

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

Annual Report

01 April 2017 - 31 March 2018



Part 1 – Committee Membership and Training

Name of REC:	London - West London & GTAC Research Ethics Committee
Type of REC:	RECs recognised to review CTIMPS in healthy volunteers - type i RECs recognised to review CTIMPS in patients - type iii
Type of Flag:	Gene Therapy or Stem Cell Clinical Trials Phase 1 Studies in Healthy Volunteers Phase 1 Studies in Patients Research Involving Children
Chair:	Dr Catherine Urch
Vice-Chair:	Reverend Keith Lackenby
Alternate Vice-Chair:	Vacant position
REC Manager:	Carolyn Halliwell - May 2018 - present Nischinth Cherodian – October 2017 – April 2018 Andrea Graham – April 2017 – September 2017
REC Assistant:	Tad Jones – April 2017 – January 2018 George Martin – April 2017 – January 2018 Teagan Allen – February 2018 - present
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 for the West London and GTAC committee. We sadly said good bye to a longstanding colleague Fraser who left with our thanks and best wishes for his new life in Oxford. We are fortunate to welcome Mary who will bring a wealth of experience and ethical questioning.

The committee remains fully booked with lively discussions at the meeting, fascinating research presented, and frequent thanks from researchers. Our return rate from teams and the willingness to wait for a slot for us is testament to the high quality and consistency of the whole committee. Our work with early phase trials and GTAC remains the mainstay of our work which is fascinating to see the development over time.

My thanks as always goes to the HRA staff who support us all and the research teams, and to the whole committee.

Dr Catherine Urch
Chair West London and GTAC

London - West London & GTAC Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Mrs Mary Chapman	Chartered Director	Lay Plus	01/05/2017	
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	15/11/2017
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	01/05/2001	
Miss Ravinder Summan	Research Nurse	Expert	05/05/2015	
Dr Catherine Urch	Consultant Palliative Medicine	Expert	21/12/2007	

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

Name	Profession	Status	Meeting dates attended
Ms Maja Balic	Pharmacist	Expert	17/05/2017 21/06/2017 17/08/2017 21/09/2017 19/10/2017 14/12/2017 22/03/2018
Dr Tassos Georgiadis	Senior Research Associate	Expert	21/09/2017 14/12/2017 22/02/2018 22/03/2018

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

Name	Profession	Status	Meeting dates attended
Mrs Lynne Fryatt	Retired Assistant Chief Nurse	Lay	PR 13/09/2017

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

Name	Declaration of Interest	Date
Mrs Mary Chapman	Chair of the General Chiropractic Council, a health care regulator. There are no current plans to commission any research.	31/03/2018
Mr Ron Driver	None declared	31/03/2018
Miss Gayle D'Souza	Director: Gayleforce Scientific LTD. Services include paid/unpaid clinical project management for clinical trials consultancy services. Director: Gayleforce Scientific LTD. Providing paid/unpaid clinical management consultancy services. Been contracting through Hays and providing consultancy services to Roche Products Ltd (F.Hoffman - La Roche) Currently declaring conflict of interest is participating in any REC reviews of any F. Hoffmann-La Roche studies or any studies I may be working on with a sponsor/funder/IMP provider.	31/03/2018
Dr Tassos Georgiadis	Consultant for MeiraGTx Ltd. Gene therapy company for inherited retinal degenerations.	31/03/2018
Reverend Keith Lackenby	None declared	31/03/2018
Dr Elizabeth Lund	Works as a freelance consultant on ethical aspects of food intervention studies and assists with writing protocols and ethical submissions. Recently lectured on a range of aspects running human intervention studies in nutrition and public health in Nairobi. Most of Liz's work is funded by the bbsrc and European research funds. Continues to seek further consultancy work. Trustee of Asperger East Anglia and in this respect is a member of a steering group on the Nuffield funded ASSENT study. Regularly reviews papers for journals such as Carcinogenesis, Gut, Cancer Research, American Journal of Clinical Nutrition, British Journal of Nutrition etc.	31/03/2018
Ms Cinead Eileen O'Sullivan	None declared	31/03/2018
Dr Roger David Palmer	None declared.	31/03/2018
Mr Roy Sinclair	None declared	31/03/2018
Miss Ravinder Summan	At present research nurse at the Imperial Clinical Research Facility, Hammersmith Hospital since September 2013. Leaving on 27th May 2018 to start new post on 28th May 2018 as paediatric sister at the Royal Free Hospital. Worked as a bank research nurse since January 2009 at Burlington Danes formally for GSK, now called Invico.	31/03/2018
Dr Catherine Urch	Supervises PhD students / post doctoral students who are involved in clinical research	31/03/2018

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

Month	Date	Number of Members Present at Meeting
April	19/04/2017	8
May	17/05/2017	11
June	21/06/2017	9
August	17/08/2017	8
September	21/09/2017	12
October	19/10/2017	10
December	14/12/2017	9
January	18/01/2018	10
February	22/02/2018	10
March	22/03/2018	10

10 full committee meetings were held during the reporting period.

Proportionate Review Sub-Committee Meetings held during 01 April 2017 - 31 March 2018:

Month	Date	Number of Members Present at Meeting
May	24/05/2017	3
June	28/06/2017	3
August	22/08/2017	3
September	18/09/2017	4
September	27/09/2017	3
November	20/11/2017	3
January	24/01/2018	3
February	28/02/2018	3
March	28/03/2018	3

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

Sub-Committee Meetings held during 01 April 2017 - 31 March 2018:

Month	Date	Number of Members Present at Meeting
April	13/04/2017	2
April	27/04/2017	2
May	11/05/2017	2
May	25/05/2017	2
June	08/06/2017	2
June	22/06/2017	2
July	06/07/2017	2
July	20/07/2017	2
August	03/08/2017	2
August	25/08/2017	2
September	07/09/2017	2
September	22/09/2017	2
October	05/10/2017	2
October	19/10/2017	2

November	02/11/2017	2
November	16/11/2017	2
November	30/11/2017	2
December	14/12/2017	2
January	04/01/2018	2
January	18/01/2018	2
February	01/02/2018	2
February	15/02/2018	2
February	25/02/2018	3
March	01/03/2018	2
March	15/03/2018	2
March	29/03/2018	2

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

Details of inquorate meeting held: 01 April 2017 - 31 March 2018

None

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

Name	Number of Meetings Attended
Ms Maja Balic	7
Mrs Mary Chapman	4
Mr Ron Driver	9
Miss Gayle D'Souza	6
Dr Tassos Georgiadis	4
Professor Uta Griesenbach	2
Reverend Keith Lackenby	10
Ms Victoria Latham	2
Dr Elizabeth Lund	9
Dr Fraser Macfarlane	2
Ms Cinead Eileen O'Sullivan	7
Dr Roger David Palmer	6
Mr Roy Sinclair	9
Miss Ravinder Summan	10
Dr Catherine Urch	10

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

Name	Number of Meetings Attended
Miss Gayle D'Souza	6
Reverend Keith Lackenby	9
Dr Elizabeth Lund	3
Mr Roy Sinclair	5
Miss Ravinder Summan	4

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

Name	Number of Meetings Attended
Mr Ron Driver	4
Professor Uta Griesenbach	2
Reverend Keith Lackenby	5
Dr Elizabeth Lund	3
Dr Fraser Macfarlane	2
Ms Cinead Eileen O'Sullivan	2
Mr Roy Sinclair	9
Dr Catherine Urch	26

Training 01 April 2017 - 31 March 2018

Name of Member	Date	Event(s) attended
Ms Maja Balic	25/07/2017	Induction
Ms Maja Balic	28/02/2018	Ethical Issues in Phase 1 Research - An Advanced Training Course
Mrs Mary Chapman	16/11/2017	Members Induction face to face
Mrs Mary Chapman	12/12/2017	National Members Training Day
Mrs Mary Chapman	07/02/2018	Introduction to Phase 1 Research - Trials & Regulation
Dr Tassos Georgiadis	16/11/2017	Members induction face to face
Reverend Keith Lackenby	24/11/2017	HRA National REC Chairs Training Day and Policy Event 2017
Reverend Keith Lackenby	12/12/2017	National Members Training Day
Reverend Keith Lackenby	05/05/2017	Chairs' Meeting - East Midlands
Reverend Keith Lackenby	02/11/2017	Chairs' Meeting – East/West Midlands
Ms Victoria Latham	29/09/2017	Regional Training Day - Nottingham
Dr Elizabeth Lund	31/01/2018	Publication of paper entitled 'Comparing Diet and Exercise Monitoring Using Smartphone App and Paper Diary: A Two-Phase Intervention Study'
Dr Elizabeth Lund	28/02/2018	Teaching a one week course in Nairobi on the design and ethical conduct of human research studies in the area of Nutrition and Public Health
Dr Elizabeth Lund	31/03/2018	Reviewing for scientific journals
Dr Fraser Macfarlane	26/07/2017	Read and reflected on: Patient funded trials: opportunity or liability. (Wenner et al 2015)
Dr Fraser Macfarlane	26/07/2017	Read and reflected on: Clinical research: should patients pay to play (Emanuel et al 2015)
Dr Fraser Macfarlane	02/10/2017	Equality and Diversity
Dr Roger David Palmer	29/09/2017	Regional Training Day Nottingham
Dr Roger David Palmer	12/12/2017	National Members training day
Miss Ravinder Summan	12/07/2017	Genetic and Genomic Research (previously HTA Advanced)
Miss Ravinder Summan	12/09/2017	Genetic and Genomic research
Miss Ravinder Summan	13/02/2018	Training - The Ethical Issues of Research Involving Children
Miss Ravinder Summan	13/02/2018	The Ethical Issues of Research Involving Children
Miss Ravinder Summan	07/03/2018	GCP Refresher
Dr Catherine Urch	03/05/2017	Chairs Meeting
Dr Catherine Urch	07/06/2017	Read and reflected on: Should patients pay to play (Emmanuel 2015)
Dr Catherine Urch	07/06/2017	Read and reflected on; Patient

		funded trials; opportunity of liability (Wenner, Stem cell forum)
Dr Catherine Urch	07/06/2017	Preventing TB: Effectiveness of MVA85A
Dr Catherine Urch	09/06/2017	Taking Consent
Dr Catherine Urch	06/11/2017	Chairs Meeting
Dr Catherine Urch	24/11/2017	HRA National Chairs' Day and Policy Event

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	23.64
Phase 1	1	1.82
Gene Therapy	23	41.82
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	0	0.00
Others	18	32.73
Total Applications Reviewed	55	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	2
Number of student applications reviewed	5
Number of paediatric applications reviewed	18
Number of device applications reviewed	1
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	10.91
Unfavourable Opinion	11	20.00
Provisional Opinion	38	69.09
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	55	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	31	56.36
Further Information Favourable Opinion with Additional Conditions	3	5.45
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	6	10.91
Unfavourable Opinion	11	20.00
Provisional Opinion	3	5.45
Provisional Opinion Pending Consultation with Referee	0	0.00
Further Information response not complete	1	1.82
No decision entered on system	0	0.00
Number of studies withdrawn after the meeting	0	0.00
Total	55	100

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

Total Applications Reviewed	19
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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	2
Number of studies withdrawn prior to the meeting	0
Number of student applications reviewed	8
Number of paediatric applications reviewed	3
Number of device applications reviewed	1
Number of qualitative applications reviewed	2

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	1	5.26
Favourable Opinion with Additional Conditions	4	21.05
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	11	57.89
Unfavourable Opinion	3	15.79
Total	19	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	5.50
Number of completed applications for full ethical review	55
Number of completed applications for full ethical review over 60 days	1
Number of completed applications over 60 days as a % of total	1.82%
Number of days taken to final decision – average (mean)	36
Number of completed proportionate review applications for ethical review	19
Number of completed proportionate review applications for ethical review over 21 days	2
Number of completed proportionate review applications over 21 days as a % of total	10.53%
Number of SSAs (non-Phase 1) reviewed	8
Number of completed applications for SSA review over 25 days	3
Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs	37.50%
Number of SSAs (Phase 1) reviewed	2
Number of completed applications for SSA review over 14 days	1
Number of completed applications for SSA review over 14 days as % of all Phase 1 SSAs	50.00%
Number of substantial amendments reviewed	181
Number of completed substantial amendments over 35 days	7
Number of completed substantial amendments over 35 days as a % of total substantial amendments	3.87%
Number of modified amendments reviewed	13
Number of completed modified amendments over 14 days	2
Number of completed modified amendments over 14 days as a % of total modified amendments	15.38%
Number of non substantial amendments received	114
Number of substantial amendments received for information	4
Number of substantial amendments received for new sites/PIs	27
Number of annual progress reports received	96
Number of safety reports received	143
Number of Serious Adverse Events received	1
Number of final reports received	20

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
17/LO/0481	Mental Health Profiles of children with congenital visual impairment	27
17/LO/0492	PROTECT: ProTmune in Hematologic Malignancies	39
17/LO/0506	AMELIA	40
17/LO/0566	MS:TSPO study	37
17/LO/0721	IMETAB6	42
17/LO/0779	CheckMate908	45
17/LO/0801	A Factor IX Gene Therapy Study (FIX-GT)	43
17/LO/0812	Treatment with CD19/CD22 CAR redirected T cells for DLBCL- ALEXANDER	42
17/LO/0842	Naso-ethmoidal EEG recording - A pilot study	49
17/LO/0975	Isolation of DMD mesoangioblasts for the development of novel ATIMP	44
17/LO/1019	AFPc332T Cell Therapy in Advanced Hepatocellular Carcinoma (HCC)	40
17/LO/1067	Efficacy & Safety of cryopreserved LV Gene Therapy in ADA-SCID patients	37
17/LO/1069	LV Gene Therapy for Fanconi Anaemia	54
17/LO/1299	Neurobiology of cognitive function	44
17/LO/1323	Differences between Poor and Good responders to bariatric surgery	48
17/LO/1397	A Phase I trial of AST-VAC2 vaccine in patients with NSCLC	52
17/LO/1472	LN-145 in Advanced Cervical Carcinoma	36
17/LO/1496	SOAR Study Intervention v1	31
17/LO/1649	A Phase 3 Gene Replacement Therapy for Spinal Muscular Atrophy Type 1	47
17/LO/1695	BMN 270-301: Gene Therapy Study in Severe Haemophilia A Patients	48
17/LO/1730	Phase I/II study - AUTO4 in patients with T cell non-Hodgkin Lymphoma	69
17/LO/1891	Phase 1b/2a study of WVE-120101 in patients with Huntington's Disease	21
17/LO/1892	Phase 1b/2a study of WVE-120102 in patients with Huntington's Disease	21
17/LO/2060	ZUMA-7	35
17/LO/2110	XPAND trial: Enhancing XP Photoprotection Activities - New Directions	43
18/LO/0009	Tactical	46
18/LO/0020	A trial of cardiac injections of iMP cells during CABG surgery (V1).	46
18/LO/0138	AUTO-LT1 Long Term Follow Up Patients Treated with Autologous T Cells	59
18/LO/0165	POLEM	39
18/LO/0342	EVOLVE 48 (S2356) SYNERGY Stent System	41
18/LO/0493	Physiotherapy assessment for children with brain tumours	39

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
17/LO/1103	Repeat doses of BAY1817080 in healthy males & PoC in chronic cough pts	34
17/LO/1471	LN-144 in Metastatic Melanoma	55
18/LO/0229	Combination therapy with Isatuximab in solid tumour patients	32

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

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
17/LO/0494	A Phase 3 Gene Therapy Study	28
17/LO/1068	CO39303: Ipatasertib+Abiraterone vs Placebo+Abiraterone in mCRPC	23
17/LO/1502	ISIS-443139-CS2 - Open label extension study	26
17/LO/1727	EuroNet-PHL-C2	26
18/LO/0043	Physiological role of kisspeptin in delayed puberty	26
18/LO/0521	GS-LHON-CLIN-05 REFLECT	22

Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock
17/LO/0547	A Phase I trial of AST-VAC2 vaccine in patients with NSCLC	14
17/LO/0807	IMM-101-012 v1.0	29
17/LO/0984	A Phase I trial of AST-VAC2 vaccine in patients with NSCLC	23
17/LO/1027	Clinical comparison of silicone hydrogel monthly lenses (CLL541-P001)	29
17/LO/1269	Phase 1b/2a study of WVE-120101 in patients with Huntington's Disease	30
17/LO/1270	Phase 1b/2a study of WVE-120102 in patients with Huntington's Disease	30
17/LO/1736	Physiological Role of kisspeptin in Puberty	26
17/LO/1796	Diaphragm EMG during caffeine loading in ventilated preterm infants	26
17/LO/2108	GLP-1 and its blockade on post-bariatric surgery hypoglycaemia	30

18/LO/0013	GS-LHON-CLIN-05 REFLECT	26
18/LO/0082	EVOLVE 48 (S2356) SYNERGY™ Stent System	26

Provisional Opinion		
REC Reference	Title	Number of Days on Clock
18/LO/0240	APPLE	n/a
18/LO/0311	Receptor Trafficking in Incretin Action (RETRO study)	n/a
18/LO/0430	PRN1008 – an Oral BTK Inhibitor in Patients with Relapsed ITP	n/a

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

Further information response not complete		
REC Reference	Title	Number of Days on Clock
18/LO/0393	Phase 1 Gene Therapy study of SB-FIX in Severe Haemophilia B	n/a

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

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

Further Information Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
17/LO/0868	Patient specific modelling in mitral valve surgery, version 1.0	14
17/LO/0896	REMATCH study	13
17/LO/1108	QoL in PSC	11
17/LO/1455	Exploring health websites with people with learning disabilities	30
17/LO/1457	RCT of Mechanochemical Ablation versus Cyanoacrylate Adhesive	20
17/LO/1611	BEFORE-MS	21
18/LO/0187	Understanding Anomalies in Primary Care Prescribing Data	20
18/LO/0191	Physiological Predictors of Clinical Outcomes after Antireflux Surgery	23

18/LO/0369	START Foundation Laying	16
18/LO/0522	BATWINgS	21

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

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

Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
17/LO/1606	Biological therapy for pouches	17

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
17/LO/1113	Complex back pain: the follow up	5
17/LO/1460	Developing screening tests to detect chronic kidney disease	14
17/LO/1680	An exploration of how community care staff view "frailty"	7
18/LO/0519	Celebrating Success	16

Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock
17/LO/1604	Automated image analysis	17
17/LO/2044	Evaluating a tablet-based perimetric screening device	17
18/LO/0371	Patient decision-making.	17

Provisional Opinion		
REC Reference	Title	Number of Days on Clock
17/LO/1112	Eating Speed between Lean and Obese using 10S Fork	n/a

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
05/Q0406/178/AM11	Metabonomics and integrative biology for gynaecological cancer	SA#07	15/03/2017	16
06/Q0406/20/AM05	Bacterial products and their effects on the patient. Version 1	3	11/12/2017	25
07/H0707/105/AM20	Quantification of fetal brain growth and development using MRI	SA 14 05/01/2018	05/01/2018	15
07/H0707/139/AM12	Postmortem MR imaging to study the developing brain	9.0	08/11/2017	13
09/H0707/58/AM19	1200.38 BIBW 2992 Glioblastoma Trial	SA18	23/05/2017	16
09/H0707/82/AM15	An investigation of cognitive function in traumatic brain injury.	Version 3 01/09/2017	01/09/2017	34
11/LO/0883/AM06	New sequencing technologies for investigation of Mendelian disease	SA#05	20/03/2017	17
11/LO/1772/AM10	IMM-101-008 Long Term Follow Up Study of Phase I IMM-101-001	9	18/10/2017	29
12/LO/0095/AM13	AI444-046 Observational f'up from BMS-650032/790052 Hepatitis C trials	8	03/11/2017	16
12/LO/0507/AM05	Physiological role of kisspeptin on reproductive hormone release	4	29/11/2017	28
12/LO/0847/AM17	Study to Test a New Drug for Treating Non-small Cell Lung Cancer	Protocol amendment 10	21/10/2016	19
12/LO/1834/AM12	T4 immunotherapy of head and neck cancer	Substantial Amendment 7	08/03/2018	15
12/LO/1955/AM07	Stress and Brain Function	5.0	24/08/2017	17
13/LO/0473/AM05	LUNA Trial - Pasireotide LAR and/or Everolimus in Lung NETs	5	07/11/2016	20
13/LO/1174/AM16	Efficacy study of CTX0E03 injected into the brain of stroke patients	10	25/09/2017	20
13/LO/1489/AM15	Phase 3 study for the treatment of HBeAg-Negative, Chronic Hepatitis B	SA10	23/06/2017	26
13/LO/1490/AM17	TAF vs TDF for the Treatment of HBeAg Positive, Chronic Hepatitis B	SA: 23.6.17	23/06/2017	26
13/LO/1691/AM21	ProCAID	14	16/08/2017	15
14/LO/0056/AM06	PREOB-®-ON3 - A bone cell therapy for hip osteonecrosis	SA#05	30/05/2017	28
14/LO/0056/AM08	PREOB-®-ON3 - A bone cell therapy for hip osteonecrosis	SA 5	27/02/2018	24

14/LO/0227/AM08	LAIV Immuno	Amendment 7	08/08/2016	18
14/LO/0395/AM08	Gene Therapy for WAS follow-up, version 1.0	SA6	10/01/2018	31
14/LO/0592/AM06	Pregnancy in overweight women	SA4	28/09/2017	34
14/LO/0592/AM07	Pregnancy in overweight women	SA 5 - 09/02/18	18/02/2018	15
14/LO/0829/AM03	The Healthy Adolescent Heart Study	03	31/08/2017	15
14/LO/1042/AM12	GO29293 Anti-PDL1 in Bladder Cancer	9	15/09/2017	18
14/LO/1042/AM13	GO29293 Anti-PDL1 in Bladder Cancer	10	12/12/2017	30
14/LO/1197/AM06	Acelarin(NUC-1031) + Carboplatin for recurrent ovarian cancer	SA#05	30/03/2017	26
14/LO/1403/AM03	DEferiprone Evaluation in Paediatrics	SA02	28/07/2017	15
14/LO/1426/AM10	Biomarker Study with T-Vec in Unresected Stage IIIB to IVM1c Melanoma	9	19/12/2017	41
14/LO/1486/AM08	T-Vec with MK-3475 for Treatment of Stage IIIB to IVM1c Melanoma	SA#08	28/04/2017	24
14/LO/1486/AM09	T-Vec with MK-3475 for Treatment of Stage IIIB to IVM1c Melanoma	9	05/07/2017	20
14/LO/1486/AM10	T-Vec with MK-3475 for Treatment of Stage IIIB to IVM1c Melanoma	SA10	31/07/2017	14
14/LO/1486/AM11	T-Vec with MK-3475 for Treatment of Stage IIIB to IVM1c Melanoma	SA11	28/09/2017	16
14/LO/1486/AM14	T-Vec with MK-3475 for Treatment of Stage IIIB to IVM1c Melanoma	12	21/12/2017	39
14/LO/1638/AM04	SEQTOR	3.0	23/11/2017	31
14/LO/1644/AM09	Phase I/II study of gene-modified WT1 TCR therapy in MDS & AML patient	06.07.17	06/07/2017	13
14/LO/1644/AM10	Phase I/II study of gene-modified WT1 TCR therapy in MDS & AML patient	08	22/09/2017	13
14/LO/1798/AM13	GO29294 Anti-PDL1 Bladder Cancer Phase III Version 1.0	11	08/08/2017	23
14/LO/1798/AM14	GO29294 Anti-PDL1 Bladder Cancer Phase III Version 1.0	12	24/11/2017	14
14/LO/2215/AM04	Chlorhexidine Gluconate Chip in Therapy of Peri-implantitis	3	11/12/2017	31
15/LO/0072/AM01	Surgery and Alzheimer's pathology	1	17/10/2017	18
15/LO/0317/AM07	Ph1b study PIM447 with INC424 + LEE011 in patients with myelofibrosis	Protocol amendment 2	03/08/2017	25
15/LO/0317/AM08	Ph1b study PIM447 with INC424 + LEE011 in patients with myelofibrosis	August 2017	15/08/2017	22
15/LO/0342/AM12	Withdrawal Period study of LUM001 in patients with Alagille Syndrome	Amendment 4 28th March 2017	19/05/2017	18

15/LO/0347/AM02	Structural brain abnormalities and hypoxia in sickle cell anaemia	2	17/10/2017	22
15/LO/0444/AM02	RESPI-SAM	SA 2 14th February 2018	14/02/2018	29
15/LO/0448/AM05	JCVU: The RAINFALL Study	Substantial Amendment 3	18/04/2017	19
15/LO/0599/AM05	Phase 1b of MPDL3280A + Obinutuzumab in Follicular and B-cell lymphoma	Substantial Amendment #5	24/03/2017	32
15/LO/0599/AM06	Phase 1b of MPDL3280A + Obinutuzumab in Follicular and B-cell lymphoma	SA5 2018/02/16	16/02/2018	15
15/LO/0605/AM04	1200.120 Phase I monotherapy basket trial of afatinib in children.	Substantial Amendment 4	02/06/2017	25
15/LO/0605/AM05	1200.120 Phase I monotherapy basket trial of afatinib in children.	SA5	02/11/2017	21
15/LO/0618/AM01	CaspaCide TCR $\alpha\beta$ haplo HSCT	1 20/04/2017	12/05/2017	22
15/LO/0618/AM02	CaspaCide TCR $\alpha\beta$ haplo HSCT	SA#02	29/09/2017	14
15/LO/0618/AM03	CaspaCide TCR $\alpha\beta$ haplo HSCT	Substantial Amendment 3, 05	05/03/2018	16
15/LO/0785/AM04	Allogeneic HSCT in CCALD	SA2	16/01/2018	34
15/LO/1079/AM08	A safety and efficacy study of Multistem Cell Therapy for ARDS	7	13/06/2017	19
15/LO/1079/AM09	A safety and efficacy study of Multistem Cell Therapy for ARDS	SA10	30/08/2017	16
15/LO/1308/AM06	RESCUE study	3	28/03/2017	28
15/LO/1309/AM04	REVERSE study	3	28/03/2017	28
15/LO/1379/AM08	REGENERATE (REP1 Gene Replacement Therapy) Trial: Version 1.0	SA7	10/10/2017	13
15/LO/1480/AM04	Holocore	4	21/04/2017	13
15/LO/1481/AM01	Neurokinin 3 Receptor Antagonism for Menopausal Flushes	1	24/01/2018	23
15/LO/1509/AM05	COBALT	3.0	02/09/2016	15
15/LO/1609/AM04	Astroglial activation, β 2-amyloid deposition and neuronal activity	Substantial Amendment 2	16/06/2017	12
15/LO/1677/AM06	Long term follow-up of subjects with CALD treated with Lenti-D	SA#02	05/05/2017	25
15/LO/1677/AM08	Long term follow-up of subjects with CALD treated with Lenti-D	3	01/12/2017	33
15/LO/2045/AM12	SMT C1100 in Ambulatory Boys with DMD	SA10 2018/03/12	12/03/2018	12
15/LO/2124/AM05	METRIC a study in GPNMB over expressing triple negative breast cancer	27.11.17	27/11/2017	18
16/LO/0013/AM05	T-Vec in combination with Pembrolizumab in	Substantial	08/06/2017	20

	recurrent/metastatic SCCHN	Amendment 5		
16/LO/0013/AM06	T-Vec in combination with Pembrolizumab in recurrent/metastatic SCCHN	Substantial Amendment 6	03/08/2017	20
16/LO/0013/AM07	T-Vec in combination with Pembrolizumab in recurrent/metastatic SCCHN	Substantial Amendment 7	24/08/2017	7
16/LO/0013/AM09	T-Vec in combination with Pembrolizumab in recurrent/metastatic SCCHN	SA9	08/02/2018	27
16/LO/0043/AM06	IMCgp100-102 Phase 1 IMCgp100 in patients with Advanced Uveal Melanoma	SA#06	12/05/2017	25
16/LO/0043/AM07	IMCgp100-102 Phase 1 IMCgp100 in patients with Advanced Uveal Melanoma	Substantial Amendment 7	08/06/2017	19
16/LO/0086/AM04	STAR Study	SA03	22/09/2017	12
16/LO/0086/AM06	STAR Study	SA 4 2018/02/09	09/02/2018	18
16/LO/0126/AM04	Gene Therapy Trial for LCA2 OPTIRPE65 (AAV2/5-OPTIRPE65)	3	13/04/2017	13
16/LO/0126/AM05	Gene Therapy Trial for LCA2 OPTIRPE65 (AAV2/5-OPTIRPE65)	4	31/08/2017	15
16/LO/0126/AM07	Gene Therapy Trial for LCA2 OPTIRPE65 (AAV2/5-OPTIRPE65)	SA5 23.02.2018	23/02/2018	17
16/LO/0283/AM05	CARPALL	Amendment #6	15/05/2017	15
16/LO/0440/AM04	UCART19 PALL study (Paediatric Acute Lymphoblastic Leukaemia)	SA#04	27/04/2017	25
16/LO/0440/AM05	UCART19 PALL study (Paediatric Acute Lymphoblastic Leukaemia)	SA5	11/07/2017	14
16/LO/0440/AM06	UCART19 PALL study (Paediatric Acute Lymphoblastic Leukaemia)	SA#06	26/01/2018	17
16/LO/0462/AM02	HGT-MLD-071 Study of HGT-1110 in Patients with MLD	SA - IB update	24/08/2017	12
16/LO/0487/AM04	B4711005 Stem cell transplantation in wet AMD - Safety follow-up Study	1	07/12/2017	35
16/LO/0567/AM04	HARE-40	SA002	24/08/2017	13
16/LO/0648/AM09	Phase 3 Study of Epacadostat and Pembrolizumab in Melanoma	SA#05	03/04/2017	21
16/LO/0648/AM10	Phase 3 Study of Epacadostat and Pembrolizumab in Melanoma	SA06	31/07/2017	15
16/LO/0648/AM12	Phase 3 Study of Epacadostat and Pembrolizumab in Melanoma	SA07 2017/08/22	22/08/2017	9

16/LO/0648/AM13	Phase 3 Study of Epacadostat and Pembrolizumab in Melanoma	08	29/09/2017	14
16/LO/0662/AM03	CALM study: UCART19 in adults with B-cell malignancies	SA#03	27/04/2017	25
16/LO/0662/AM05	CALM study: UCART19 in adults with B-cell malignancies	05	26/06/2017	23
16/LO/0662/AM07	CALM study: UCART19 in adults with B-cell malignancies	7	15/09/2017	33
16/LO/0663/AM05	Long-term follow-up study of patients previously exposed to UCART19	05	23/06/2017	16
16/LO/0831/AM05	CAP-IT	4	01/09/2017	15
16/LO/0831/AM07	CAP-IT	5	01/11/2017	9
16/LO/0877/AM03	Study of Avelumab Plus Best Supportive Care in Urothelial Cancer	Protocol Amendment 3 for B9991	19/12/2016	29
16/LO/0877/AM04	Study of Avelumab Plus Best Supportive Care in Urothelial Cancer	7	31/03/2017	18
16/LO/0877/AM05	Study of Avelumab Plus Best Supportive Care in Urothelial Cancer	SA4	23/06/2017	15
16/LO/0877/AM07	Study of Avelumab Plus Best Supportive Care in Urothelial Cancer	1.0	25/10/2017	28
16/LO/1066/AM03	A Phase 3 Single Arm Gene Therapy Study	SA#03	02/06/2017	29
16/LO/1066/AM04	A Phase 3 Single Arm Gene Therapy Study	3	22/12/2017	61
16/LO/1164/AM01	Patients decision making for primary prevention cardiac devices	1	27/11/2017	30
16/LO/1244/AM04	Study to test Pexa-Vec and Sorafenib vs Sorafenib in Liver Cancer	11/09/2017	11/09/2017	22
16/LO/1244/AM05	Study to test Pexa-Vec and Sorafenib vs Sorafenib in Liver Cancer	02	10/11/2017	24
16/LO/1540/AM02	Gene therapy for Achromatopsia: CNGB3	2	09/10/2017	21
16/LO/1562/AM01	Weight loss surgery for knee pain – a qualitative study V1.0	SA 1 24.11.2017	24/11/2017	23
16/LO/1721/AM04	CARD	4	09/08/2017	19
16/LO/1766/AM02	To assess the effects of inhaled RPL554 in adults with cystic fibrosis	SA#02	30/05/2017	17
16/LO/1766/AM03	To assess the effects of inhaled RPL554 in adults with cystic fibrosis	Substantial Amendment 3 2017/0	23/08/2017	7
16/LO/1788/AM01	Uterine Protection in Lynch Syndrome (UP study)	1	13/04/2017	14
16/LO/1800/AM04	Epilepsy: TSPO imaging	SA#1	18/07/2017	7

16/LO/1941/AM01	Synaptic and neural function	SA1	06/06/2017	26
16/LO/1948/AM01	Cell shape recognition technology	1	03/09/2017	15
16/LO/1981/AM03	ADIPOA 2	SA 01 2018/01/11	11/01/2018	25
16/LO/2005/AM01	SP017 (EudraCT number 2016-000567-16)	SA02	03/10/2017	12
16/LO/2008/AM07	Phase I/II study evaluating AUTO2 in patients with multiple myeloma V1	SA 4 19/12/2017	19/12/2017	24
16/LO/2008/AM08	Phase I/II study evaluating AUTO2 in patients with multiple myeloma V1	Substantial Amendment 5.0:	30/01/2018	15
17/LO/0001/AM02	A safety and dose finding study of DTX301 in late onset OTC deficiency	SA01	11/07/2017	14
17/LO/0001/AM03	A safety and dose finding study of DTX301 in late onset OTC deficiency	3	28/11/2017	36
17/LO/0002/AM01	Inflammation and brain function	SA#01	26/04/2017	12
17/LO/0002/AM02	Inflammation and brain function	2.0	11/11/2017	14
17/LO/0020/AM01	Gene Therapy for XLRP RPGR	SA#01	05/05/2017	12
17/LO/0020/AM02	Gene Therapy for XLRP RPGR	SA#02	25/05/2017	16
17/LO/0020/AM03	Gene Therapy for XLRP RPGR	3	13/11/2017	29
17/LO/0020/AM04	Gene Therapy for XLRP RPGR	SA04 2018/02/27	27/02/2018	12
17/LO/0034/AM01	GenScan II	1	27/06/2017	22
17/LO/0048/AM01	MAGE-A10c796T for advanced NSCLC	SA1	10/05/2017	19
17/LO/0048/AM03	MAGE-A10c796T for advanced NSCLC	2	20/12/2017	67
17/LO/0048/AM04	MAGE-A10c796T for advanced NSCLC	SA03 2018/02/26	26/02/2018	9
17/LO/0117/AM02	ALLCAR19	1	06/12/2017	28
17/LO/0126/AM02	Ursodeoxycholic acid and gut hormone response	SA1	06/10/2017	14
17/LO/0152/AM01	COSMOS: The metabolic response to major surgery	1	23/10/2017	16
17/LO/0415/AM01	The Community Lung Health Study	SA#01	07/04/2017	13
17/LO/0415/AM02	The Community Lung Health Study	SA2	16/01/2018	27
17/LO/0425/AM02	Tumour Biopsy Driven Tx of Metastatic Carcinoma of Head and Neck	SA#1	30/06/2017	12
17/LO/0427/AM01	N3	SA#01	01/06/2017	15
17/LO/0447/AM04	LIGHT-UP: Loss of weight in prediabetes and type 2 diabetes	2	25/01/2018	33
17/LO/0494/AM01	A Phase 3 Gene Therapy Study	SA - IMPD 2017/10/01	01/10/2017	16
17/LO/0506/AM02	AMELIA	1	24/10/2017	15
17/LO/0506/AM03	AMELIA	SA 2 2/2/2018	02/02/2018	16
17/LO/0566/AM01	MS:TSPO study	1	24/11/2017	12

17/LO/0779/AM01	CheckMate908	SA 1 2017/11/09	09/09/2017	8
17/LO/0801/AM01	A Factor IX Gene Therapy Study (FIX-GT)	SA1	05/10/2017	18
17/LO/1019/AM02	AFPc332T Cell Therapy in Advanced Hepatocellular Carcinoma (HCC)	Substantial Amendment 1	08/03/2018	14
17/LO/1067/AM01	Efficacy & Safety of cryopreserved LV Gene Therapy in ADA-SCID patients	Substantial Amendment 1	20/12/2017	21
17/LO/1067/AM02	Efficacy & Safety of cryopreserved LV Gene Therapy in ADA-SCID patients	Substantial Amendment 2	23/02/2018	18
17/LO/1067/AM03	Efficacy & Safety of cryopreserved LV Gene Therapy in ADA-SCID patients	SA 3, Version 1	27/03/2018	4
17/LO/1068/AM01	CO39303: Ipatasertib+Abiraterone vs Placebo+Abiraterone in mCRPC	1	30/08/2017	20
17/LO/1068/AM05	CO39303: Ipatasertib+Abiraterone vs Placebo+Abiraterone in mCRPC	5	30/01/2018	16
17/LO/1103/AM01	Repeat doses of BAY1817080 in healthy males & PoC in chronic cough pts	SA1	24/01/2018	19
17/LO/1103/AM03	Repeat doses of BAY1817080 in healthy males & PoC in chronic cough pts	2	06/03/2018	33
17/LO/1471/AM02	LN-144 in Metastatic Melanoma	2	06/12/2017	28
17/LO/1502/AM01	ISIS-443139-CS2 - Open label extension study	Protocol Amendment 2 2018/01/3	30/01/2018	31
17/LO/1695/AM01	BMN 270-301: Gene Therapy Study in Severe Haemophilia A Patients	Substantial Amendment 1	09/03/2018	14
GTAC128/AM12	WT1 TCR Gene Therapy for Leukaemia: A Phase I/II Safety and Toxicity St	06.07.17	06/07/2017	13
GTAC128/AM13	WT1 TCR Gene Therapy for Leukaemia: A Phase I/II Safety and Toxicity St	14	13/10/2017	21
GTAC146/AM10	Phase I/II clinical trial of haematopoietic stem cell gene therapy for the Wiskott-Aldrich Syndrome	SA10	16/01/2018	27
GTAC178/AM20	LV Gene Therapy for ADA Deficiency	SA#14	09/06/2017	16
GTAC178/AM21	LV Gene Therapy for ADA Deficiency	15	30/06/2017	19
GTAC178/AM22	LV Gene Therapy for ADA Deficiency	16	20/12/2017	39
GTAC178/AM23	LV Gene Therapy for ADA Deficiency	Substantial Amendment no 17	26/02/2018	17
GTAC187/AM12	Lenti-D ALD-102 (Version 2; Dated 30 January 2012)	7	27/11/2017	30

GTAC190/AM07	Pre-Operative JX-594	6	17/08/2017	16
GTAC194/AM06	B4711001 Stem cell transplantation in wet AMD	6	07/12/2017	35

Unfavourable opinion				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
08/H0707/21/AM11	Obstetric Cholestasis Research Study	6	11/08/2017	15
13/LO/1860/AM12	LUM001 in paediatric patients with cholestasis	SA4	04/04/2017	14
14/LO/0722/AM11	RegenVOX: Clinical trial of voicebox implants using tissue engineering	9	31/10/2017	21
15/LO/0519/AM05	AI438-047: Attachment inhibitor study in HTE patients with MDR HIV-1	Substantial Amendment 04	30/03/2017	20
15/LO/2045/AM08	SMT C1100 in Ambulatory Boys with DMD	SA#08	14/07/2017	13
16/LO/0043/AM08	IMCgp100-102 Phase 1 IMCgp100 in patients with Advanced Uveal Melanoma	SA8	26/01/2018	18
16/LO/0648/AM16	Phase 3 Study of Epacadostat and Pembrolizumab in Melanoma	SA10 2018/02/20	20/02/2018	33
16/LO/0662/AM04	CALM study: UCART19 in adults with B-cell malignancies	SA#04	16/05/2017	27
16/LO/1558/AM03	SHAREHD	SA02	12/07/2017	8
16/LO/1558/AM05	SHAREHD	AM03 15-FEB-18	15/02/2018	18
16/LO/1941/AM02	Synaptic and neural function	SA 2 29/11/2017	29/11/2017	18
17/LO/0425/AM03	Tumour Biopsy Driven Tx of Metastatic Carcinoma of Head and Neck	2	21/12/2017	43
17/LO/1472/AM03	LN-145 in Advanced Cervical Carcinoma	2	06/12/2017	29
17/LO/2110/AM01	XPAND trial: Enhancing XP Photoprotection Activities - New Directions	SA1 1 22/02/2018	22/02/2018	14
2004/6745/AM07	A PET study of brain dopamine in the early phase of psychosis	16	07/06/2017	6

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

Favourable opinion timeline				
Amendment REC	Title	Version	Date	Number of Days on

Reference				Clock
08/H0707/21/AM11/1	Obstetric Cholestasis Research Study	6	28/09/2017	14
13/LO/1860/AM12/1	LUM001 in paediatric patients with cholestasis	Modified amendment 09.05.2017	08/05/2017	9
15/LO/0519/AM05/1	AI438-047: Attachment inhibitor study in HTE patients with MDR HIV-1	Modified amendment	18/05/2017	19
15/LO/0681/AM09/1	ISIS-443139-CS1	Protocol Amendment 3 (modified)	25/05/2017	14
15/LO/2045/AM07/1	SMT C1100 in Ambulatory Boys with DMD	Modified SA07	16/05/2017	14
15/LO/2045/AM08/1	SMT C1100 in Ambulatory Boys with DMD	Modified SA08	11/08/2017	14
16/LO/0043/AM08/1	IMCgp100-102 Phase 1 IMCgp100 in patients with Advanced Uveal Melanoma	Modified Amendment SA8	07/03/2018	7
16/LO/0662/AM04/1	CALM study: UCART19 in adults with B-cell malignancies	SA#4	16/05/2017	12
16/LO/1558/AM03/1	SHAREHD	Modified Amendment AM02	02/08/2017	14
16/LO/1558/AM05/1	SHAREHD	Modified AM03 07-MAR-18	07/03/2018	11
17/LO/0425/AM03/1	Tumour Biopsy Driven Tx of Metastatic Carcinoma of Head and Neck	Modified Amendment 2018/03/27	27/03/2018	4
17/LO/1472/AM03/1	LN-145 in Advanced Cervical Carcinoma	SA2Mod1	24/01/2018	23
2004/6745/AM07/1	A PET study of brain dopamine in the early phase of psychosis	Modified Amendment 17	17/12/2017	13

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
17/LO/1730	Phase I/II study - AUTO4 in patients with T cell non-Hodgkin Lymphoma	69

Proportionate review applications for ethical review over 21 day timeline

REC Reference	Title	Number of Days on Clock
17/LO/1455	Exploring health websites with people with learning disabilities	30
18/LO/0191	Physiological Predictors of Clinical Outcomes after Antireflux Surgery	23

SSAs (non Phase 1) over 25 day timeline

REC Reference	Title	Number of Days on Clock
17/LO/2148	ISIS-443139-CS2 - Open label extension study	29
17/LO/2158	SOAR Study Intervention v1.1	41
18/LO/0269	ISIS-443139-CS2Open-Label Extension Study	33

SSAs (Phase 1) over 14 day timeline

REC Reference	Title	Number of Days on Clock
18/LO/0280	Repeat doses of BAY1817080 in healthy males & PoC in chronic cough pts	17

Substantial Amendments over 35 day timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
14/LO/1426/AM10	Biomarker Study with T-Vec in Unresected Stage IIIB to IVM1c Melanoma	9	19/12/2017	41
14/LO/1486/AM14	T-Vec with MK-3475 for Treatment of Stage IIIB to IVM1c Melanoma	12	21/12/2017	39
16/LO/1066/AM04	A Phase 3 Single Arm Gene Therapy Study	3	22/12/2017	61
17/LO/0001/AM03	A safety and dose finding study of DTX301 in late onset OTC deficiency	3	28/11/2017	36

17/LO/0048/AM03	MAGE-A10c796T for advanced NSCLC	2	20/12/2017	67
17/LO/0425/AM03	Tumour Biopsy Driven Tx of Metastatic Carcinoma of Head and Neck	2	21/12/2017	43
GTAC178/AM22	LV Gene Therapy for ADA Deficiency	16	20/12/2017	39

Modified Amendments over 14 day timeline				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
15/LO/0519/AM05/1	AI438-047: Attachment inhibitor study in HTE patients with MDR HIV-1	Modified amendment	18/05/2017	19
17/LO/1472/AM03/1	LN-145 in Advanced Cervical Carcinoma	SA2Mod1	24/01/2018	23