

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

Annual Report

01 April 2015 - 31 March 2016



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 III
Type of Flag:	Gene Therapy or Stem Cell Clinical Trials Phase I studies in Healthy Volunteers, Phase I studies in Patients Research Involving Children
Chair:	Dr Catherine Urch
Vice-Chair:	Professor Gary Frost until 31 st December 2015 Vacant position from 1 st January 2016
Alternate Vice-Chair:	Dr Fraser Macfarlane
REC Manager:	Miss Andrea Graham
REC Assistant:	Tad Jones from 15 th December 2015 Vacant position from 1.4.15 to 15 th December 2015
Committee Address:	Nottingham REC Centre The Old Chapel Royal Standard Place NG1 6FS
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Chair's overview of the past year:

Reading this report of the year has emphasized again just how busy the REC has been. My thanks goes to the dedication and hard work that goes into the ethical review process from our managers and administrative team who are as always outstanding to my co-volunteers who spend many happy hours reading and re-reading applications. The committee has changed over the year as we said goodbye to some and a welcome hello to others. However the ethos of robust discussion, open thinking, pertinent observation and humour helps to make the meetings intellectually stimulating, fun and useful for applicants. As in previous years researchers return to us and some have been gracious enough to email us with their thanks. The proportion of GTAC studies continues to grow and the whole committee is now very versed in gene manipulation and ethical issues. But as always our thanks to our experts and the expert committee for their views.

We are looking forward to the new integrated system for all applications and hoping this enables and supports our research colleagues. HARP whilst it has its own little quirks is proving to be useful and saves many trees!

All that remains is to voice my thanks to the whole REC committee past and present, and all our thanks to our amazing administrator in Andrea who manages the process, applications and us all with charm and efficiency. Thank you.

Dr Katie Urch

London - West London & GTAC Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Ted Barker	Reader in Developmental Psychopathology	Lay Plus	01/01/2016	
Mr Arden Bhattacharya	Independent Barrister	Lay Plus	15/05/2013	14/03/2016
Mr Ron Driver	Retired Lecturer/Statistician	Lay	01/12/2014	
Miss Gayle D'Souza	Senior Trials Coordinator	Expert	01/04/2015	
Professor Gary Frost	Chair in Nutrition and Dietetics	Expert	23/09/2009	01/12/2015
Professor Uta Griesenbach	Professor of Molecular Medicine	Expert	30/09/2013	
Ms Victoria Latham	Lead Pharmacist Clinical Trials & Pharmacovigilance	Expert	23/07/2008	
Professor David Lewis	Principal Investigator – Clinical Trials Unit Imperial College	Expert	19/08/2014	17/06/2015
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	Medicolegal Advisor	Expert	10/06/2013	
Ms Alison Simcock	Lay Member	Lay	30/09/2013	20/09/2015
Mr Roy Sinclair	Pharmacist	Lay	01/09/2015	
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 date attended
None			

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

Name	Profession	Status	Meeting date attended
Mr David Grayson	Retired Local Government Administrator	Lay Plus	17 th June 2016
Dr John Keen	GP	Expert	20 th May 2015

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

Name	Declaration of Interest	Date
Ted Barker	Reader of developmental Psychopathology at Kings College London	17/02/2016
Mr Ron Driver	None Declared	16/03/2016
Miss Gayle D'Souza	Senior Trials Coordinator at UCLH Involvement with R&D CRO - medpace	01/04/2015
Ms Victoria Latham	Lead Pharmacist for Clinical Trials for Imperial College Healthcare Trust.	14/12/2015
Ms Cinead Eileen O'Sullivan	None declared	16/03/2016
Dr Roger David Palmer	None declared	16/12/2015
Mr Roy Sinclair	None declared	16/03/2016
Miss Ravinder Summan	Bank Research Nurse at Immanova	16/12/2015
Dr Catherine Urch	PI on Service delivery transformation project with Macmillan. CI Applicant; NIHR grant in progress	16/03/2016
Professor Uta Griesenback	Professor of Molecular Medicine at Imperial College and involved in Research and Development. Member of several care review bodies and involved in reviewing grant applications, peer reviewer for numerous scientific journals.	16/03/2016
Dr Fraser Macfarlane	None declared	16/03/2016

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

Month	Date	Number of Members Present at Meeting
April	15/04/2015	10
May	20/05/2015	11
June	17/06/2015	9
August	19/08/2015	8
September	16/09/2015	11
October	21/10/2015	11
December	16/12/2015	9
January	20/01/2016	9
February	17/02/2016	11
March	16/03/2016	9

10 full committee meetings were held during the reporting period.

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

Month	Date	Number of Members Present at Meeting
October	21/10/2015	4
January	20/01/2016	3
February	17/02/2016	3
March	16/03/2016	3

4 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	02/04/2015	2
April	16/04/2015	2
April	30/04/2015	2
May	14/05/2015	2
May	14/05/2015	2
May	28/05/2015	2
June	11/06/2015	2
June	25/06/2015	2
July	09/07/2015	2
July	23/07/2015	2
August	06/08/2015	2
August	20/08/2015	2
September	03/09/2015	2
September	17/09/2015	2
October	01/10/2015	2
October	15/10/2015	2
October	29/10/2015	2

November	12/11/2015	2
November	26/11/2015	2
December	10/12/2015	2
December	30/12/2015	2
January	14/01/2016	2
January	28/01/2016	2
February	11/02/2016	2
February	25/02/2016	2
March	10/03/2016	2
March	24/03/2016	2

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

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

Date	Reason	Action taken
None		

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

Name	Number of Meetings Attended
Ted Barker	2
Mr Arden Bhattacharya	5
Mr Ron Driver	10
Miss Gayle D'Souza	7
Professor Gary Frost	4
Professor Uta Griesenbach	7
Ms Victoria Latham	7
Professor David Lewis	2
Dr Elizabeth Lund	8
Dr Fraser Macfarlane	7
Ms Cinead Eileen O'Sullivan	7
Dr Roger David Palmer	9
Mr Roy Sinclair	4
Miss Ravinder Summan	8
Dr Catherine Urch	9

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

Name	Number of Meetings Attended
Miss Gayle D'Souza	1
Dr Elizabeth Lund	4
Dr Roger David Palmer	2
Mr Roy Sinclair	4
Miss Ravinder Summan	1
Dr Catherine Urch	1

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

Name	Number of Meetings Attended
Mr Ron Driver	7
Professor Gary Frost	3
Professor Uta Griesenbach	3
Dr Fraser Macfarlane	10
Ms Cinead Eileen O'Sullivan	4
Dr Catherine Urch	27

Training 01 April 2015 - 31 March 2016

Name of Member	Date	Event(s) attended
Dr Fraser Macfarlane	15/07/2015	Good research Practice
Dr Fraser Macfarlane	16/07/2015	Research Data and Confidentiality e-learning course
Dr Fraser Macfarlane	16/07/2015	Research and Human Tissue Legislation
Dr Roger David Palmer	15/06/2015	Equality and Diversity (e-learning module)
Dr Roger David Palmer	13/01/2016	Assessing the consequences (benefits and harm) of research
Ms Alison Simcock	07/04/2015	Equality and Diversity (e-learning)
Mr Roy Sinclair	25/09/2015	Genetic and Genomic Research
Miss Ravinder Summan	24/09/2015	Members Induction
Dr Catherine Urch	27/11/2015	CTIMP Training Day
Dr Catherine Urch	09/12/2015	National Chairs Training Day
Cinead O'Sullivan	01/03/2016	IRAS Training Module
Cinead O'Sullivan	01/03/2016	MRC Research data and confidentiality (online training)

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	20	34.48
Phase 1	2	3.45
Gene Therapy	16	27.59
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	1	1.72
Others	19	32.76
Total Applications Reviewed	58	100

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

Number of applications made invalid by the REC Manager	1
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	7
Number of paediatric applications reviewed	18
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	1	1.72
Favourable Opinion with Additional Conditions	6	10.34
Unfavourable Opinion	6	10.34
Provisional Opinion	45	77.59
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	58	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	39	67.24
Further Information Favourable Opinion with Additional Conditions	3	5.17
Further Information Unfavourable Opinion	1	1.72
Favourable Opinion with Standard Conditions	1	1.72
Favourable Opinion with Additional Conditions	6	10.34
Unfavourable Opinion	6	10.34
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	3.45
Total	58	100

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

Total Applications Reviewed	7
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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	3
Number of paediatric applications reviewed	1
Number of device applications reviewed	0
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	0	0.00
Favourable Opinion with Additional Conditions	2	28.57
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	3	42.86
Unfavourable Opinion	2	28.57
Total	7	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	5.80
Number of completed applications for full ethical review	56
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	7
Number of completed applications over 40 days as a % of total	12.07%
Number of days taken to final decision – average (mean)	29
Number of completed proportionate review applications for ethical review	7
Number of completed proportionate review applications for ethical review over 14 days	0
Number of completed proportionate review applications over 14 days as a % of total	0.00%
Number of SSAs (non-Phase 1) reviewed	2
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	1
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	162
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	1
Number of completed substantial amendments over 28 days as a % of total substantial amendments	0.62%
Number of modified amendments reviewed	17
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	123
Number of substantial amendments received for information	1
Number of substantial amendments received for new sites/Pis	24
Number of annual progress reports received	147

Number of safety reports received	86
Number of Serious Adverse Events received	0
Number of final reports received	26

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/0519	AI438-047: Attachment inhibitor study in HTE patients with MDR HIV-1	31
15/LO/0598	PAVMs, exercise, and airflow obstruction	24
15/LO/0599	Phase 1b of MPDL3280A + Obinutuzumab in Follicular and B-cell lymphoma	32
15/LO/0605	1200.120 Phase I monotherapy basket trial of afatinib in children.	48
15/LO/0618	CaspaCide TCR $\alpha\beta$ haplo HSCT	35
15/LO/0681	ISIS-443139-CS1	22
15/LO/0780	GRAVITAS	26
15/LO/0813	LONG LIMB	29
15/LO/0814	Effects of AZD7325 on cutaneous sensation	25
15/LO/0898	Extension HGT1410 Study in Pediatric Patients with Early Stage MPS IIIA	26
15/LO/0920	SMTC11004 - Phase 1 study in healthy volunteers and DMD patients	32
15/LO/1000	GABA-B function in alcohol dependence	26
15/LO/1011	Oral sodium bicarbonate supplementation in haemodialysis patients	23
15/LO/1079	A safety and efficacy study of Multistem Cell Therapy for ARDS	25
15/LO/1266	IMPACT	27
15/LO/1277	UCH Preterm Infection Project	23
15/LO/1308	RESCUE study	27
15/LO/1309	REVERSE study	27
15/LO/1379	REGENERATE (REP1 Gene Replacement Therapy) Trial: Version 1.0	22
15/LO/1480	Holocore	34
15/LO/1481	Neurokinin 3 Receptor Antagonism for Menopausal Flushes	22
15/LO/1509	COBALT	36
15/LO/1510	A Phase I trial of anti-GD2 CAR transduced T-cells (1RG-CART) v1.	28
15/LO/1609	Astroglial activation, β -amyloid deposition and neuronal activity	24
15/LO/1677	Long term follow-up of subjects with CCALD treated with Lenti-D	29
15/LO/2045	SMT C1100 in Ambulatory Boys with DMD	29
15/LO/2124	METRIC a study in GPNMB over expressing triple negative breast cancer	29
15/LO/2129	Testagen α , ϕ Dose Ranging D1-09-13	55
15/LO/2131	Role of ambulatory oxygen in improving the effectiveness of PR in COPD	30
15/LO/2165	Testagen α , ϕ Transference T1-09-13	34
16/LO/0013	T-Vec in combination with Pembrolizumab in recurrent/metastatic SCCHN	47
16/LO/0043	IMCgp100-102 Phase 1 IMCgp100 in patients with Advanced Uveal Melanoma	31

16/LO/0084	Comparison of two CPAP systems v0.1	25
16/LO/0086	STAR Study	30
16/LO/0155	MHCYP 2016 v1	42
16/LO/0283	CARPALL	42
16/LO/0391	Physiological Studies of Hormonal Control of Metabolism & Reproduction	42
16/LO/0462	HGT-MLD-071 Study of HGT-1110 in Patients with MLD	27

Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/LO/1028	Glutamate and cognitive function	24
16/LO/0126	Gene Therapy Trial for LCA2 OPTIRPE65 (AAV2/5-OPTIRPE65)	34
16/LO/0261	MBCT206 A Phase IIa, two-part, randomised, study for adults with COPD	37

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/0665	LENTICOL-F	22

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/LO/0581	CLFX453X2201	23
15/LO/0785	Allogeneic HSCT in CCALD	22
15/LO/0852	Impact of care transition on medication adherence in cardiac patients	22
15/LO/1482	Tiagabine challenge [11C]-Ro15 4513 PET in Alcohol Dependence	21
16/LO/0079	HepFree sub-study version 1	21
16/LO/0130	Investigating the role of glutamate in brain function	23

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
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15/LO/1467	NUC-3373 in Advanced Solid Tumours	20
15/LO/1606	An Information Registry About Patients With Multiple Sclerosis	21
16/LO/0048	CCSJ137X2201	21
16/LO/0081	Cardiac Risk in the Young Research	21
16/LO/0132	Extension Study for SMA patients who participated in ISIS396443 study	23
16/LO/0437	Efficacy of ENTEROSGEL in managing acute atopic skin conditions	21

Provisional Opinion

REC Reference	Title	Number of Days on Clock
16/LO/0421	ELAD for treatment of alcohol induced liver decompensation (VTL-308)	n/a
16/LO/0440	UCART19 PALL study (Paediatric Acute Lymphoblastic Leukaemia)	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
15/LO/1269	Enhanced, Personalized and Integrated Care for Infection Management	20
15/LO/1498	Belonarib Efficacy, Safety and Tolerability in Prader-Willi Syndrome	20

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/0386	Measuring user and carer involvement in physical health care planning	8
16/LO/0511	The Psychological Impact of Joint Hypermobility	12

16/LO/0518	The impact of polytrauma in children at least one year post injury	9
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Further Information Favourable Opinion with Additional Conditions

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

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

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

REC Reference	Title	Number of Days on Clock
15/LO/1895	EPOD, version 1	7
16/LO/0215	Does frailty help predict postoperative outcomes in cardiac surgery?	8

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
15/LO/1896	Lutonix Global BTK Registry - CL0024-01_v1-04Aug2015	10
16/LO/0381	Evaluating the headache pathway	9

Provisional Opinion

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

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

REC Reference	Title	Number of Days on Clock
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Table 10.1: Breakdown of current status of all substantial amendments reviewed within the reporting period

Favourable opinion				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
04/Q0406/151/AM04	Physiological role of kisspeptin-54 on reproductive hormone secretion	SA2	15/06/2015	9
05/Q0406/178/AM10	Metabonomics and integrative biology for gynaecological cancer	SA6	19/10/2015	21
05/Q0803/57/AM08	Role of antioxidant therapy in preventing diabetic kidney disease	SA7	03/11/2015	20
07/H0707/105/AM15	Quantification of fetal brain growth and development using MRI	SA11	01/10/2015	10
08/H0803/154/AM02	Cell senescence and melanoma progression Ver. 1	SA2	02/10/2015	20
09/H0707/38/AM11	IDEAL-CRT	SA 20-07-2015	30/10/2015	20
09/H0707/58/AM16	1200.38 BIBW 2992 Glioblastoma Trial	Amendment 15	31/07/2015	16
09/H0707/67/AM04	Borderline Ovarian Tumours Study	SA4	18/02/2015	16
09/H0707/82/AM10	An investigation of cognitive function in traumatic brain injury.	SA 2.6f	28/04/2015	21
09/H0707/82/AM11	An investigation of cognitive function in traumatic brain injury.	30/11/2015	30/11/2015	22
09/H0707/98/AM14	Evaluation of preterm images (ePrime).	SA9	29/04/2015	20
10/H0707/2/AM06	The use of the hormone kisspeptin in IVF treatment	03	01/02/2015	12
10/H0707/98/AM05	MRgFUS prostate:feasibility study	Protocol version 3	20/07/2015	11
10/H0803/161/AM02	A foundation for the oral microbiome and metagenome	SA#02	18/01/2016	21
11/LO/0082/AM18	Study of Pomalidomide in Subjects with Multiple Myeloma	SA: IB v21, PIS/CF v6.2	07/10/2015	19
11/LO/0082/AM19	Study of Pomalidomide in Subjects with Multiple Myeloma	SA dated 7.1.16	07/01/2016	12
11/LO/1500/AM08	NITRITE-AMI	SA#06	15/03/2016	7
11/LO/1538/AM06	COMPARE study: COMparing treatment options for ProstAte canceR	SA3	13/05/2015	8
11/LO/1733/AM11	Blinatumomab (MT103) in adult patients with relapsed/refractory ALL	09	31/03/2015	18
11/LO/1772/AM09	IMM-101-008 Long Term Follow Up Study of Phase I IMM-101-001	SA8	16/06/2015	15
11/LO/1861/AM06	Catheter Contact Force and Electrogram Characteristics	SA6	20/04/2015	9
12/LO/0004/AM04	Drug Lung Deposition In COPD	SA2	07/08/2015	9
12/LO/0095/AM08	A1444-046 Observational f'up from BMS-650032/790052 Hepatitis C trials	EC05	10/08/2015	22

12/LO/0191/AM12	Rollover Study: GSK2118436 Continued Treatment for BRAF+ Tumours	08/12/2015	08/12/2015	14
12/LO/0443/AM10	Vemurafenib in patients with BRAF V600 mutation-positive cancers	SA 1.4.15	01/04/2015	14
12/LO/0443/AM11	Vemurafenib in patients with BRAF V600 mutation-positive cancers	SA9	29/04/2015	22
12/LO/0507/AM01	Physiological role of kisspeptin on reproductive hormone release	SA#01	17/03/2016	12
12/LO/0845/AM23	Study of Carfilzomib with Dexamethasone vs Velcade with Dexamethasone	SA16	09/06/2015	8
12/LO/0845/AM24	Study of Carfilzomib with Dexamethasone vs Velcade with Dexamethasone	SA17	22/07/2015	9
12/LO/0845/AM25	Study of Carfilzomib with Dexamethasone vs Velcade with Dexamethasone	18	17/12/2015	22
12/LO/1132/AM05	Hepatitis B vaccination in infants (version 1.1)	SA dated 20.7.15	20/07/2015	9
12/LO/1247/AM06	Investigating Preterm brain development with functional MRI (v1)	SA3	01/10/2015	7
12/LO/1834/AM07	T4 immunotherapy of head and neck cancer	SA 8.10.15	08/10/2015	24
12/LO/2039/AM05	ASTRO-LAB study	SA4	15/10/2015	17
13/LO/0039/AM07	DAWN PCI-32765FLR2002	SA4	14/09/2015	12
13/LO/0039/AM08	DAWN PCI-32765FLR2002	SA#07	05/01/2016	14
13/LO/0682/AM04	Imaging inflammation in tumours	Amendment 4	17/07/2015	14
13/LO/0684/AM02	Who will relapse into depression following Step 2 IAPT intervention?	1	26/03/2015	19
13/LO/0733/AM18	AGS-003 Plus Standard Treatment in Advanced RCC (ADAPT)	SA013	16/02/2016	6
13/LO/1141/AM04	GRIPHON OL/Protocol AC-065A303	Global amendment 4	26/03/2015	14
13/LO/1174/AM07	Efficacy study of CTX0E03 injected into the brain of stroke patients	SA6	20/04/2015	17
13/LO/1174/AM10	Efficacy study of CTX0E03 injected into the brain of stroke patients	SA8	13/03/2016	6
13/LO/1224/AM04	PSILODEP-pilot	13HH0762	19/10/2015	14
13/LO/1308/AM04	Treatment Intensities and Targets in Rheumatoid Arthritis Therapy RCT	03	13/04/2015	7
13/LO/1489/AM06	Phase 3 study for the treatment of HBeAg-Negative, Chronic Hepatitis B	SA5	20/04/2015	17

13/LO/1489/AM07	Phase 3 study for the treatment of HBeAg-Negative, Chronic Hepatitis B	SA6	11/06/2015	20
13/LO/1489/AM10	Phase 3 study for the treatment of HBeAg-Negative, Chronic Hepatitis B	SA7	11/03/2016	15
13/LO/1490/AM07	TAF vs TDF for the Treatment of HBeAg Positive, Chronic Hepatitis B	SA5	20/04/2015	17
13/LO/1490/AM08	TAF vs TDF for the Treatment of HBeAg Positive, Chronic Hepatitis B	SA6	11/06/2015	20
13/LO/1490/AM12	TAF vs TDF for the Treatment of HBeAg Positive, Chronic Hepatitis B	SA7	11/03/2016	15
13/LO/1510/AM03	Do gut hormones mediate the beneficial effects of Roux-en-Y bypass?	SA4	14/05/2015	21
13/LO/1510/AM04	Do gut hormones mediate the beneficial effects of Roux-en-Y bypass?	SA5	02/10/2015	19
13/LO/1510/AM05	Do gut hormones mediate the beneficial effects of Roux-en-Y bypass?	6.0	01/12/2015	20
13/LO/1654/AM02	FOCUS Study	SA2	15/11/2015	17
13/LO/1691/AM07	ProCAID	SA4	28/04/2015	14
13/LO/1691/AM13	ProCAID	SA8	01/03/2016	7
13/LO/1694/AM08	HGT-1410 in Pediatric Patients with Early Stage MPS IIIA	SA7	26/05/2015	16
13/LO/1860/AM05	LUM001 in paediatric patients with cholestasis	07/12/2015	07/12/2015	15
13/LO/1860/AM06	LUM001 in paediatric patients with cholestasis	SA#03	28/01/2016	27
14/LO/0056/AM03	PREOBA®-ON3 - A bone cell therapy for hip osteonecrosis	SA2	11/01/2016	19
14/LO/0227/AM03	LAIV Immuno	Amendment 6	22/05/2015	15
14/LO/0227/AM04	LAIV Immuno	SA7	21/07/2015	21
14/LO/0227/AM05	LAIV Immuno	SA protocol 8	11/01/2016	14
14/LO/0592/AM01	Pregnancy in overweight women	SA1	03/09/2015	19
14/LO/0679/AM01	Androgens and adipose tissue	Amendment 1	13/07/2015	16
14/LO/0722/AM04	RegenVOX: Clinical trial of voicebox implants using tissue engineering	3.0	16/12/2015	32
14/LO/0824/AM06	Phase 1B and 1C Clinical trials of PP1420	Amendment 5	04/06/2015	13
14/LO/0824/AM07	Phase 1B and 1C Clinical trials of PP1420	SA#07	12/01/2016	12
14/LO/0862/AM04	Health Survey for England 2015	SA3	16/07/2015	15
14/LO/1042/AM05	GO29293 Anti-PDL1 in Bladder Cancer	Amendment 3	02/06/2015	15
14/LO/1042/AM07	GO29293 Anti-PDL1 in Bladder Cancer	SA4	13/11/2015	24
14/LO/1042/AM08	GO29293 Anti-PDL1 in Bladder Cancer	6.0	06/01/2016	19

14/LO/1197/AM02	Acelarin(NUC-1031) + Carboplatin for recurrent ovarian cancer	SA2	25/06/2015	15
14/LO/1197/AM03	Acelarin(NUC-1031) + Carboplatin for recurrent ovarian cancer	SA3	24/09/2015	13
14/LO/1197/AM04	Acelarin(NUC-1031) + Carboplatin for recurrent ovarian cancer	4.0	02/12/2015	19
14/LO/1403/AM02	DEferiprone Evaluation in Paediatrics	1	28/05/2015	14
14/LO/1426/AM03	Biomarker Study with T-Vec in Unresected Stage IIIB to IVM1c Melanoma	3	13/04/2015	7
14/LO/1426/AM05	Biomarker Study with T-Vec in Unresected Stage IIIB to IVM1c Melanoma	SA4	24/07/2015	24
14/LO/1426/AM07	Biomarker Study with T-Vec in Unresected Stage IIIB to IVM1c Melanoma	SA6	19/11/2015	12
14/LO/1435/AM10	Coherus ETA302 - RA	SA5	21/04/2015	16
14/LO/1486/AM02	T-Vec with MK-3475 for Treatment of Stage IIIB to IVM1c Melanoma	2.0	16/12/2015	23
14/LO/1638/AM01	SEQTOR	SA1	26/11/2014	8
14/LO/1638/AM03	SEQTOR	08/12/2015	08/12/2015	14
14/LO/1741/AM01	I2PETHV – Imidazoline2 Binding Site in healthy volunteers	SA1	26/11/2015	25
14/LO/1773/AM07	A study to test the safety of the SMT C1100 in boys with DMD.	SA2	18/05/2015	18
14/LO/1795/AM02	Imaging opioid release after stimulants in adults with ADHD	SA2	01/10/2015	4
14/LO/1798/AM03	GO29294 Anti-PDL1 Bladder Cancer Phase III Version 1.0	3	15/04/2015	7
14/LO/1798/AM06	GO29294 Anti-PDL1 Bladder Cancer Phase III Version 1.0	SA#05	19/01/2016	21
14/LO/1799/AM01	Study to assess the Clinical Efficacy and Safety of ISIS 396443	SA1	23/04/2015	22
14/LO/1799/AM02	Study to assess the Clinical Efficacy and Safety of ISIS 396443	SA2	10/06/2015	20
14/LO/2196/AM01	A phase 2 study of OBE001 versus placebo in the delay of preterm birth	SA1	21/04/2015	16
14/LO/2196/AM02	A phase 2 study of OBE001 versus placebo in the delay of preterm birth	SA 17.7.15	17/07/2015	14
14/LO/2196/AM04	A phase 2 study of OBE001 versus placebo in the delay of preterm birth	SA Protocol v5	11/09/2015	17
14/LO/2196/AM07	A phase 2 study of OBE001 versus placebo in the delay of preterm birth	6.0	18/12/2015	21
14/LO/2215/AM01	Chlorhexidine Gluconate Chip in Therapy of Peri-implantitis	SA#01	20/01/2016	19
14/LO/2222/AM03	Histone Deacetylase Inhibitor FRM-0334 vs placebo in Dementia (V 1.0)	SA1	04/11/2015	25
15/LO/0013/AM01	PBR 28 PET and inflammatory arthritis version1	SA1	14/05/2015	19
15/LO/0091/AM01	Understanding Fatigue in Paediatric Onset MS: Version 1	SA1	23/06/2015	11
15/LO/0091/AM02	Understanding Fatigue in Paediatric Onset MS: Version 1	SA2	10/08/2015	15

15/LO/0223/AM01	Use of blood and blood derived cells to study inflammation and disease	SA1	17/06/2015	15
15/LO/0223/AM02	Use of blood and blood derived cells to study inflammation and disease	SA2	27/10/2015	6
15/LO/0317/AM01	Ph1b study PIM447 with INC424 + LEE011 in patients with myelofibrosis	SA1	27/04/2015	10
15/LO/0317/AM02	Ph1b study PIM447 with INC424 + LEE011 in patients with myelofibrosis	SA – Patient brochure	23/06/2015	9
15/LO/0317/AM03	Ph1b study PIM447 with INC424 + LEE011 in patients with myelofibrosis	Protocol amendment 1	16/10/2015	19
15/LO/0317/AM04	Ph1b study PIM447 with INC424 + LEE011 in patients with myelofibrosis	11/12/2015	11/12/2015	25
15/LO/0317/AM05	Ph1b study PIM447 with INC424 + LEE011 in patients with myelofibrosis	SA PISICFv4	15/01/2016	25
15/LO/0342/AM01	Withdrawal Period study of LUM001 in patients with Alagille Syndrome	SA1	05/05/2015	15
15/LO/0342/AM03	Withdrawal Period study of LUM001 in patients with Alagille Syndrome	SA2	08/05/2015	14
15/LO/0342/AM05	Withdrawal Period study of LUM001 in patients with Alagille Syndrome	6.0	13/10/2015	20
15/LO/0342/AM06	Withdrawal Period study of LUM001 in patients with Alagille Syndrome	protocol amendment 3	10/02/2016	21
15/LO/0433/AM01	Clinical Trial of ALNAS1 in Patients with Acute Intermittent Porphyria	Protocol Amendment 5	13/07/2015	14
15/LO/0433/AM04	Clinical Trial of ALNAS1 in Patients with Acute Intermittent Porphyria	SA8	09/02/2016	27
15/LO/0444/AM01	RESPI-SAM	SA1	02/11/2015	11
15/LO/0448/AM01	JCVU: The RAINFALL Study	SA1	06/05/2015	15
15/LO/0519/AM01	A1438-047: Attachment inhibitor study in HTE patients with MDR HIV-1	SA1	01/07/2015	15
15/LO/0599/AM02	Phase 1b of MPDL3280A + Obinutuzumab in Follicular and B-cell lymphoma	2.0	10/12/2015	25
15/LO/0605/AM01	1200.120 Phase I monotherapy basket trial of afatinib in children.	SA1	04/05/2015	16
15/LO/0665/AM01	LENTICOL-F	SA1	10/06/2015	8
15/LO/0665/AM03	LENTICOL-F	SA 7.3.16	07/03/2016	13

15/LO/0780/AM01	GRAVITAS	SA1	02/11/2015	23
15/LO/0814/AM02	Effects of AZD7325 on cutaneous sensation	SA1	21/09/2015	12
15/LO/0920/AM02	SMTC11004 - Phase 1 study in healthy volunteers and DMD patients	Amendment 2	23/09/2015	12
15/LO/0920/AM05	SMTC11004 - Phase 1 study in healthy volunteers and DMD patients	3.0	18/12/2015	24
15/LO/1000/AM01	GABA-B function in alcohol dependence	1.0	23/12/2015	20
15/LO/1079/AM02	A safety and efficacy study of Multistem Cell Therapy for ARDS	SA1	06/10/2015	15
15/LO/1510/AM01	A Phase I trial of anti-GD2 CAR transduced T-cells (1RG-CART) v1.	SA1	15/01/2016	22
15/LO/2045/AM01	SMT C1100 in Ambulatory Boys with DMD	SA#01	12/02/2016	18
GTAC115/AM09	An open label dose-escalation study of a self complementary adeno-associated viral vector (scAAV2/8-LP1-hFIXco) for gene transfer in subjects with hemophilia B	SA 7.1.16	07/01/2016	13
GTAC128/AM09	WT1 TCR Gene Therapy for Leukaemia: A Phase I/II Safety and Toxicity St	SA 14.8.15	14/08/2015	18
GTAC136/AM07	SERCA2a Gene Therapy Trial	SA6	05/05/2015	2
GTAC136/AM08	SERCA2a Gene Therapy Trial	Substantial amendment 7 02.09.	03/09/2015	24
GTAC170/AM05	Phase I/II study of safety, efficacy and dose evaluation of ProSavin®	SA6	07/09/2015	20
GTAC171/AM06	Gene therapy for choroideraemia: Version 1	SA 23.5.15	23/05/2015	22
GTAC177/AM09	Intrapleural delivery of HSV1716 in patients with mesothelioma	SA10	23/06/2015	14
GTAC178/AM12	LV Gene Therapy for ADA Deficiency	7	19/03/2015	13
GTAC178/AM13	LV Gene Therapy for ADA Deficiency	SA8	29/09/2015	17
GTAC182/AM13	TroVax in patients with asymptomatic relapsed ovarian cancer (TRIOC)	SA7	30/04/2015	21
GTAC182/AM15	TroVax in patients with asymptomatic relapsed ovarian cancer (TRIOC)	SA 008	01/03/2016	6
GTAC187/AM07	Lenti-D ALD-102 (Version 2; Dated 30 January 2012)	SA4 - Temporary Halt	15/05/2015	17
GTAC187/AM08	Lenti-D ALD-102 (Version 2; Dated 30 January 2012)	SA5	07/12/2015	13
GTAC188/AM06	Gene Therapy for Netherton Syndrome	Amendment 3	04/08/2015	19
GTAC190/AM04	Pre-Operative JX-594	SA3	08/10/2015	5

GTAC194/AM03	B4711001 Stem cell transplantation in wet AMD	SA3	26/03/2015	13
GTAC194/AM04	B4711001 Stem cell transplantation in wet AMD	Amendment 4	22/07/2015	9
GTAC194/AM05	B4711001 Stem cell transplantation in wet AMD	SA5	10/02/2016	14
GTAC195/AM06	Celladon (CELL-004) CUPID 2 Study	5	02/04/2015	18
GTAC195/AM07	Celladon (CELL-004) CUPID 2 Study	Amendment 6	01/07/2015	15
GTAC196/AM10	LV gene therapy for CGD	SA#06	09/02/2016	14
GTAC198/AM04	Follow-up Study to Research with Retinal Cells Derived from Stem Cells	SA2	01/02/2016	23

Unfavourable opinion				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
06/Q0406/33/AM08	BIOBANK TO FACILITATE FUTURE THERAPY OF NEUROMUSCULAR DISORDERS	SA7	13/07/2015	17
11/LO/0063/AM14	1280.2 BI 836845 IGF Study	SA6	22/04/2015	13
13/LO/0229/AM02	LSD	SA2	11/11/2015	12
14/LO/0592/AM02	Pregnancy in overweight women	SA2	22/01/2016	23
14/LO/1444/AM02	520-215 AfFIRM A Phase 2 Trial of Filanesib in Relapsed/Refractory MM	Protocol amendment 1	13/04/2015	13
14/LO/1486/AM01	T-Vec with MK-3475 for Treatment of Stage IIIB to IVM1c Melanoma	SA1	15/07/2015	19
15/LO/0433/AM02	Clinical Trial of ALNAS1 in Patients with Acute Intermittent Porphyria	Protocol amendment 7	16/10/2015	15
15/LO/0898/AM02	Extension HGT1410 Study in Pediatric Patients with Early Stage MPS IIIA	SA#01	08/02/2016	21
2004/6745/AM05	A PET study of brain dopamine in the early phase of psychosis	SA13	20/07/2015	15
GTAC146/AM06		SA6	24/09/2015	6
GTAC147/AM08		10 November 2015	10/11/2015	16
GTAC170/AM04	Phase I/II study of safety, efficacy and dose evaluation of ProSavin®	SA5	15/04/2015	26
GTAC185/AM12	Efficacy study of PROSTVAC vaccine in patients with prostate cancer	Protocol amendment 6	20/08/2015	7

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
06/Q0406/33/AM08/1	BIOBANK TO FACILITATE FUTURE THERAPY OF NEUROMUSCULAR DISORDERS	Modified SA7	03/08/2015	9
07/H0707/105/AM13/2	Quantification of fetal brain growth and development using MRI	Modified amendment 9.1	12/05/2015	12
09/H0707/69/AM08/1	Genetic studies of cardiomyopathies and arrhythmia. Version1	Modified SA7	14/05/2015	3
09/H0707/83/AM06/1	MR imaging in neonates at risk of perinatal brain injury	Modified amendment 4.1	15/07/2015	7
11/LO/0063/AM14/1	1280.2 BI 836845 IGF Study	Resubmission of SA6	15/05/2015	7
13/LO/0229/AM02/1	LSD	modSA#01	14/01/2016	10
14/LO/0592/AM02/1	Pregnancy in overweight women	Modified SA2	04/03/2016	14
14/LO/1426/AM01/2	Biomarker Study with T-Vec in Unresected Stage IIIB to IVM1c Melanoma	Modified	29/04/2015	5
14/LO/1444/AM02/1	520-215 AfFIRM A Phase 2 Trial of Filanesib in Relapsed/Refractory MM	Modified 27.5.15	27/05/2015	9
14/LO/1486/AM01/1	T-Vec with MK-3475 for Treatment of Stage IIIB to IVM1c Melanoma	Modified amendment 1	14/08/2015	10
15/LO/0433/AM02/1	Clinical Trial of ALNAS1 in Patients with Acute Intermittent Porphyria	Modified: PA7	18/12/2015	13
2004/6745/AM05/1	A PET study of brain dopamine in the early phase of psychosis	Modified amendment 20.10.15	20/10/2015	4
GTAC146/AM06/1	Phase I/II clinical trial of haematopoietic stem cell gene therapy for the Wiskott-Aldrich Syndrome	6	21/10/2015	5
GTAC147/AM08/1	Immunotherapy with CD19 ⁺ chimeric antigen receptor gene-modified EBV-specific CTLs after stem cell transplant in children with high-risk acute lymphoblastic leukaemia	Modified amendment 7.12.15	07/12/2015	11
GTAC170/AM04/1	Phase I/II study of safety, efficacy and dose evaluation of	Modified	21/08/2015	12

	ProSavin®	amendment SA5		
GTAC185/AM12/1	Efficacy study of PROSTVAC vaccine in patients with prostate cancer	Protocol amendment 6	20/10/2015	6

Unfavourable opinion timeline				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
14/LO/1426/AM01/1	Biomarker Study with T-Vec in Unresected Stage IIIB to IVM1c Melanoma	Modified Amendment 1	07/04/2015	7

Table 11: Items exceeding timelines

Full applications for ethical review over 60 day timeline

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

REC Reference	Title	Number of Days on Clock
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SSAs (non Phase 1) over 25 day timeline

REC Reference	Title	Number of Days on Clock
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SSAs (Phase 1) over 14 day timeline

REC Reference	Title	Number of Days on Clock
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Substantial Amendments over 35 day timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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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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