

**London - West London & GTAC Research Ethics
Committee**

Annual Report

01 April 2016 - 31 March 2017



Part 1 – Committee Membership and Training

Name of REC:	London - West London & GTAC Research Ethics Committee
Type of REC:	Recognised to review CTIMPS in Healthy Volunteers – type I Recognised to review CTIMPS in Patients – type II
Type of Flag:	Gene therapy or Stem Cells Trials Phase I studies in Healthy Volunteers Phase I Studies in Patients Research Involving Children
Chair:	Dr Catherine Urch
Vice-Chair:	Reverend Keith Lackenby
Alternate Vice-Chair:	Dr Fraser Macfarlane
REC Manager:	Miss Andrea Graham
REC Assistant:	Tad Jones
Committee Address:	The Old Chapel Royal Standard Place Nottingham NG1 6FS
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Chair's overview of the past year:

Another busy year. The committee has seen an increased number of GTAC submissions and the whole committee has become expert in assessing viral vectors, side effects and long term risks. The ethical issues and discussions for these and all our applications remain vital, engaged and interested. The committee is able to present and debate contrasting views and ethical points of views. The presence of the researchers is a bonus and the sometimes lengthy but effective debates have resulted in thanks from researchers, and a waiting list by researchers who value the committee's input.

We could not achieve our high work output without the hard work from all the committee members. Whether on sub committee the active proportionate review or full committee the commitment and work is acknowledged with thanks. None of this would be possible without the unfailing help, advice and good humour of our administrator Andrea. She manages to cajole us all into timely opinions and bears with the debates at the meetings.

Lastly I would like to thank those members who have served their time and now left us to other interests, those who can't quite leave us and have opted for shared positions and to those who have agreed to join us this year. A huge thank you to those past and present for their work and help and welcome to our new comers.

London - West London & GTAC Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Mr Ted Barker	Reader in Developmental Psychopathology	Lay Plus	01/01/2016	15/02/2017
Mr Ron Driver	Retired Lecturer/Statistician	Lay	01/12/2014	
Miss Gayle D'Souza	Senior Trials Coordinator	Expert	01/04/2015	
Professor Uta Griesenbach	Professor of Molecular Medicine	Expert	30/09/2013	
Reverend Keith Lackenby	Reverend	Lay Plus	19/10/2016	
Ms Victoria Latham	Lead Pharmacist Clinical Trials & Pharmacovigilance	Expert	23/07/2008	
Dr Elizabeth Lund	Independent Consultant, Nutrition and Gastrointestinal Health	Lay	17/06/2015	
Dr Fraser Macfarlane	Senior Lecturer in Health Care Management	Lay Plus	01/09/2009	
Ms Cinead Eileen O'Sullivan	Legal Advisor (Solicitor)	Lay Plus	30/09/2013	
Dr Roger David Palmer	Senior Medicolegal Advisor	Expert	10/06/2013	
Mr Roy Sinclair	Pharmacist	Lay	01/09/2015	
Miss Ravinder Summan	Research Nurse	Expert	05/05/2015	
Dr Catherine Urch	Consultant Palliative Medicine (Chair)	Expert	21/12/2007	

London - West London & GTAC Research Ethics Committee: Deputy Members

None

London - West London & GTAC Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended
Mrs Elayne Nasr	Retired School Matron	Lay plus	20/04/2016

London - West London & GTAC Research Ethics Committee: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Miss Gayle D'Souza	Director of Gayleforce Scientific Limited Employed by Roche Products Limited	19/10/2016
Reverend Keith Lackenby	None declared	31/03/2017
Ms Victoria Latham	Lead Pharmacist for Clinical Trials at Imperial College Healthcare NHS Trust	13/12/2016
Dr Elizabeth Lund	Acts as Consultant on ethical aspects of food intervention studies on one European Union projects and writing protocols and ethical submission for two others. Trustee of Asperger East Anglia. Regularly review papers for journals such as Carcinogenesis, Gut, Cancer Research, American Journal of Clinical Nutrition, British Journal of Nutrition	16/08/2016
Dr Fraser Macfarlane	None declared	31/03/2017
Dr Roger David Palmer	None declared	14/12/2016
Mr Roy Sinclair	None declared	14/12/2016
Miss Ravinder Summan	Research Bank Nurse at Imanova	14/12/2016
Dr Catherine Urch	Executive board member for Imperial College Healthcare Trust. Supervision of PhD Student funded by Imperial College Institute for Global Health	31/03/2017
Mr Ron Driver	Peer Review for Journal of Advanced Nursing	31/03/2017
Cinead O'Sullivan	None declared	31/03/2017

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

Month	Date	Number of Members Present at Meeting
April	20/04/2016	9
May	18/05/2016	10
June	15/06/2016	10
August	17/08/2016	10
September	21/09/2016	10
October	19/10/2016	12
December	14/12/2016	8
January	18/01/2017	9
February	15/02/2017	11
March	15/03/2017	9

10 full committee meetings were held during the reporting period.

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

Month	Date	Number of Members Present at Meeting
April	20/04/2016	3
May	18/05/2016	3
June	15/06/2016	3
August	17/08/2016	3
September	21/09/2016	3
October	19/10/2016	3
November	16/11/2016	3
December	14/12/2016	3
January	25/01/2017	3
February	22/02/2017	3
March	22/03/2017	3

11 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	07/04/2016	2
April	21/04/2016	2
May	05/05/2016	2
May	19/05/2016	2
June	02/06/2016	2
June	10/06/2016	2
June	16/06/2016	2
June	30/06/2016	2
July	14/07/2016	2
July	28/07/2016	2

August	11/08/2016	2
August	25/08/2016	2
September	06/09/2016	2
September	08/09/2016	2
September	22/09/2016	2
October	06/10/2016	2
October	20/10/2016	2
November	03/11/2016	2
November	16/11/2016	2
November	17/11/2016	2
December	01/12/2016	2
December	15/12/2016	2
December	29/12/2016	2
January	12/01/2017	2
January	26/01/2017	2
February	09/02/2017	2
February	23/02/2017	2
March	16/03/2017	2
March	30/03/2017	2

29 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
Mr Ted Barker	3
Mr Ron Driver	8
Miss Gayle D'Souza	6
Professor Uta Griesenbach	5
Reverend Keith Lackenby	6
Ms Victoria Latham	9
Dr Elizabeth Lund	9
Dr Fraser Macfarlane	6
Ms Cinead Eileen O'Sullivan	7
Dr Roger David Palmer	9
Mr Roy Sinclair	9
Miss Ravinder Summan	10
Dr Catherine Urch	10

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

Name	Number of Meetings Attended
Mr Ted Barker	3
Mr Ron Driver	3
Miss Gayle D'Souza	6
Reverend Keith Lackenby	3
Dr Elizabeth Lund	9
Mr Roy Sinclair	3
Miss Ravinder Summan	6

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

Name	Number of Meetings Attended
Mr Ron Driver	4
Professor Uta Griesenbach	2
Dr Elizabeth Lund	5
Dr Fraser Macfarlane	9
Ms Cinead Eileen O'Sullivan	3
Mr Roy Sinclair	6
Dr Catherine Urch	29

Training 01 April 2016 - 31 March 2017

Name of Member	Date	Event(s) attended
Mr Ted Barker	13/04/2016	Read: Nuffield council on bioethics; children and clinical research
Mr Ted Barker	16/08/2016	Good research practice online learning
Mr Ted Barker	17/08/2016	Medical devices online learning
Mr Ron Driver	15/08/2016	Read BMJ article on: Role of Consent
Mr Ron Driver	19/08/2016	Read: HRA paper on care after research
Mr Ron Driver	19/08/2016	Read: Approval for research involving ionising radiation
Mr Ron Driver	22/08/2016	Equality and Diversity
Miss Gayle D'Souza	11/04/2016	Ethics and GCP forum
Miss Gayle D'Souza	04/07/2016	CTIMP Training day
Miss Gayle D'Souza	30/08/2016	Equality and Diversity
Reverend Keith Lackenby	02/12/2016	Sense and readability; Participant Information Sheet for research studies
Reverend Keith Lackenby	02/12/2016	When should placebo surgery as a control in clinical trials be carried out
Ms Victoria Latham	10/09/2016	Information Governance Training
Dr Elizabeth Lund	06/04/2016	Handling health findings in research (joint MRC/HRA)
Dr Fraser Macfarlane	14/04/2016	Read and reflected on the Nuffield Council on Bioethics paper on Children and Clinical Research: ethical issues
Dr Fraser Macfarlane	16/04/2016	Read and reflected on the HRA's response to the Nuffield Council on Bioethics paper on Children and Clinical Research: ethical issues.
Dr Fraser Macfarlane	14/12/2016	Read and reflected on: Sense and readability, Participant information Sheets for Research Studies
Dr Fraser Macfarlane	14/12/2016	Read and reflected on: When should placebo surgery in Clinical trials be carried out. George et al (2016)
Ms Cinead Eileen O'Sullivan	01/04/2016	Children and Ethical issues and the HRA response
Dr Roger David Palmer	04/07/2016	CTIMP training
Dr Roger David Palmer	23/09/2016	Members Regional Training Day
Dr Roger David Palmer	16/02/2017	National Members Training Day
Mr Roy Sinclair	14/04/2016	Guidelines for Research with

		Children and young people
Mr Roy Sinclair	14/04/2016	REC guidance documents: Research involving Children and Young People
Mr Roy Sinclair	14/04/2016	Guidance on clinical research involving infants, children, and young people: an update for researchers and research ethics committees.
Mr Roy Sinclair	16/04/2016	HRA response to: Children and clinical research - ethical issues
Mr Roy Sinclair	02/07/2016	Read Section 1 of Hippocratic oaths: Consent and Research
Mr Roy Sinclair	12/08/2016	Read: New rules of consent; the patient decides
Mr Roy Sinclair	14/08/2016	Children and Clinical research - ethical issues
Miss Ravinder Summan	05/04/2016	GCP Refresher
Miss Ravinder Summan	16/05/2016	Presentation on advantages and disadvantages of single and multicentre trials
Miss Ravinder Summan	16/08/2016	Human Tissue Authority code of Practice 1: Consent
Miss Ravinder Summan	16/08/2016	Medical research involving adults who cannot consent
Miss Ravinder Summan	17/08/2016	Read: new rules on consent: the patient decides
Miss Ravinder Summan	20/11/2016	Equality and diversity
Miss Ravinder Summan	20/11/2016	Training for non-commercial studies
Miss Ravinder Summan	20/11/2016	Training for commercial studies
Miss Ravinder Summan	21/11/2016	Reviewing the research design of clinical trials
Miss Ravinder Summan	16/02/2017	Regional members training day
Dr Catherine Urch	07/11/2016	Regional Chairs meeting

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	13	22.03
Phase 1	3	5.08
Gene Therapy	22	37.29
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	0	0.00
Others	21	35.59
Total Applications Reviewed	59	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	10
Number of paediatric applications reviewed	13
Number of device applications reviewed	4
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	0	0.00
Favourable Opinion with Additional Conditions	6	10.17
Unfavourable Opinion	13	22.03
Provisional Opinion	40	67.80
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	59	100
Number of studies sent back to full committee meeting for final opinion	1	

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	59.32
Further Information Favourable Opinion with Additional Conditions	1	1.69
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	6	10.17
Unfavourable Opinion	13	22.03
Provisional Opinion	2	3.39
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	3.39
Total	59	100

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

Total Applications Reviewed	23
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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	1
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	3

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	2	8.70
Favourable Opinion with Additional Conditions	3	13.04
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	17	73.91
Unfavourable Opinion	1	4.35
Total	23	100

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

Average number of applications reviewed per full meeting	5.90
Number of completed applications for full ethical review	57
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	8
Number of completed applications over 40 days as a % of total	13.56%
Number of days taken to final decision – average (mean)	28
Number of completed proportionate review applications for ethical review	23
Number of completed proportionate review applications for ethical review over 14 days (please note, the timeline for the review of PR applications was extended from 14 to 21 calendar days in December 2016)	3
Number of completed Proportionate review applications for ethical review over 21 days	1
Number of completed proportionate review applications over 14 days as a % of total	13.04%
Number of SSAs (non-Phase 1) reviewed	3
Number of completed applications for SSA review over 25 days	0
Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs	0.00%
Number of SSAs (Phase 1) reviewed	2
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	188
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	7
Number of completed substantial amendments over 28 days as a % of total substantial amendments	3.72%
Number of modified amendments reviewed	9
Number of completed modified amendments over 14 days	0
Number of completed modified amendments over 14 days as a % of total modified amendments	0.00%
Number of non substantial amendments received	133

Number of substantial amendments received for information	0
Number of substantial amendments received for new sites/PIs	25
Number of annual progress reports received	108
Number of safety reports received	119
Number of Serious Adverse Events received	1
Number of final reports received	24

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

Further Information Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
16/LO/0487	B4711005 Stem cell transplantation in wet AMD - Safety follow-up Study	25
16/LO/0567	HARE-40	27
16/LO/0589	Outcomes after radiofrequency ablation of uterine fibroids	31
16/LO/0648	Phase 3 Study of Epacadostat and Pembrolizumab in Melanoma	28
16/LO/0663	Long-term follow-up study of patients previously exposed to UCART19	28
16/LO/0801	Autonomic function studies	25
16/LO/0831	CAP-IT	26
16/LO/1001	BI 1026706 and placebo in patients with diabetic macular edema.	57
16/LO/1026	Neonatal Vancomycin Trial (NeoVanc)	25
16/LO/1040	The effect of L-phenylalanine on appetite v1.0	23
16/LO/1066	A Phase 3 Single Arm Gene Therapy Study	51
16/LO/1179	Comparative study for Orencia Biosimilar (M834) in healthy subjects	36
16/LO/1244	Study to test Pexa-Vec and Sorafenib vs Sorafenib in Liver Cancer	35
16/LO/1254	LONG-TERM FOLLOW-UP GENE THERAPY STUDY FOR LCA OPTIRPE65	35
16/LO/1441	Efficacy and acceptability of a Renew anal insert	35
16/LO/1452	Do statins increase sensitivity to glucagon? Version 1.0	23
16/LO/1457	ELAD for treatment of alcohol induced liver decompensation (VTL-308)	40
16/LO/1540	Gene therapy for Achromatopsia: CNGB3	24
16/LO/1721	CARD	25
16/LO/1766	To assess the effects of inhaled RPL554 in adults with cystic fibrosis	33
16/LO/1800	Epilepsy: TSPO imaging	18
16/LO/1981	ADIPOA 2	29
16/LO/2005	SP017 (EudraCT number 2016-000567-16)	34
16/LO/2008	Phase I/II study evaluating AUTO2 in patients with multiple myeloma V1	27
17/LO/0001	A safety and dose finding study of DTX301 in late onset OTC deficiency	29
17/LO/0002	Inflammation and brain function	42
17/LO/0020	Gene Therapy for XLRP RPGR	57
17/LO/0034	GenScan II	49
17/LO/0048	MAGE-A10c796T for advanced NSCLC	52
17/LO/0117	ALLCAR19	51
17/LO/0126	Ursodeoxycholic acid and gut hormone response	33
17/LO/0152	COSMOS: The metabolic response to major surgery	45

17/LO/0387	Long-Term Follow-Up Gene Therapy Study for Achromatopsia (CNGB3)	30
17/LO/0425	Tumour Biopsy Driven Tx of Metastatic Carcinoma of Head and Neck	25
17/LO/0427	N3	30

Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/LO/0877	Study of Avelumab Plus Best Supportive Care in Urothelial Cancer	20

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
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Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/LO/0618	Optimising cognitive outcomes in epilepsy surgery	24
16/LO/0662	CALM study: UCART19 in adults with B-cell malignancies	24
16/LO/0879	Extend-3 v2.6 (19.4.16)	19
16/LO/1126	Platelet -omics in Acute Myocardial Infarction	22
16/LO/1892	Epilepsy: Pioglitazone pilot study	18
16/LO/1941	Synaptic and neural function	17

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
16/HRA/6014	A knowledge mobilisation case study in palliative and end of life care	21
16/LO/0880	CL04041023 - Clinical Rheumatoid Arthritis Development for Olokizumab	19
16/LO/0987	Extension Study for SMA patients who participated in ISIS396443 study	17
16/LO/1434	SP015:Combination of DCVAC/PCa and ONCOS-102 in mCRPC	16
16/LO/1435	SP017 (EudraCT number 2016-000567-16)	16
16/LO/1671	STATEC	17

16/LO/1706	Sing to Your Bump: Music for well-being in pregnancy	17
16/LO/1832	Sensitivity of babies in the environment	18
16/LO/2077	RAPID-1 Diabetic Foot Ulcer Study	18
17/LO/0003	SP015:Combination of DCVAC/PCa and ONCOS-102 in mCRPC	21
17/LO/0192	Vascular Injury and repair in children with infection	27
17/LO/0237	Long term safety of Everolimus in patients with TSC related seizures	24
17/LO/0252	Patient Views on Immune Thrombocytopenia (ITP) and Research Studies	24

Provisional Opinion

REC Reference	Title	Number of Days on Clock
17/LO/0275	NY-ESO-1c259T in Advanced NSCLC	n/a
17/LO/0447	LIGHT-UP: Loss of weight in prediabetes and type 2 diabetes	n/a

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
16/LO/1043	Effects of Z-994 on Inflammation in Healthy Volunteers	22
16/LO/1737	JCAR015-ALL-001_Phase 2_B-Cell Acute Lymphoblastic Leukaemia_JCAR015	18

Table 9.2: Breakdown of current status of all PRS applications reviewed within the reporting period

Further Information Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
16/LO/0811	The effects of exercise in patients with Systemic Sclerosis	8
16/LO/0963	Medication beliefs and adherence in paediatric sickle cell disease (1)	13
16/LO/0992	Cognitive stratification in Huntington's disease - STRAT-HD	13
16/LO/1164	Patients decision making for primary prevention cardiac devices	13
16/LO/1558	SHAREHD	12
16/LO/1562	Weight loss surgery for knee pain – a qualitative study V1.0	13
16/LO/1788	Uterine Protection in Lynch Syndrome (UP study)	10
16/LO/1789	Stress biomarker profile in total knee replacements V1.0	8
16/LO/1948	Cell shape recognition technology	12
16/LO/2073	A retrospective study on Humalog 200 units/ml KwikP (H200) insulin	16
16/LO/2085	Exploring unmet needs for care and support	9
16/LO/2229	Haemodialysis-related fatigue	13
16/LO/2245	Differentiation of the Athlete's Heart from Cardiomyopathy	12
17/LO/0213	Development of a dysphagia management protocol in Care Homes.	11
17/LO/0532	Carers' experiences of ward rounds in mental health settings V1	20
17/LO/0537	RSV and vaccination in pregnancy	22

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
16/LO/1154	Intraoperative Hypotension in Elder Patients (IHypE)	14

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

Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
17/LO/0229	Comparing different methods of obtaining static lung volumes	8
17/LO/0415	The Community Lung Health Study	8

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
16/LO/1939	Children and Young People's Inpatient and Day Case Survey 2016	8
17/LO/0217	Point prevalence study of platelet transfusion in PICU	10
17/LO/0361	Parental Illness Perceptions in Type 1 Diabetes and JIA	11

Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock
16/LO/0810	Acceptability of risk-based breast cancer screening v1.0	10

Provisional Opinion		
REC Reference	Title	Number of Days on Clock

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

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

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

Favourable opinion				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
07/H0707/105/AM16	Quantification of fetal brain growth and development using MRI	SA#12	23/09/2016	17
07/H0707/139/AM09	Postmortem MR imaging to study the developing brain	SA6	02/02/2016	8
07/H0707/139/AM10	Postmortem MR imaging to study the developing brain	SA7	12/05/2016	18
07/H0707/139/AM11	Postmortem MR imaging to study the developing brain	SA#08	19/01/2017	13
07/H0707/152/AM03	Lesion-Function Mapping	SA2	08/08/2016	20
07/H0707/152/AM04	Lesion-Function Mapping	SA#03	25/01/2017	8
09/H0707/38/AM12	IDEAL-CRT	IDL/010-02-03-2017	08/03/2017	15
09/H0707/58/AM17	1200.38 BIBW 2992 Glioblastoma Trial	Afatinib IB version 17	25/08/2016	20
09/H0707/69/AM14	Genetic studies of cardiomyopathies and arrhythmia. Version1	SA#08	23/09/2016	22
09/H0707/82/AM13	An investigation of cognitive function in traumatic brain injury.	SA#2.7 05/10/2016	08/11/2016	13
10/H0707/29/AM13	Plasticity following amputation - v1	SA#08	16/06/2016	13
10/H0803/102/AM04	Immune studies in Primary Lymphoedema	SA#04	09/01/2017	24
10/H0803/121/AM04	Genetic Linkage Evaluation in ICCs v1	SA#02	21/09/2016	6
10/H0803/121/AM05	Genetic Linkage Evaluation in ICCs v1	SA#03	05/12/2016	11
10/H0803/161/AM03	A foundation for the oral microbiome and metagenome	SA#03	28/07/2016	25
10/H0803/72/AM04	Molecular Autopsy in SADS Clinic Patients v1	SA#07	16/05/2016	15
10/H0803/73/AM02	Identification of Genetic Risk in Unexplained Sudden Death v1	SA#02	04/08/2016	12
10/H0803/96/AM05	SISTERS: Spasticity in Stroke – Randomized Study - v1 13 Mar 2009	SA3	04/05/2016	4
11/LO/0082/AM20	Study of Pomalidomide in Subjects with Multiple Myeloma	SA#07	02/09/2016	15
11/LO/0883/AM04	New sequencing technologies for investigation of Mendelian disease	Amendment 4	27/06/2016	15
11/LO/1733/AM13	Blinatumomab (MT103) in adult patients with relapsed/refractory ALL	SA#12 IB update	23/06/2016	7
12/LO/0004/AM05	Drug Lung Deposition In COPD	SA#03	11/04/2016	18
12/LO/0095/AM09	A1444-046 Observational f'up from BMS-650032/790052 Hepatitis C trials	SA new IB	22/07/2016	14
12/LO/0095/AM11	A1444-046 Observational f'up from BMS-650032/790052	EC07	14/10/2016	17

	Hepatitis C trials			
12/LO/0191/AM13	Rollover Study: GSK2118436 Continued Treatment for BRAF+ Tumours	SA#07 (IB update)	11/04/2016	18
12/LO/0191/AM14	Rollover Study: GSK2118436 Continued Treatment for BRAF+ Tumours	SA#08	28/02/2017	21
12/LO/0443/AM12	Vemurafenib in patients with BRAF V600 mutation-positive cancers	SA10	12/05/2016	10
12/LO/0507/AM03	Physiological role of kisspeptin on reproductive hormone release	Amendment 4	22/08/2016	21
12/LO/0845/AM27	Study of Carfilzomib with Dexamethasone vs Velcade with Dexamethasone	SA#19	26/05/2016	7
12/LO/0845/AM29	Study of Carfilzomib with Dexamethasone vs Velcade with Dexamethasone	21	21/12/2016	15
12/LO/1132/AM08	Hepatitis B vaccination in infants (version 1.1)	SA 18.08.2016	18/08/2016	19
12/LO/1247/AM07	Investigating Preterm brain development with functional MRI (v1)	SA#04	09/02/2017	29
12/LO/1834/AM10	T4 immunotherapy of head and neck cancer	SA#06	07/02/2017	28
12/LO/1955/AM06	Stress and Brain Function	SA#04	11/08/2016	24
13/LO/0733/AM20	AGS-003 Plus Standard Treatment in Advanced RCC (ADAPT)	IB v014	26/07/2016	15
13/LO/0733/AM21	AGS-003 Plus Standard Treatment in Advanced RCC (ADAPT)	SA - ICF addendum and DMC	02/03/2017	26
13/LO/1141/AM08	GRIPHON OL/Protocol AC-065A303	SA new IB	05/08/2016	11
13/LO/1141/AM10	GRIPHON OL/Protocol AC-065A303	Protocol amendment 6 + IB update	10/02/2017	28
13/LO/1174/AM14	Efficacy study of CTX0E03 injected into the brain of stroke patients	SA#09	25/01/2017	12
13/LO/1489/AM12	Phase 3 study for the treatment of HBeAg-Negative, Chronic Hepatitis B	SA#08	18/08/2016	18
13/LO/1489/AM14	Phase 3 study for the treatment of HBeAg-Negative, Chronic Hepatitis B	SA9	16/02/2017	22
13/LO/1490/AM14	TAF vs TDF for the Treatment of HBeAg Positive, Chronic Hepatitis B	TAF IB Edition 10.1	18/08/2016	19
13/LO/1490/AM16	TAF vs TDF for the Treatment of HBeAg Positive, Chronic Hepatitis B	9	16/02/2017	22

13/LO/1510/AM06	Do gut hormones mediate the beneficial effects of Roux-en-Y bypass?	SA#07	27/06/2016	8
13/LO/1510/AM07	Do gut hormones mediate the beneficial effects of Roux-en-Y bypass?	SA#08	15/11/2016	7
13/LO/1654/AM03	FOCUS Study	SA#03	31/10/2016	11
13/LO/1691/AM16	ProCAID	SA#10	21/04/2016	20
14/LO/0056/AM05	PREOBÁ®-ON3 - A bone cell therapy for hip osteonecrosis	SA11	06/02/2017	29
14/LO/0227/AM06	LAIV Immuno	SA9	12/08/2016	20
14/LO/0395/AM04	Gene Therapy for WAS follow-up, version 1.0	SA#03	18/08/2016	19
14/LO/0395/AM06	Gene Therapy for WAS follow-up, version 1.0	SA#05	17/01/2017	10
14/LO/0411/AM01	The National Study of Health and Wellbeing 2014	SA#01	02/12/2016	12
14/LO/0722/AM07	RegenVOX: Clinical trial of voicebox implants using tissue engineering	SA#05	19/07/2016	12
14/LO/0722/AM09	RegenVOX: Clinical trial of voicebox implants using tissue engineering	Substantial Amendment 7 Temporary halt	23/03/2017	12
14/LO/1042/AM10	GO29293 Anti-PDL1 in Bladder Cancer	SA#07	15/12/2016	23
14/LO/1426/AM08	Biomarker Study with T-Vec in Unresected Stage IIIB to IVM1c Melanoma	Amendment 7	01/06/2016	6
14/LO/1426/AM09	Biomarker Study with T-Vec in Unresected Stage IIIB to IVM1c Melanoma	SA#08	24/01/2017	5
14/LO/1444/AM04	520-215 AfFIRM A Phase 2 Trial of Filanesib in Relapsed/Refractory MM	2	17/02/2017	21
14/LO/1486/AM04	T-Vec with MK-3475 for Treatment of Stage IIIB to IVM1c Melanoma	SA#04	01/06/2016	6
14/LO/1486/AM06	T-Vec with MK-3475 for Treatment of Stage IIIB to IVM1c Melanoma	SA#06	12/10/2016	20
14/LO/1552/AM03	Imaging opioid system in alcohol dependence	SA#01	26/05/2016	7
14/LO/1552/AM04	Imaging opioid system in alcohol dependence	SA#02	13/01/2017	13
14/LO/1644/AM07	Phase I/II study of gene-modified WT1 TCR therapy in MDS &AML patients	Amendment 7	07/07/2016	10
14/LO/1798/AM09	GO29294 Anti-PDL1 Bladder Cancer Phase III Version 1.0	SA#07	18/05/2016	13
14/LO/1798/AM10	GO29294 Anti-PDL1 Bladder Cancer Phase III Version 1.0	SA#08	13/09/2016	14
14/LO/1798/AM11	GO29294 Anti-PDL1 Bladder Cancer Phase III Version 1.0	SA#09	26/01/2017	12
14/LO/1799/AM04	Study to assess the Clinical Efficacy and Safety of ISIS 396443	SA03	07/06/2016	23
14/LO/1799/AM05	Study to assess the Clinical Efficacy and Safety of ISIS 396443	SA#04	17/08/2016	19

14/LO/2026/AM03	Patient Diaries in the Paediatric Intensive Care Unit (PICU)	SA#01	07/12/2016	9
14/LO/2215/AM03	Chlorhexidine Gluconate Chip in Therapy of Peri-implantitis	Substantial Amendment 2.0 2017	20/02/2017	14
15/LO/0013/AM02	PBR 28 PET and inflammatory arthritis version1	SA#02	01/06/2016	25
15/LO/0317/AM06	Ph1b study PIM447 with INC424 + LEE011 in patients with myelofibrosis	SA#06	31/05/2016	8
15/LO/0342/AM07	Withdrawal Period study of LUM001 in patients with Alagille Syndrome	SA#04	18/05/2016	8
15/LO/0347/AM01	Structural brain abnormalities and hypoxia in sickle cell anaemia	SA#01	08/09/2016	15
15/LO/0433/AM05	Clinical Trial of ALNAS1 in Patients with Acute Intermittent Porphyrria	SA#09	25/04/2016	16
15/LO/0433/AM07	Clinical Trial of ALNAS1 in Patients with Acute Intermittent Porphyrria	SA#10	09/08/2016	21
15/LO/0519/AM02	AI438-047: Attachment inhibitor study in HTE patients with MDR HIV-1	SA#02	29/03/2016	27
15/LO/0519/AM03	AI438-047: Attachment inhibitor study in HTE patients with MDR HIV-1	SA#03	16/06/2016	21
15/LO/0519/AM04	AI438-047: Attachment inhibitor study in HTE patients with MDR HIV-1	EC04	14/10/2016	17
15/LO/0599/AM03	Phase 1b of MPDL3280A + Obinutuzumab in Follicular and B-cell lymphoma	SA#03	04/05/2016	12
15/LO/0605/AM02	1200.120 Phase I monotherapy basket trial of afatinib in children.	SA#02	27/04/2016	16
15/LO/0605/AM03	1200.120 Phase I monotherapy basket trial of afatinib in children.	SA3	18/08/2016	9
15/LO/0681/AM04	ISIS-443139-CS1	Protocol amendment 2	25/05/2016	9
15/LO/0780/AM05	GRAVITAS	SA 2	03/11/2016	26
15/LO/0785/AM01	Allogeneic HSCT in CCALD	SA#01	27/07/2016	8
15/LO/0920/AM09	SMTc11004 - Phase 1 study in healthy volunteers and DMD patients	SA#04	06/04/2016	7
15/LO/1011/AM01	Oral sodium bicarbonate supplementation in haemodialysis patients	SA#01	13/05/2016	18
15/LO/1079/AM04	A safety and efficacy study of Multistem Cell Therapy for	SA#02	25/05/2016	6

	ARDS			
15/LO/1079/AM05	A safety and efficacy study of Multistem Cell Therapy for ARDS	Amendment 5	06/10/2016	19
15/LO/1266/AM02	IMPACT	SA#01	20/07/2016	15
15/LO/1308/AM01	RESCUE study	SA#01	17/05/2016	16
15/LO/1309/AM01	REVERSE study	SA#01	17/05/2016	16
15/LO/1379/AM04	REGENERATE (REP1 Gene Replacement Therapy) Trial: Version 1.0	SA#01	16/11/2016	6
15/LO/1379/AM05	REGENERATE (REP1 Gene Replacement Therapy) Trial: Version 1.0	SA#02	19/01/2017	19
15/LO/1379/AM06	REGENERATE (REP1 Gene Replacement Therapy) Trial: Version 1.0	Substantial Amendment 5.0 2017	15/03/2017	17
15/LO/1480/AM01	Holocore	SA#01	18/05/2016	18
15/LO/1480/AM02	Holocore	SA#02	22/11/2016	13
15/LO/1480/AM03	Holocore	SA#03	22/03/2017	13
15/LO/1509/AM01	COBALT	SA#01	18/05/2016	19
15/LO/1509/AM02	COBALT	SA2 protocol v3	02/09/2016	7
15/LO/1609/AM01	Astroglial activation, I ² -amyloid deposition and neuronal activity	SA#01	05/07/2016	14
15/LO/1677/AM03	Long term follow-up of subjects with CALD treated with Lenti-D	SA#01	07/04/2016	21
15/LO/2045/AM03	SMT C1100 in Ambulatory Boys with DMD	SA#03	05/04/2016	9
15/LO/2045/AM04	SMT C1100 in Ambulatory Boys with DMD	SA#04	13/07/2016	6
15/LO/2045/AM05	SMT C1100 in Ambulatory Boys with DMD	SA#06	14/10/2016	17
15/LO/2124/AM01	METRIC a study in GPNMB over expressing triple negative breast cancer	SA#01	21/09/2016	6
15/LO/2129/AM02	Testagenâ Dose Ranging D1-09-13	SA#01	06/08/2016	14
16/LO/0013/AM01	T-Vec in combination with Pembrolizumab in recurrent/metastatic SCCHN	SA#01	01/06/2016	6
16/LO/0013/AM02	T-Vec in combination with Pembrolizumab in recurrent/metastatic SCCHN	SA#02	13/10/2016	19
16/LO/0013/AM03	T-Vec in combination with Pembrolizumab in recurrent/metastatic SCCHN	SA#03	25/01/2017	8
16/LO/0013/AM04	T-Vec in combination with Pembrolizumab in recurrent/metastatic SCCHN	SA#04	08/03/2017	35
16/LO/0043/AM01	IMCgp100-102 Phase 1 IMCgp100 in patients with Advanced Uveal Melanoma	SA#01	31/03/2016	14

16/LO/0043/AM02	IMCgp100-102 Phase 1 IMCgp100 in patients with Advanced Uveal Melanoma	SA2	05/05/2016	26
16/LO/0043/AM03	IMCgp100-102 Phase 1 IMCgp100 in patients with Advanced Uveal Melanoma	SA#03	08/07/2016	6
16/LO/0043/AM05	IMCgp100-102 Phase 1 IMCgp100 in patients with Advanced Uveal Melanoma	SA#05	20/12/2016	22
16/LO/0086/AM01	STAR Study	SA#01	08/04/2016	9
16/LO/0086/AM02	STAR Study	SA2	06/05/2016	26
16/LO/0126/AM01	Gene Therapy Trial for LCA2 OPTIRPE65 (AAV2/5-OPTIRPE65)	SA#01	13/06/2016	14
16/LO/0126/AM03	Gene Therapy Trial for LCA2 OPTIRPE65 (AAV2/5-OPTIRPE65)	Change of Sponsor	10/02/2017	25
16/LO/0155/AM01	MHCYP 2016 v1	SA1	28/04/2016	22
16/LO/0155/AM02	MHCYP 2016 v1	SA#02	29/09/2016	21
16/LO/0261/AM02	MBCT206 A Phase IIa, two-part, randomised, study for adults with COPD	SA#04	10/06/2016	17
16/LO/0261/AM05	MBCT206 A Phase IIa, two-part, randomised, study for adults with COPD	SA protocol amendment 5	05/12/2016	15
16/LO/0261/AM06	MBCT206 A Phase IIa, two-part, randomised, study for adults with COPD	SA#06	21/12/2016	22
16/LO/0261/AM08	MBCT206 A Phase IIa, two-part, randomised, study for adults with COPD	SA#07	21/02/2017	33
16/LO/0440/AM01	UCART19 PALL study (Paediatric Acute Lymphoblastic Leukaemia)	SA#01	08/08/2016	24
16/LO/0440/AM02	UCART19 PALL study (Paediatric Acute Lymphoblastic Leukaemia)	SA#02	14/09/2016	13
16/LO/0440/AM03	UCART19 PALL study (Paediatric Acute Lymphoblastic Leukaemia)	SA#03	12/12/2016	8
16/LO/0462/AM01	HGT-MLD-071 Study of HGT-1110 in Patients with MLD	SA#01	08/11/2016	13
16/LO/0567/AM01	HARE-40	Substantial Amendment 1	19/12/2016	20
16/LO/0648/AM01	Phase 3 Study of Epacadostat and Pembrolizumab in Melanoma	SA#01	04/07/2016	16
16/LO/0648/AM03	Phase 3 Study of Epacadostat and Pembrolizumab in Melanoma	SA2	23/08/2016	22
16/LO/0648/AM05	Phase 3 Study of Epacadostat and Pembrolizumab in	SA#03	07/11/2016	13

	Melanoma			
16/LO/0648/AM08	Phase 3 Study of Epcadostat and Pembrolizumab in Melanoma	SA#04	16/03/2017	13
16/LO/0662/AM01	CALM study: UCART19 in adults with B-cell malignancies	SA#01	17/08/2016	20
16/LO/0662/AM02	CALM study: UCART19 in adults with B-cell malignancies	SA#02	30/11/2016	7
16/LO/0663/AM01	Long-term follow-up study of patients previously exposed to UCART19	SA#01	15/09/2016	12
16/LO/0663/AM03	Long-term follow-up study of patients previously exposed to UCART19	SA#03	07/12/2016	13
16/LO/0831/AM01	CAP-IT	SA#01	17/08/2016	20
16/LO/0831/AM03	CAP-IT	3	20/12/2016	22
16/LO/0879/AM01	Extend-3 v2.6 (19.4.16)	2.9.3	13/11/2016	6
16/LO/1026/AM01	Neonatal Vancomycin Trial (NeoVanc)	SA#01	12/09/2016	11
16/LO/1066/AM01	A Phase 3 Single Arm Gene Therapy Study	SA#01	15/11/2016	11
16/LO/1066/AM02	A Phase 3 Single Arm Gene Therapy Study	SA#02	23/12/2016	27
16/LO/1179/AM01	Comparative study for Orencia Biosimilar (M834) in healthy subjects	SA#01	20/01/2017	12
16/LO/1244/AM02	Study to test Pexa-Vec and Sorafenib vs Sorafenib in Liver Cancer	Global amendment 1: IB v13	15/12/2016	14
16/LO/1254/AM01	LONG-TERM FOLLOW-UP GENE THERAPY STUDY FOR LCA OPTIRPE65	1	16/12/2016	30
16/LO/1452/AM01	Do statins increase sensitivity to glucagon? Version 1.0	Substantial Amendment 1 2017/0	20/02/2017	14
16/LO/1457/AM07	ELAD for treatment of alcohol induced liver decompensation (VTL-308)	1	20/02/2017	31
16/LO/1540/AM01	Gene therapy for Achromatopsia: CNGB3	1	03/03/2017	20
16/LO/1558/AM01	SHAREHD	SA#01	27/11/2016	8
16/LO/1721/AM01	CARD	SA#01	23/01/2017	15
16/LO/1766/AM01	To assess the effects of inhaled RPL554 in adults with cystic fibrosis	Substantial Amendment 1 2017/0	03/03/2017	13
2004/6745/AM06	A PET study of brain dopamine in the early phase of psychosis	SA#15	31/01/2017	6
GTAC098/AM09		Protocol amendment 4 - 24th No	22/12/2016	27

GTAC115/AM10		Protocol amendment 11.1	10/06/2016	17
GTAC115/AM11		Protocol amendment 11.2	02/12/2016	18
GTAC132/AM05	Gene therapy for SCID-X1 using (SIN) gammaretroviral vector.	SA5	02/06/2016	18
GTAC146/AM07	Phase I/II clinical trial of haematopoietic stem cell gene therapy for the Wiskott-Aldrich Syndrome	SA#07	12/05/2016	18
GTAC146/AM08	Phase I/II clinical trial of haematopoietic stem cell gene therapy for the Wiskott-Aldrich Syndrome	SA#08	18/08/2016	19
GTAC169/AM07	CMV TCR Gene Therapy (CMV TCR-001)	SA#06	24/11/2016	8
GTAC172/AM11	Study of SCIB1 in Melanoma: SCIB1-001	Temporary halt	27/06/2016	9
GTAC177/AM11	Intraleural delivery of HSV1716 in patients with mesothelioma	SA#12	27/04/2016	15
GTAC178/AM16	LV Gene Therapy for ADA Deficiency	SA#10	05/08/2016	5
GTAC178/AM18	LV Gene Therapy for ADA Deficiency	SA#12	31/01/2017	13
GTAC178/AM19	LV Gene Therapy for ADA Deficiency	Substantial Amendment no. 13:	16/03/2017	20
GTAC180/AM08	HA-1 heterologous prime boost vaccine study	SA#07	25/10/2016	17
GTAC182/AM16	TroVax in patients with asymptomatic relapsed ovarian cancer (TRIOC)	SA#09	12/08/2016	24
GTAC182/AM17	TroVax in patients with asymptomatic relapsed ovarian cancer (TRIOC)	10	18/01/2017	34
GTAC187/AM11	Lenti-D ALD-102 (Version 2; Dated 30 January 2012)	SA6	19/12/2016	15
GTAC188/AM07	Gene Therapy for Netherton Syndrome	SA#04	30/06/2016	7
GTAC190/AM05	Pre-Operative JX-594	SA#04	16/09/2016	5
GTAC196/AM11	LV gene therapy for CGD	SA#07	27/06/2016	8
GTAC196/AM12	LV gene therapy for CGD	SA#08	08/11/2016	1
GTAC198/AM05	Follow-up Study to Research with Retinal Cells Derived from Stem Cells	SA3	24/08/2016	21
GTAC198/AM07	Follow-up Study to Research with Retinal Cells Derived from Stem Cells	SA#05	23/02/2017	28

Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
14/LO/0067/AM05	Dopamine dysregulation following TBI	SA#05	06/07/2016	13
14/LO/0592/AM03	Pregnancy in overweight women	SA#03	09/05/2016	16

15/LO/0681/AM09	ISIS-443139-CS1	Protocol amendment 3	30/11/2016	8
15/LO/1308/AM05	RESCUE study	SA#02	07/12/2016	26
15/LO/1309/AM03	REVERSE study	SA#02	07/12/2016	26
15/LO/1510/AM02	A Phase I trial of anti-GD2 CAR transduced T-cells (1RG-CART) v1.	2	14/12/2016	26
15/LO/2045/AM07	SMT C1100 in Ambulatory Boys with DMD	SA07 2017/03/15	15/03/2017	20
16/LO/0043/AM04	IMCgp100-102 Phase 1 IMCgp100 in patients with Advanced Uveal Melanoma	SA#04	06/10/2016	14
16/LO/0130/AM01	Investigating the role of glutamate in brain function	SA#01	02/12/2016	7
16/LO/0811/AM01	The effects of exercise in patients with Systemic Sclerosis	1	08/07/2016	7
GTAC178/AM14	LV Gene Therapy for ADA Deficiency	SA#09	18/03/2016	16
GTAC178/AM17	LV Gene Therapy for ADA Deficiency	SA#11	25/10/2016	15

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/0067/AM05/1	Dopamine dysregulation following TBI	Modified amendment 12.08.16	09/08/2016	14
14/LO/0592/AM03/1	Pregnancy in overweight women	Modified amendment 23/06/16	23/06/2016	14
15/LO/0898/AM02/1	Extension HGT1410 Study in Paediatric Patients with Early Stage MPS IIIA	Modified amendment 1	08/02/2016	7
15/LO/1510/AM02/1	A Phase I trial of anti-GD2 CAR transduced T-cells (1RG-CART) v1.	Modified amendment 2	03/02/2017	7
16/LO/0043/AM04/1	IMCgp100-102 Phase 1 IMCgp100 in patients with Advanced Uveal Melanoma	modified SA#04	31/10/2016	14
16/LO/0130/AM01/1	Investigating the role of glutamate in brain function	2	21/12/2016	9
16/LO/0811/AM01/1	The effects of exercise in patients with Systemic Sclerosis	Modified AM01	20/07/2016	13
GTAC178/AM14/1	LV Gene Therapy for ADA Deficiency		09/05/2016	13
GTAC178/AM17/1	LV Gene Therapy for ADA Deficiency	Modified amendment 11	28/11/2016	3

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

Table 11: Items exceeding timelines

Full applications for ethical review over 60 day timeline

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

REC Reference	Title	Number of Days on Clock
17/LO/0537	RSV and vaccination in pregnancy	22

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
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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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