass	26/11/2015	Local Training Day - London REC Members' Training Day
Miss Isobel Vass	11/01/2016	Local Training Day
Ms Mary Watkinson	07/10/2015	Training - Introduction to Phase 1 Research - Trials & Regulation
Ms Mary Watkinson	27/11/2015	Training - CTIMP Training Day
Ms Mary Watkinson	11/01/2016	Local Training Day
Mr Fraser Wilson	20/04/2015	HRA Online E&D Training
Mr Fraser Wilson	07/05/2015	Introduction to Phase 1 Research - Trials & Regulation
Mr Fraser Wilson	17/06/2015	Committee Member Induction
Mr Fraser Wilson	11/01/2016	Local Training Day

PART 2: REC WORKLOAD AND ACTIVITY DURING THE REPORTING PERIOD

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

Applications for full ethical review – Study Type	Number	%
Clinical Trial of Investigational Medicinal Product	23	46.00
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	2	4.00
Others	25	50.00
Total Applications Reviewed	50	100

Table 2: Breakdown of full applications and other activity during reporting period

Number of applications made invalid by the REC Manager	0
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	7
Number of paediatric applications reviewed	5
Number of device applications reviewed	3
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	0
Number of applications reviewed that are funded by the US DHHS	0
Number of qualitative applications reviewed	1

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

Decisions taken at meetings following review of applications	Number	%
Favourable Opinion with Standard Conditions	2	4.00
Favourable Opinion with Additional Conditions	9	18.00
Unfavourable Opinion	1	2.00
Provisional Opinion	38	76.00
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	50	100
Number of studies sent back to full committee meeting for final opinion	0	

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

Status of applications at date of generation of report	Number	%
Further Information Favourable Opinion with Standard Conditions	35	70.00
Further Information Favourable Opinion with Additional Conditions	1	2.00
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	2	4.00
Favourable Opinion with Additional Conditions	9	18.00
Unfavourable Opinion	1	2.00
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	2	4.00
Total	50	100

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

Total Applications Reviewed	22
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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	16
Number of studies withdrawn prior to the meeting	0
Number of student applications reviewed	10
Number of paediatric applications reviewed	3
Number of device applications reviewed	0
Number of qualitative applications reviewed	5

Table 7: Decisions given at proportionate review sub-committee meetings held within the reporting period

Decisions taken at proportionate review sub-committee meetings	Number	%
Favourable Opinion with Standard Conditions	5	22.73
Favourable Opinion with Additional Conditions	9	40.91
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	8	36.36
Unfavourable Opinion	0	0.00
Total	22	100

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

Average number of applications reviewed per full meeting	5.56
Number of completed applications for full ethical review	48
Number of completed applications for full ethical review over 60 days	0
Number of completed applications over 60 days as a % of total	0.00%
Number of completed applications for full ethical review over 40 days	4
Number of completed applications over 40 days as a % of total	8.00%
Number of days taken to final decision – average (mean)	31
Number of completed proportionate review applications for ethical review	22
Number of completed proportionate review applications for ethical review over 14 days	1
Number of completed proportionate review applications over 14 days as a % of total	4.55%
Number of SSAs (non-Phase 1) reviewed	16
Number of completed applications for SSA review over 25 days	2
Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs	12.50%
Number of SSAs (Phase 1) reviewed	0
Number of completed applications for SSA review over 14 days	0
Number of completed applications for SSA review over 14 days as % of all Phase 1 SSAs	0.00%
Number of substantial amendments reviewed	178
Number of completed substantial amendments over 35 days	0
Number of completed substantial amendments over 35 days as a % of total substantial amendments	0.00%
Number of completed substantial amendments over 28 days	2
Number of completed substantial amendments over 28 days as a % of total substantial amendments	1.12%
Number of modified amendments reviewed	2
Number of completed modified amendments over 14 days	0
Number of completed modified amendments over 14 days as a % of total modified amendments	0.00%
Number of minor amendments received	87
Number of substantial amendments received for information	2
Number of substantial amendments received for new sites/PIs	58
Number of annual progress reports received	55

Number of safety reports received	106
Number of Serious Adverse Events received	1
Number of final reports received	0

Table 9.1: Breakdown of current status of all full applications reviewed within the reporting period

Further Information Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
15/LO/0548	The role of Home packs of HIV PEPSE in High Risk Individuals	32
15/LO/0551	FDHT - version 1, 9 March 2015	40
15/LO/0564	ARMOR3-SV	37
15/LO/0622	Production of iPSC derived RPE Cells for transplantation in AMD	55
15/LO/0638	PAVE trial v1.0	42
15/LO/0642	A Study into the Impact of Cystic Fibrosis on Healthy Siblings	35
15/LO/0655	Paired Biopsies in Lung Cancer	24
15/LO/0735	QGE031 dose finding study in CSU patients	55
15/LO/0776	LOCATE Version 1	31
15/LO/0791	Collection of lung secretions from COPD patients and healthy smokers,v1	25
15/LO/0958	AZD1775 in patients with Ovarian, Fallopian Tube, or Peritoneal Cancer	35
15/LO/0975	EDEN-OX the effect of dietary nitrate on exercise in hypoxia	31
15/LO/1116	Effect of Remote Ischaemic Conditioning in Oncology Patients (ERICONC)	24
15/LO/1166	Efficacy and Safety of RTH258 versus Aflibercept	50
15/LO/1175	RPC01-3101 True North study	30
15/LO/1478	The PEAR Study	32
15/LO/1502	Phase I study of IPH4102 treatment in patients with CTCL	30
15/LO/1528	How stress effects decision making in borderline personality disorder	32
15/LO/1636	Effect of Serelaxin on cardiac troponin I release in patients with CHF	39
15/LO/1648	Is a Virus Infection the Trigger That Leads to Type 1 Diabetes?	34
15/LO/1668	Gut Hormones after Oesophagectomy and Gastrointestinal Symptoms	29
15/LO/1670	U31287-A-U203: Double Blind Phase 2 Study of Patritumab (U31287).	37
15/LO/1676	1269 - Phase 2/3 open label study of F/TAF in HIV-1 infected children	40
15/LO/1749	Spleen stiffness in HIV	26
15/LO/1759	Reading networks in the developing brain	36
15/LO/1765	Pathfinder Fistula Probe System	30
15/LO/1812	39039039STM4001: Rivaroxaban in Cancer Patients with high risk of VTE	26
15/LO/1816	ECLIPSE Study 2: Comparison of acceptability between CRT methods	31
15/LO/1891	Tendyne Mitral Study	24
15/LO/1988	MOMENTUM	27
15/LO/1992	BARCODE 1 Pilot Study	34
15/LO/2026	Prolonging remission of ulcerative colitis with the probiotic Symprove	37

15/LO/2060	Twin Reversed Arterial Perfusion Intervention Study (TRAPIST)	25
16/LO/0180	Role of avastin and 5-fluorouracil in trabeculectomy surgery (RAFTS)	24
16/LO/0205	Identifying Treatable Aspects of Chronic Embitterment - Version 4	26

Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/LO/1132	A Phase II Study of Pembrolizumab in Subjects with Triple-Negative Bre	30

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/0746	Database for Infectious Disease Surveillance Models	21
16/LO/0218	Aegle: Analytics framework for healthcare	23

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/LO/0834	WO29522 - A Study of MPDL3280A and Nab-paclitaxel in Breast Cancer	21
15/LO/0869	Peak V02 and individuals with dilated left ventricles.	20
15/LO/0882	EORTC 1217	29
15/LO/1141	The PERM Study	24
15/LO/1174	Open label ISIS 420915-CS3	24
15/LO/1512	RPC01-3102 Open-label extension study	28
15/LO/2014	BCX7353 in prevention of HAE attacks	23
16/LO/0210	Patient and Clinician Views on Robotic Assisted Fracture Surgery	23
16/LO/0223	Mindfulness and Older Adults with Subjective Cognitive Impairment V1	23

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
16/LO/0244	Genome Instability in Childhood Obesity	23

Provisional Opinion		
REC Reference	Title	Number of Days on Clock

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

Further information response not complete		
REC Reference	Title	Number of Days on Clock

Withdrawn after the meeting		
REC Reference	Title	Number of Days on Clock
15/LO/0976	A Phase 2 study of Apremilast in active ulcerative colitis	29
15/LO/1434	A Randomized, Double-Blind Phase 1/2 Study of INCB039110 and erlotinib	28

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/0786	The relationship between postnatal care and neonatal admission Ver. 1	14
15/LO/1697	Mindfulness in Maternity	8
15/LO/1703	Point of care testing in the diagnosis and management of COPD	9
15/LO/1924	Microbiome and Inflammation in Preterm Infants	10
16/LO/0408	Dietary issues facing parents of the under 5s with type 1 diabetes	11
16/LO/0610	Prematurity and the Lipid Profiles of Newborns	13
16/LO/0612	Patients perspectives of clinical trials.	13

Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/LO/0171	Exploring antibiotic stewardship, nutrition & vitamin D levels in HAP	10

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/1930	DNA damage response deficiency assay validation (version 1)	8
15/LO/2206	Cell Therapy for Type 1 Diabetes	14
16/LO/0137	Vitamin B12 status in adults with diabetes, taking metformin Version 1	13
16/LO/0596	Text message appointment reminders - diabetic retinopathy screening	17
16/LO/0616	Care and Outcomes of Older Persons with Lung Cancer in England and US	10

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/LO/0782	Integrated Care Demonstrator Site: Mental Health Social Work	11
15/LO/1354	Rhinoconjunctivitis Quality of Life Questionnaire 12+ v1.0	6
15/LO/1364	CHEER	5
15/LO/1695	Observational study of Mcm5 in bladder cancer patients.	7
15/LO/2207	Assessing Circulating Tumour Cells as biomarkers for colorectal cancer	13
15/LO/2208	Diabetic Foot and Retinopathy Screening feasibility study	13
16/LO/0135	Exploring methods in PPI for research study development	13
16/LO/0165	Evaluating support for carers of people with dementia	12
16/LO/0396	PHysical activity Implementation Study In Community-dwelling AduLts	11

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

Withdrawn after the meeting		
REC Reference	Title	Number of Days on Clock

Table 10.1: Breakdown of current status of all substantial amendments reviewed within the reporting period

Favourable opinion				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
04/Q0801/60/AM08	Molecular characterisation of hormone refractory prostate cancer	Substantial Amendment 10	22/04/2015	12
04/Q0801/60/AM09	Molecular characterisation of hormone refractory prostate cancer	Substantial Amendment 11	03/11/2015	14
04/Q0801/60/AM10	Molecular characterisation of hormone refractory prostate cancer	Substantial amendment 12	05/01/2016	26
06/Q0404/15/AM12	Long term analysis of specimens in the investigation of heart disease.	Substantial Amendment 12	16/10/2015	14
07/H0801/132/AM02	Erythrocyte encapsulated thymidine phosphorylase therapy	Substantial Amendment 2	03/06/2015	13
07/H0801/135/AM03	SEPARATION OF CIRCULATING TUMOUR CELLS USING APHERESIS IN PATIENTS WIT	Substantial Amendment 2	03/03/2016	18
07/Q0404/43/AM03	Investigation of Mechanisms in Seasonal Allergic Rhinitis	Substantial Amendment 2	03/02/2016	13
09/H0801/49/AM04	Surveillance Ultrasound of Nodes in Melanoma	Substantial Amendment 4	26/03/2015	30
09/H0801/49/AM05	Surveillance Ultrasound of Nodes in Melanoma	Substantial Amendment 4	04/12/2015	13
09/H0801/75/AM16	Oral MDV3100 for progressive castration-resistant prostate cancer	Substantial Amendment 13	02/01/2015	13
09/H0801/75/AM17	Oral MDV3100 for progressive castration-resistant prostate cancer	Substantial Amendment 8	09/06/2015	19
11/LO/0153/AM16	BMN 673 in Patients with Advanced or Recurrent Solid Tumours A1 9DEC10	Substantial Amendment 11	21/08/2015	24
11/LO/0551/AM13	Phase I study of a FAK inhibitor in subjects with solid tumours	Substantial Amendment 12	22/06/2015	26
11/LO/0954/AM15	1200.131 LUX-Head & Neck 2; Afatinib in Squamous Cell Carcinoma	Substantial Amendment 11	18/08/2015	14
11/LO/0954/AM16	1200.131 LUX-Head & Neck 2; Afatinib in Squamous Cell Carcinoma	Substantial Amendment 12	22/02/2016	15
11/LO/0957/AM14	DC Vax-Brain Phase III trial for GBM- Current	Substantial	21/04/2015	6

		Amendment 9		
11/LO/0957/AM15	DC Vax-Brain Phase III trial for GBM- Current	Substantial Amendment dated 06	06/05/2015	11
11/LO/0957/AM16	DC Vax-Brain Phase III trial for GBM- Current	Substantial Amendment 10	22/07/2015	19
11/LO/0957/AM17	DC Vax-Brain Phase III trial for GBM- Current	Substantial Amendment 11	12/08/2015	16
11/LO/1563/AM12	Viamet Phase I/II Study VMT-VT-464-CL-001	Substantial Amendment 9	23/06/2015	17
11/LO/1619/AM17	Comparing safety & efficacy of AI/lapatinib/trastuzumab in HR+HER2 MBC	Substantial Amendment 8	22/07/2015	11
11/LO/1915/AM10	Phase III prostate cancer trial: surgery, radiotherapy, stereotactic	Substantial Amendment 7	22/06/2015	10
11/LO/1915/AM14	Phase III prostate cancer trial: surgery, radiotherapy, stereotactic	Substantial Amendment 8	01/03/2016	16
11/LO/1973/AM01	GABA-B receptor function in healthy volunteers	Substantial Amendment 1	20/03/2015	6
11/LO/1974/AM04	Extension Study with AMG 145 in Subjects With Hypercholesterolemia	Substantial Amendment 4	02/04/2015	21
12/LO/0051/AM11	LenD (Lenalidomide in CLL)	11	23/04/2015	21
12/LO/0565/AM15	A phase II study of GDC-0068 or GDC-0980 in patients with CRPC	Substantial Amendment 7	01/09/2015	18
12/LO/0879/AM01	Pregnancy dating test - II	Substantial Amendment 1 dated	10/03/2015	25
12/LO/1027/AM13	Phase III comparative study of OGX-011 in men with prostate cancer	Substantial Amendment 5	07/12/2015	12
12/LO/1527/AM01	Expression of micro RNA signatures in malignant melanoma	Substantial Amendment 1	17/11/2015	14
12/LO/1540/AM11	BKM120 + fulvestrant in patients with HR+ HER2- after mTOR	Substantial Amendment 6.0	07/05/2015	25
12/LO/1540/AM12	BKM120 + fulvestrant in patients with HR+ HER2- after mTOR	Substantial Amendment 7	20/08/2015	8
12/LO/1540/AM14	BKM120 + fulvestrant in patients with HR+ HER2- after mTOR	8	17/02/2016	9
13/LO/0022/AM01	White cell survival in vivo	Substantial	17/11/2015	8

		Amendment 1		
13/LO/0066/AM09	A Phase I trial of AZD2014 in combination with paclitaxel	Substantial Amendment 5	10/03/2015	12
13/LO/0066/AM11	A Phase I trial of AZD2014 in combination with paclitaxel	Substantial Amendment 6	07/07/2015	8
13/LO/0066/AM12	A Phase I trial of AZD2014 in combination with paclitaxel	Substantial Amendment 7	10/11/2015	11
13/LO/0108/AM09	LEGEND	Substantial Amendment 7 [Proto	17/02/2015	7
13/LO/0108/AM10	LEGEND	Substantial Amendment 9	22/01/2016	18
13/LO/0264/AM03	Advanced Bolus Calculator for Type 1 Diabetes (ABC4D) v1.0	Substantial Amendment 1.3	15/06/2015	13
13/LO/0434/AM02	In-vivo Studies of Chronic Lymphocytic Leukaemia Kinetics V.I	Substantial Amendment 2	28/04/2015	18
13/LO/0491/AM10	CATCH-AMI	Substantial Amendment 8	21/04/2015	15
13/LO/0491/AM12	CATCH-AMI	Substantial Amendment 9	26/06/2015	24
13/LO/0668/AM06	Onyx:Study of Carfilzomib in Newly Diagnosed Multiple Myeloma Patients	Substantial Amendment dated 14	14/04/2015	22
13/LO/0668/AM07	Onyx:Study of Carfilzomib in Newly Diagnosed Multiple Myeloma Patients	Substantial Amendment 7	19/06/2015	11
13/LO/0668/AM09	Onyx:Study of Carfilzomib in Newly Diagnosed Multiple Myeloma Patients	Substantial Amendment dated 29	29/12/2015	21
13/LO/0693/AM01	Defining the intestinal microbiota in premature neonates: Follow-up	Substantial Amendment 1	08/02/2016	13
13/LO/0702/AM15	EVP-6124 as a treatment to improve mental function in Schizophrenia	Substantial Amendment 3	30/09/2015	13
13/LO/1252/AM09	The MILO Study (MEK Inhibitor in Low-grade Serous Ovarian Cancer)	Substantial Amendment 5	27/02/2015	14
13/LO/1252/AM10	The MILO Study (MEK Inhibitor in Low-grade Serous Ovarian Cancer)	Substantial Amendment 1	31/03/2015	17

		dated		
13/LO/1252/AM11	The MILO Study (MEK Inhibitor in Low-grade Serous Ovarian Cancer)	Substantial Amendment 8	16/09/2015	14
13/LO/1265/AM09	First in Human, Dose-Escalating Study of HuMaX [®] -TF-ADC in solid Tumour	Substantial Amendment 5	26/06/2015	23
13/LO/1265/AM13	First in Human, Dose-Escalating Study of HuMaX [®] -TF-ADC in solid Tumour	Substantial Amendment 7	14/10/2015	20
13/LO/1265/AM14	First in Human, Dose-Escalating Study of HuMaX [®] -TF-ADC in solid Tumour	Substantial Amendment 8	01/12/2015	9
13/LO/1270/AM02	CMVVASC	Substantial Amendment 2	20/05/2015	21
13/LO/1417/AM06	FINESSE	Substantial Amendment 6	22/10/2015	11
13/LO/1417/AM08	FINESSE	Substantial Amendment 7	02/02/2016	15
13/LO/1579/AM02	SPOT Trial v 1.0 (13th June 2013)	Substantial Amendment 3	01/05/2015	10
13/LO/1827/AM05	AZD5363 Formulation Comparison, Effect of Food, Safety & Tolerability	Substantial Amendment 3	07/04/2015	8
14/LO/0292/AM01	ABC-BIO: Biological Sample Collection Protocol	Substantial Amendment dated 16	16/03/2015	11
14/LO/0298/AM07	Single Arm Study of Enzalutamide in Patients with Prostate Cancer	Substantial Amendment 5	02/07/2015	14
14/LO/0372/AM07	Vertex VX13-970-002	Substantial Amendment dated 01	01/06/2015	13
14/LO/0372/AM08	Vertex VX13-970-002	Substantial Amendment 4	28/05/2015	17
14/LO/0673/AM05	MLN9708 in Multiple Myeloma after Autologous Stem Cell Transplant	Substantial Amendment dated 14	14/08/2015	7
14/LO/0673/AM07	MLN9708 in Multiple Myeloma after Autologous Stem Cell Transplant	Substantial Amendment dated 17	17/12/2015	14
14/LO/0712/AM01	Phase 1 Study of GSK2857916 in Subjects with Haematologic	Substantial	15/04/2015	9

	Malignancies	Amendment 01 dated		
14/LO/0712/AM02	Phase 1 Study of GSK2857916 in Subjects with Haematologic Malignancies	Substantial Amendment 1	08/07/2015	19
14/LO/0712/AM03	Phase 1 Study of GSK2857916 in Subjects with Haematologic Malignancies	Substantial Amendment 2	25/09/2015	14
14/LO/1034/AM06	BAY63-2521 in adult DeltaF508 homozygous Cystic Fibrosis patients. 1	Substantial Amendment Version	15/04/2015	21
14/LO/1034/AM09	BAY63-2521 in adult DeltaF508 homozygous Cystic Fibrosis patients. 1	Substantial Amendment 7	28/09/2015	15
14/LO/1034/AM13	BAY63-2521 in adult DeltaF508 homozygous Cystic Fibrosis patients. 1	Substantial Amendment 8	12/11/2015	13
14/LO/1034/AM15	BAY63-2521 in adult DeltaF508 homozygous Cystic Fibrosis patients. 1	Substantial Amendment 9	12/01/2016	18
14/LO/1053/AM05	(duplicate) Momelotinib vs. Ruxolitinib in subjects with Myelofibrosis	Substantial Amendment 4	17/11/2015	7
14/LO/1068/AM01	Randomised study of Adalimumab in subjects with Ulcerative Colitis.	Substantial Amendment 1	02/06/2014	12
14/LO/1068/AM02	Randomised study of Adalimumab in subjects with Ulcerative Colitis.	Substantial Amendment 3	29/05/2015	15
14/LO/1068/AM04	Randomised study of Adalimumab in subjects with Ulcerative Colitis.	Protocol Amendment 2 [M14-033]	27/01/2016	17
14/LO/1151/AM02	1280.8 - BI 836845 in metastatic castration resistant prostate cancer	Substantial Amendment 2	01/04/2015	20
14/LO/1151/AM04	1280.8 - BI 836845 in metastatic castration resistant prostate cancer	Substantial Amendment 3	13/05/2015	22
14/LO/1151/AM06	1280.8 - BI 836845 in metastatic castration resistant prostate cancer	Substantial Amendment 4	13/08/2015	15
14/LO/1151/AM07	1280.8 - BI 836845 in metastatic castration resistant prostate cancer	Substantial Amendment 5	16/09/2015	11
14/LO/1151/AM09	1280.8 - BI 836845 in metastatic castration resistant prostate cancer	Substantial Amendment 6	06/01/2016	13
14/LO/1163/AM03	Drug-Drug interaction study with ARN509 and abiraterone	Substantial Amendment 2	20/02/2015	13

14/LO/1163/AM05	Drug-Drug interaction study with ARN509 and abiraterone	Substantial Amendment 3	16/12/2015	18
14/LO/1363/AM01	The Southampton Mealtime Assistance Roll-out Trial (SMART) V1	Substantial Amendment 1	19/06/2015	14
14/LO/1493/AM02	SSAT056:Efavirenz to Dolutegravir switch in patients with CNS toxicity	Substantial Amendment 1	05/05/2015	24
14/LO/1512/AM05	Single & multiple inhaled doses of RPL554 in healthy males and in COPD	Substantial Amendment 2(EG) da	01/05/2015	21
14/LO/1512/AM07	Single & multiple inhaled doses of RPL554 in healthy males and in COPD	Substantial Amendment 3	21/05/2015	11
14/LO/1539/AM03	CANDLE (Noctura400 for DMO)	Substantial Amendment 3	09/07/2015	15
14/LO/1539/AM08	CANDLE (Noctura400 for DMO)	Substantial Amendment 4	20/01/2016	21
14/LO/1568/AM05	TIER	Substantial Amendment 4	10/11/2015	17
14/LO/1574/AM02	Clinical Phenotyping and Genotyping of HIV-Associated Neuropathy	Substantial Amendment 2	10/06/2015	18
14/LO/1574/AM03	Clinical Phenotyping and Genotyping of HIV-Associated Neuropathy	Substantial amendment 3	27/10/2015	9
14/LO/1587/AM01	PET /MRI pre-RadiOtherapy for Post-Prostatectomy Salvage	Substantial Amendment 1	07/08/2015	23
14/LO/1598/AM05	Phase 1 - study of GSK2636771 plus Enzalutamide in mCRProstate Cancer	Substantial Amendment 3	26/02/2015	26
14/LO/1598/AM08	Phase 1 - study of GSK2636771 plus Enzalutamide in mCRProstate Cancer	Substantial Amendment 4	26/02/2015	16
14/LO/1981/AM02	PIPA: Combination of PI3 kinase inhibitors and PAIbociclib	Substantial Amendment 2	19/10/2015	5
14/LO/1981/AM04	PIPA: Combination of PI3 kinase inhibitors and PAIbociclib	Substantial Amendment 3	07/03/2016	20
14/LO/1994/AM08	The AMARANTH Study	Substantial Amendment 4	12/03/2015	18
14/LO/1994/AM12	The AMARANTH Study	5	12/06/2015	14
14/LO/1994/AM22	The AMARANTH Study	Substantial amendment dated	15/12/2015	16

		15		
14/LO/1994/AM23	The AMARANTH Study	03/03/2016	03/03/2016	13
14/LO/2020/AM05	AZD8835 in patients with advanced cancer	Substantial Amendment 4	01/04/2015	25
14/LO/2020/AM06	AZD8835 in patients with advanced cancer	Substantial Amendment Edition	08/04/2015	28
14/LO/2020/AM08	AZD8835 in patients with advanced cancer	Substantial Amendment Version	29/04/2015	20
14/LO/2020/AM09	AZD8835 in patients with advanced cancer	Substantial Amendment 1	18/05/2015	9
14/LO/2020/AM12	AZD8835 in patients with advanced cancer	Substantial Amendment	24/09/2015	19
14/LO/2127/AM02	Effects of BNC210 on human brain activity in anxious subjects	Substantial Amendment 2	24/03/2015	13
14/LO/2127/AM04	Effects of BNC210 on human brain activity in anxious subjects	Substantial Amendment 3	22/10/2015	11
14/LO/2151/AM01	Re-contact in mainstreaming genetics V1	Substantial Amendment 1	25/09/2015	20
14/LO/2151/AM02	Re-contact in mainstreaming genetics V1	Substantial Amendment 3	22/01/2016	12
14/LO/2151/AM03	Re-contact in mainstreaming genetics V1	Substantial Amendment 2	04/11/2015	10
14/LO/2169/AM02	The functional annotation of psoriasis susceptibility alleles (V1)	Substantial Amendment 1	30/04/2015	14
14/LO/2231/AM02	BOUDICA	Substantial Amendment 2 dated 02 April 2015	02/04/2015	22
14/LO/2231/AM04	BOUDICA	Substantial Amendment 3	18/06/2015	10
14/LO/2231/AM05	BOUDICA	Substantial Amendment 4	28/10/2015	4
15/LO/0016/AM04	Monarch 3: Breast Cancer in Postmenopausal Women (JPBM Study)	Substantial Amendment 3	04/02/2016	13
15/LO/0025/AM03	To Assess the Effect of Moderate RI on the PK of CSL112	Substantial Amendment 2	21/05/2015	20

15/LO/0025/AM05	To Assess the Effect of Moderate RI on the PK of CSL112	Substantial Amendment 3	15/05/2015	20
15/LO/0025/AM08	To Assess the Effect of Moderate RI on the PK of CSL112	Substantial Amendment 3	11/12/2015	22
15/LO/0029/AM01	Intraoperative GE-137 fluorescence imaging in breast and oral cancer	Substantial Amendment 3.0	22/04/2015	13
15/LO/0165/AM03	56021927PCR3001 - Prostate Cancer Study	Substantial Amendment 2	09/09/2015	8
15/LO/0165/AM05	56021927PCR3001 - Prostate Cancer Study	Substantial Amendment 3	11/02/2016	15
15/LO/0165/AM06	56021927PCR3001 - Prostate Cancer Study	Substantial Amendment 4	03/03/2016	13
15/LO/0171/AM02	EORTC 1209-EnTF	Substantial Amendment UK03	19/05/2015	27
15/LO/0304/AM01	Bubble	Substantial Amendment 1	20/05/2015	20
15/LO/0344/AM03	VX14-803-001 in Subjects With Advanced Solid Tumours or Lymphoma	Substantial Amendment 2	07/10/2015	19
15/LO/0383/AM02	TOP1288 RECTAL SINGLE AND MULTIPLE ASCENDING DOSES	Substantial Amendment 1	24/06/2015	9
15/LO/0383/AM04	TOP1288 RECTAL SINGLE AND MULTIPLE ASCENDING DOSES	Substantial Amendment 2	07/09/2015	11
15/LO/0383/AM06	TOP1288 RECTAL SINGLE AND MULTIPLE ASCENDING DOSES	Substantial Amendment 3	28/10/2015	10
15/LO/0383/AM07	TOP1288 RECTAL SINGLE AND MULTIPLE ASCENDING DOSES	Substantial Amendment 4	16/12/2015	18
15/LO/0388/AM01	Looking for Biomarkers in Human Joint Fluid	Substantial Amendment 1.3	11/06/2015	10
15/LO/0388/AM02	Looking for Biomarkers in Human Joint Fluid	Substantial Amendment 1.4	11/03/2016	21
15/LO/0404/AM03	TORCMEK	Substantial Amendment 2	15/09/2015	24
15/LO/0538/AM01	SPRAINED Study - Version 1.0	Substantial Amendment 1	13/11/2015	14
15/LO/0564/AM01	ARMOR3-SV	Substantial Amendment 1	11/06/2015	20

15/LO/0638/AM01	PAVE trial v1.0	Substantial Amendment 1	21/07/2015	19
15/LO/0638/AM02	PAVE trial v1.0	Substantial Amendment 2	21/10/2015	12
15/LO/0735/AM04	QGE031 dose finding study in CSU patients	Substantial Amendment 3	11/09/2015	11
15/LO/0735/AM08	QGE031 dose finding study in CSU patients	Substantial Amendment 5	15/03/2016	20
15/LO/0776/AM01	LOCATE Version 1	Substantial Amendment 1	25/10/2015	7
15/LO/0834/AM01	WO29522 - A Study of MPDL3280A and Nab-paclitaxel in Breast Cancer	Substantial Amendment 1	07/05/2015	15
15/LO/0834/AM03	WO29522 - A Study of MPDL3280A and Nab-paclitaxel in Breast Cancer	Substantial Amendment 2	15/06/2015	15
15/LO/0834/AM06	WO29522 - A Study of MPDL3280A and Nab-paclitaxel in Breast Cancer	Substantial Amendment 6	22/12/2015	18
15/LO/0958/AM01	AZD1775 in patients with Ovarian, Fallopian Tube, or Peritoneal Cancer	Substantial Amendment 3	14/08/2015	11
15/LO/0958/AM02	AZD1775 in patients with Ovarian, Fallopian Tube, or Peritoneal Cancer	Substantial Amendment 2	20/08/2015	24
15/LO/0958/AM03	AZD1775 in patients with Ovarian, Fallopian Tube, or Peritoneal Cancer	Substantial Amendment dated 28	28/08/2015	13
15/LO/0958/AM04	AZD1775 in patients with Ovarian, Fallopian Tube, or Peritoneal Cancer	Substantial Amendment dated 09	09/11/2015	8
15/LO/0958/AM05	AZD1775 in patients with Ovarian, Fallopian Tube, or Peritoneal Cancer	Substantial Amendment Edition	04/12/2015	22
15/LO/0958/AM06	AZD1775 in patients with Ovarian, Fallopian Tube, or Peritoneal Cancer	Substantial Amendment dated 17	17/12/2015	14
15/LO/0958/AM07	AZD1775 in patients with Ovarian, Fallopian Tube, or Peritoneal Cancer	Substantial Amendment 8	15/02/2016	22
15/LO/0975/AM01	EDEN-OX the effect of dietary nitrate on exercise in hypoxia	Substantial Amendment 1	15/01/2016	18
15/LO/1132/AM01	A Phase II Study of Pembrolizumab in Subjects with Triple-	Substantial	31/08/2015	6

	Negative Bre	Amendment 1		
15/LO/1132/AM02	A Phase II Study of Pembrolizumab in Subjects with Triple-Negative Bre	Substantial Amendment 002	02/02/2016	15
15/LO/1141/AM02	The PERM Study	Substantial Amendment #1	14/10/2015	19
15/LO/1166/AM01	Efficacy and Safety of RTH258 versus Aflibercept	Substantial Amendment 1	24/09/2015	15
15/LO/1166/AM05	Efficacy and Safety of RTH258 versus Aflibercept	Substantial Amendment 3	29/10/2015	14
15/LO/1174/AM02	Open label ISIS 420915-CS3	Substantial Amendment 2	10/08/2015	15
15/LO/1174/AM03	Open label ISIS 420915-CS3	Substantial Amendment	04/11/2015	15
15/LO/1175/AM01	RPC01-3101 True North study	Substantial Amendment 1	28/09/2015	16
15/LO/1175/AM02	RPC01-3101 True North study	Substantial Amendment 2	02/12/2015	14
15/LO/1175/AM03	RPC01-3101 True North study	Substantial Amendment 3	17/02/2016	20
15/LO/1478/AM01	The PEAR Study	Substantial Amendment 1	01/03/2016	18
15/LO/1502/AM01	Phase I study of IPH4102 treatment in patients with CTCL	Substantial Amendment 1	13/10/2015	7
15/LO/1512/AM01	RPC01-3102 Open-label extension study	Substantial Amendment 1	12/11/2015	8
15/LO/1512/AM04	RPC01-3102 Open-label extension study	Substantial Amendment 3	21/12/2015	28
15/LO/1512/AM05	RPC01-3102 Open-label extension study	Substantial Amendment 5	22/01/2016	19
15/LO/1512/AM06	RPC01-3102 Open-label extension study	Sub Amendment 6	17/02/2016	23
15/LO/1648/AM01	Is a Virus Infection the Trigger That Leads to Type 1 Diabetes?	Amendment 1	12/02/2016	11
15/LO/1670/AM01	U31287-A-U203: Double Blind Phase 2 Study of Patritumab (U31287).	Substantial Amendment 1	14/03/2016	21
15/LO/1697/AM01	Mindfulness in Maternity	Amendment 1	16/02/2016	21
15/LO/1816/AM01	ECLIPSE Study 2: Comparison of acceptability between CRT	Substantial	16/02/2016	21

	methods	Amendment dated 16		
15/LO/2014/AM01	BCX7353 in prevention of HAE attacks	Substantial Amendment 1	28/01/2016	18
15/LO/2014/AM02	BCX7353 in prevention of HAE attacks	Substantial Amendment 2	25/02/2016	13
16/LO/0165/AM01	Evaluating support for carers of people with dementia	Substantial Amendment 1	26/01/2016	15
CCR0283/AM01	CCR0283: DNA somatic mutational analyses	Substantial Amendment 3	02/04/2015	17
CCR2075/AM03	Tissue Collection at Radical prostatectomy	Substantial Amendment 6	04/03/2015	19

Unfavourable opinion				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
14/LO/1994/AM09	The AMARANTH Study	Substantial Amendment 7	02/07/2015	18
15/LO/1512/AM03	RPC01-3102 Open-label extension study	Substantial Amendment 2	07/12/2015	31

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
14/LO/1994/AM09/1	The AMARANTH Study	Modified Amendment 7	02/07/2015	1
15/LO/1512/AM03/1	RPC01-3102 Open-label extension study	Modified Amendment dated 19/01	19/01/2016	3

Unfavourable opinion timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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Table 11: Items exceeding timelines

Full applications for ethical review over 60 day timeline

REC Reference	Title	Number of Days on Clock
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Proportionate review applications for ethical review over 14 day timeline

REC Reference	Title	Number of Days on Clock
16/LO/0596	Text message appointment reminders - diabetic retinopathy screening	17

SSAs (non Phase 1) over 25 day timeline

REC Reference	Title	Number of Days on Clock
15/LO/0773	A 24-month, Multicenter, Rando	26
15/LO/0893	A Phase 3 Randomized, Placebo-	27

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
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Modified Amendments over 14 day timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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