NHS
Health Research Authority

Research Ethics Service

London - Surrey Borders Research Ethics Committee

Annual Report

01 April 2017 - 31 March 2018

Part 1 – Committee Membership and Training

Name of REC:	London - Surrey Borders Research Ethics Committee
Type of REC:	CTIMPS in healthy volunteers – type I CTIMPS in patients – type III
Type of Flag:	Phase I Studies in Healthy Volunteers
Chair:	Sir Adrian Baillie
Vice-Chair:	Ms. Christine Braithwaite
Alternate Vice-Chair:	Mr. Tobias Davis
REC Manager:	Mrs Barbara Cuddon
REC Assistant:	Miss Charlotte Ferris (until 07 February 2018) Mr Stephan Ramey
Committee Address:	Research Ethics Committee (REC) London Centre Ground Floor Skipton House 80 London Road London SE1 6LH
Telephone:	0207 972 2568
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Chair's overview of the past year:

Looking back, although broadly the same themes that were true of the year before remained true in 2017-2018, this year felt considerably more settled. We are delighted to still have Barbara managing us so efficiently and to remain managed out of the London office. It is a shame that a couple of excellent assistants have moved on, which has probably been a strain for Barbara, but our committee has not suffered any adverse effects for which she and the rest of the HRA team deserve our thanks.

We knew that we would be losing a number of valued members, mostly very long-standing, but I'm delighted to be able to say that having lost four members including our vice-chair and pharmacist we have welcomed six new members. The posts of vice-chair and assistant vice-chair have been filled internally and both successful candidates have stepped up confidently and highly successfully, each having now chaired meetings on their own.

We have applied to become flagged to review Medical Device studies and six members received training on this topic; we hope to hear about this shortly. We are also an early part of the pilot process for reviewing studies in the new European format. We've had to use a couple of other venues in the period, but all were very close to Skipton House and seem to have caused no practical issues.

If there is an area of concern at present I would have to say that this is in the volume of substantial amendment work that we receive which has been a real weight on the sub-committees. I'm proud to say that our newer members including our pharmacist have really risen to the challenge, perhaps sooner than I would have liked to have had to ask them, but the time commitment required of members has definitely increased.

I say each year that because of the wide range of studies that we review, we can't stress enough how grateful we are when researchers attend meetings, which they do more often than not, as this greatly aids our review and improves the process for all involved. It was enormously gratifying, therefore, to receive in the period some very positive feedback about the service we provide. It's nice to be appreciated for doing a job that we all continue to consider to be meaningful and important.

London - Surrey Borders Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Mr. Hakam Abbass	Clinical Research Nurse	Expert	01/09/2017	
Sir Adrian Baillie	Financial Investment Advisor	Lay Plus	01/04/2014	
Ms. Christine Braithwaite	Director of Standards and Policy	Lay	10/02/2015	
Mr. Derek Cock	Chief Pharmacist	Expert	03/02/2007	30/09/2017
Mr. Tobias Davis	Medical Device Expert	Expert	02/02/2015	
Mr. Dominic Fairclough	Solicitor	Lay Plus	01/04/2009	04/07/2017
Dr Khurum Khan	Clinical Research Fellow	Expert	01/05/2016	
Mrs. Anne Laurie	Lecturer in Clinical Communications	Lay	01/06/2007	01/06/2017
Ms Sharon Levy	Solicitor (Non-practising)	Lay Plus	01/09/2017	
Dr. David Lukey	Management Consultant	Expert	02/02/2015	31/08/2017
Mr Thomas Morrish	Clinical Research Manager	Lay	01/04/2017	
Miss Florence Mowlem	PhD Student	Lay	01/09/2017	
Dr. Rosemary O'Neil	Senior Lecturer (Statistics and Mathematics)	Lay Plus	01/12/2008	
Dr. Anand Patel	Medical Director (Drug Development)	Expert	01/04/2015	
Dr Imogen Savage	Pharmacist (Retired)	Expert	01/09/2017	
Miss Holly Shrimpton	RAF Medical Support Officer	Lay Plus	17/07/2017	
Dr. Elizabeth Smyth	Clinical Research Fellow	Expert	01/05/2015	
Mr. Graham Tate	Tissue Bank Manager	Expert	03/06/2013	

London - Surrey Borders Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended
Ms Sandra Eismann	Demand and Capacity Advisor	Lay Plus	19/07/2017
Ms Stephanie Ellis	Retired Civil Servant	Lay Plus	17/01/2018
Ms Susan Harrison	Health and Social Services Manager	Lay	02/11/2017
Mr Craig Moss	Research Director	Lay	19/04/2017
Mr Craig Moss	Research Director	Lay	19/07/2017
Mrs Elayne Nasr	Retired School Matron	Lay Plus	21/03/2018
Ms Bridget Penhale	Academic Supervisor, Reader in Mental Health of older people.	Expert	02/11/2017
Dr Michael Philpot	Consultant Psychiatrist	Expert	21/03/2018
Mr Michael Schachter	Clinical Pharmacologist	Expert	17/01/2018

London - Surrey Borders Research Ethics Committee: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Mr. Hakam Abbass	No declared interests.	08/08/2017
Sir Adrian Baillie	I have (with my brother in law) a small interest in a Norwegian biotech company researching stem cells called Fortuna Fix. It is possible that from time to time I may have minor shareholding(s) in stockmarket listed entities in the healthcare section, or exposure to them through investment funds. At present I can confirm that I do not hold any except (possibly) in accounts that are fully discretionally managed by external fund managers, although I will have some exposure through index trackers and the like. I have nothing approaching a significant stake in any such organisation, nor one that is financially very material to me, personally. Trustee of the Hepatitis C Trust Trustee of the Gawaine Stamp Fund - a small medical charity Shadow Governor Surrey and Sussex Healthcare Trust (SASH) Member of the Organ Donation Committee, SASH	13/02/2018
Ms. Christine Braithwaite	Director of Standards and Policy, Professional Standards Authority and Health and Social Care	01/03/2018
Mr. Tobias Davis	Full time employment - Regulatory Affairs Manager, Biosurgery EMEA –Ethicon (A Johnson and Johnson company)	13/02/2018
Dr Khurum Khan	Appointed as Locum Consultant in Oncology at the Royal Marsden Hospital, however, I'm still working for the same team.	30/03/2018
Ms Sharon Levy	No declarations of interest	27/07/2017
Mr Thomas Morrish	Site Research Manager for St Stephen's AIDS Trust/ St Stephen's Clinical research	16/05/2017
Miss Florence Mowlem	I will be completing a 3-month policy internship at the Academy of Medical Sciences. My PhD is funded in part by the Medical Research Council	05/10/2017
Dr. Rosemary O'Neil	External Research Associate - General Medical Council	14/03/2018
Dr Imogen Savage	None	05/10/2017
Miss Holly Shrimpton	Employed by the Royal Air Force Medical Service in a non-clinical role.	24/07/2017
Dr. Elizabeth Smyth	Honoraria for advisory role 2017-2018, Gritstone Oncology, Servier, Celgene,	13/02/2018
Dr. Elizabeth Smyth	Secretary of EORTC GI trials group	13/02/2018

Mr. Graham Tate	Designated Individual (Research) at Barts Health NHS Trust and QMUL Medical College (Licence 12199)	28/02/2018

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	10
June	21/06/2017	9
July	19/07/2017	8
September	20/09/2017	12
October	18/10/2017	12
November	02/11/2017	8
January	17/01/2018	10
February	21/02/2018	10
March	21/03/2018	8

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
April	12/04/2017	3
May	10/05/2017	3
June	14/06/2017	3
July	12/07/2017	3
August	09/08/2017	3
September	13/09/2017	3
October	11/10/2017	3
February	14/02/2018	3

8 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	12/04/2017	2
April	26/04/2017	2
May	10/05/2017	2
May	24/05/2017	2
June	14/06/2017	2
June	28/06/2017	3
July	06/07/2017	2
July	12/07/2017	2
July	26/07/2017	2
August	02/08/2017	3
August	07/08/2017	3
August	09/08/2017	2
August	23/08/2017	2

August	30/08/2017	5
September	13/09/2017	2
September	27/09/2017	2
October	11/10/2017	2
October	25/10/2017	2
November	08/11/2017	2
November	22/11/2017	2
December	13/12/2017	2
December	27/12/2017	2
January	10/01/2018	3
January	24/01/2018	2
February	07/02/2018	2
February	21/02/2018	3
March	07/03/2018	2
March	21/03/2018	2

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

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

0

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

Name	Number of Meetings Attended
Mr. Hakam Abbass	4
Sir Adrian Baillie	8
Ms. Christine Braithwaite	8
Mr. Derek Cock	4
Mr. Tobias Davis	8
Dr Khurum Khan	6
Ms Sharon Levy	4
Dr. David Lukey	4
Mr Thomas Morrish	6
Miss Florence Mowlem	4
Dr. Rosemary O'Neil	7
Dr. Anand Patel	1
Dr Imogen Savage	4
Miss Holly Shrimpton	4
Dr. Elizabeth Smyth	6
Mr. Graham Tate	8

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

Name	Number of Meetings Attended
Sir Adrian Baillie	1
Ms. Christine Braithwaite	7
Mr. Derek Cock	4
Mr. Tobias Davis	4
Dr Khurum Khan	1
Mr Thomas Morrish	1
Dr. Rosemary O'Neil	1
Dr. Anand Patel	2
Dr. Elizabeth Smyth	1
Mr. Graham Tate	2

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

Name	Number of Meetings Attended
Mr. Hakam Abbass	1
Sir Adrian Baillie	15
Ms. Christine Braithwaite	10
Mr. Derek Cock	5

Mr. Tobias Davis	5
Dr Khurum Khan	2
Ms Sharon Levy	1
Dr. David Lukey	1
Mr Thomas Morrish	2
Dr. Rosemary O'Neil	4
Dr. Anand Patel	4
Dr Imogen Savage	2
Miss Holly Shrimpton	1
Dr. Elizabeth Smyth	4
Mr. Graham Tate	7

Training 01 April 2017 - 31 March 2018

Name of Member	Date	Event(s) attended
Mr. Hakam Abbass	15/11/2017	Medical Device Training
Mr. Hakam Abbass	16/11/2017	Committee Members Induction
Mr. Hakam Abbass	07/02/2018	Introduction to Phase I Clinical Trials
Mr. Hakam Abbass	28/02/2018	Training Ethical Issues in Phase One Research Advanced
Sir Adrian Baillie	03/05/2017	RES Chairs' Meeting
Sir Adrian Baillie	06/11/2017	RES Chairs' Meeting
Sir Adrian Baillie	15/11/2017	Medical Device Training
Sir Adrian Baillie	24/11/2017	Chair's Day
Sir Adrian Baillie	20/02/2018	Equality and Diversity
Ms. Christine Braithwaite	15/11/2017	Medical Device Training
Mr. Tobias Davis	15/11/2017	Medical Device Training
Ms Sharon Levy	15/11/2017	Medical Device Training
Ms Sharon Levy	11/01/2018	Committee Members Induction
Mr Thomas Morrish	07/07/2017	Induction for new Research Ethics Service Committee members
Mr Thomas Morrish	25/07/2017	Committee Members Induction
Miss Florence Mowlem	20/09/2017	Equality Diversity and Human Rights
Miss Florence Mowlem	20/09/2017	Induction for new Research Ethics Service Committee members
Miss Florence Mowlem	15/11/2017	Medical Device Training
Dr. Rosemary O'Neil	15/11/2017	Medical Device Training
Dr. Rosemary O'Neil	08/03/2018	Local Training Day - London REC Members Training Day
Dr Imogen Savage	08/08/2017	Induction for new Research Ethics Service Committee members
Dr Imogen Savage	10/08/2017	Equality Diversity and Human Rights
Dr Imogen Savage	11/01/2018	Committee Members Induction
Dr Imogen Savage	08/03/2018	London REC Members Day
Miss Holly Shrimpton	11/01/2018	Committee Members Induction
Dr. Elizabeth Smyth	15/05/2017	Reviewing the Research Design of Clinical Trials
Dr. Elizabeth Smyth	15/05/2017	Training for Non-Commercial Studies
Dr. Elizabeth Smyth	15/05/2017	Training for Commercial Studies
Dr. Elizabeth Smyth	08/03/2018	London REC Members Training Day
Mr. Graham Tate	15/11/2017	Medical Device 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	15	34.09
Phase 1	1	2.27
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	0	0.00
Others	28	63.64
Total Applications Reviewed	**44**	**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	1
Number of student applications reviewed	11
Number of paediatric applications reviewed	1
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	2

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	6	13.64
Favourable Opinion with Additional Conditions	8	18.18
Unfavourable Opinion	2	4.55
Provisional Opinion	27	61.36
Provisional Opinion Pending Consultation with Referee	1	2.27
Total	**44**	**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	22	50
Further Information Favourable Opinion with Additional Conditions	3	6.82
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	6	13.64
Favourable Opinion with Additional Conditions	8	18.18
Unfavourable Opinion	2	4.55
Provisional Opinion	1	2.27
Provisional Opinion Pending Consultation with Referee	0	0.00
Further Information response not complete	1	2.27
No decision entered on system	0	0.00
Number of studies withdrawn after the meeting	1	2.27
Total	**44**	**100**

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

Total Applications Reviewed	**16**

Table 6: **Breakdown of PRS applications and other activity during reporting period:**

Number of applications made invalid by the REC Manager	5
Number of studies withdrawn prior to the meeting	0
Number of student applications reviewed	8
Number of paediatric applications reviewed	5
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	4	25.00
Favourable Opinion with Additional Conditions	2	12.50
No Opinion transfer to full committee for review	3	18.75
Provisional Opinion	7	43.75
Unfavourable Opinion	0	0.00
Total	**16**	**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	4.40
Number of completed applications for full ethical review	43
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 days taken to final decision – average (mean)	30

Number of completed proportionate review applications for ethical review	13
Number of completed proportionate review applications for ethical review over 21 days	0
Number of completed proportionate review applications over 21 days as a % of total	0.00%

Number of SSAs (non-Phase 1) reviewed	7
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	134
Number of completed substantial amendments over 35 days	5
Number of completed substantial amendments over 35 days as a % of total substantial amendments	3.73%

Number of modified amendments reviewed	1
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	89
Number of substantial amendments received for information	1
Number of substantial amendments received for new sites/PIs	31
Number of annual progress reports received	71
Number of safety reports received	74
Number of Serious Adverse Events received	0
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**
17/LO/0603	Optimal: Effectiveness of discharge advocate to reduce readmission	28
17/LO/0625	Within-participant predictors of adherence to oral HIV PrEP	29
17/LO/0627	Study of VAL-1221 in Patients with Pompe Disease (VAL-1221-201-16)	37
17/LO/0629	Use of MRI-Enema in the Assessment of Colorectal Anastomotic Integrity	32
17/LO/0631	Testing a diagnostic aid for hip dysplasia in primary care	28
17/LO/0660	A Phase 1 study of E7386 in patients with advanced Neoplasms	22
17/LO/0825	Filgotinib, GS-9876, GS-4059 in Adults with Active Sjogren's Syndrome	35
17/LO/1032	Headspace as a guided self-help mindfulness course for depression	21
17/LO/1041	TSPO PET as a measure of post-stroke brain inflammation	31
17/LO/1043	ECHO 206:epacadostat in combination with pembrolizumab and azacitadine	29
17/LO/1188	GSC function to promote repair of gingival tissue	42
17/LO/1218	ASD Arrhythmia Study	43
17/LO/1596	REACH Pregnancy Circles Trial ; Version 1.0	34
17/LO/1614	Impact of endometriosis on women. A qualitative study	39
17/LO/1793	Location of scar after caesarean section	33
18/LO/0042	NLG2107 P2/3 Study in Adults with Unresectable Stage III/IV Melanoma	27
18/LO/0059	IceCAP-A Phase I trial of ipatasertib in combination with atezolizumab	27
18/LO/0074	i-Prognosis SData study	32
18/LO/0111	Safety, tolerability, PK/PD of C21 in patients with IPF	25
18/LO/0302	What are the experiences of pregnant women with a CHD diagnosis?	55
18/LO/0367	Anti- mesothelin expression tumor activity of thorium-227 antibody	47
18/LO/0460	A first in man study of KCL-286 in healthy male participants	45

Further Information Favourable Opinion with Additional Conditions		
REC Reference	**Title**	**Number of Days on Clock**
17/LO/1022	Phase III study to evaluate efficacy and safety of C1-INH	52
17/LO/1071	Self-Binding Advance Directives in Bipolar: Phase 1	21
17/LO/1174	Phase 2 of Filgotinib in patients with active non-infectious uveitis	21

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/1159	WOMEN'S MULTIZONAL EVALUATION OF ANOGENITAL NEOPLASIA: WOMEN STUDY	20
17/LO/1432	A Study of MGA012 in Patients with Advanced Solid Tumors	22
17/LO/1737	Clinical Utility of Magnetocardiography	29
17/LO/2115	CLUE: liver fibrosis detection & assessment with MRI	52
18/LO/0272	Targeted therapy of CRC patients with anti-EGFR antibodies	28
18/LO/0486	RCT of Specialist Physiotherapy for Functional Motor Disorder	27

Favourable Opinion with Additional Conditions		
REC Reference	**Title**	**Number of Days on Clock**
17/LO/0600	Feasibility study of a Novel Efficacy Assessment Tool (NEAT)	22
17/LO/1006	Hereditary Cancer Predisposition Syndrome: EORTC QLQ-HCPS	20
17/LO/1347	A Phase 1/1b Study of Paclitaxel in Combination with BOS172722	19
17/LO/1732	MS201923-0007 Rollover Study Continued Treatment with M6620	20
17/LO/1762	PIMO Study	20
17/LO/1787	INVESTIGATION OF IMMUNOLOGICAL MECHANISMS IN NASAL POLYPOSIS	20
18/LO/0081	Systemic mitochondrial function as a biomarker for open angle glaucoma	20
18/LO/0497	Vascular Frailty - An observational cohort study	16

Unfavourable Opinion		
REC Reference	**Title**	**Number of Days on Clock**
17/LO/0851	Personalised medicine in patients with CUP and solid 'rare cancers'	20
17/LO/1211	Is evidence used to reduce overuse of interventions in labour?	22

Provisional Opinion		
REC Reference	**Title**	**Number of Days on Clock**
18/LO/0226	B7661001 - PF-06647020 in patients with Advanced Solid Tumor	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/0416	Evaluation of Avelumab combined with Talazoparib in solid tumours	n/a

Withdrawn after the meeting		
REC Reference	**Title**	**Number of Days on Clock**
17/LO/0844	Outcomes of Acute Urinary Retention patients in Darent Valley Hospital	21

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/0605	Combined Novel 3D Cell Culture and Biospectroscopy: Osteoporosis	16
17/LO/0609	Evaluation of i-THRIVE	18
17/LO/1185	Study to improve implementation of paediatric recommendations	20
17/LO/1753	Automated image analysis	16

Further Information Favourable Opinion with Additional Conditions		
REC Reference	**Title**	**Number of Days on Clock**
17/LO/0994	The use of novel measures to detect Accelerated Long-Term Forgetting	19
17/LO/1008	Upper limb movements and repeatability for clinical movement analysis	20
17/LO/1379	ISIS2 Vs TAPs in adolescent idiopathic scoliosis	19

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/1201	Outcomes in severely injured trauma patients not triaged to MTCs	14
17/LO/1382	Ankle Fracture Treatment: Enhancing Rehabilitation - the AFTER study	9
17/LO/1527	Investigating Pain in Inflammatory Bowel Disease	16
18/LO/0275	Sleep Quality and Melatonin Rhythms in Allergic Rhinitis	20

Favourable Opinion with Additional Conditions		
REC Reference	**Title**	**Number of Days on Clock**
17/LO/1746	ObeSity related Colorectal Adenoma Risk	18
18/LO/0278	GPs' views on adolescents with mental health disorders - Version 1	15

Unfavourable Opinion		
REC Reference	**Title**	**Number of Days on Clock**

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**
08/H0806/80/AM16	Metformin in obese non-diabetic pregnant women Version 1.0	SA8 1.9	28/01/2017	4
08/H0806/80/AM17	Metformin in obese non-diabetic pregnant women Version 1.0	SA8	23/11/2017	23
10/H0806/100/AM30	AZD5363 Safety & Tolerability in Patients with Advanced Solid Tumours	8	06/04/2017	33
10/H0806/118/AM10	CASPS	SA08	30/05/2017	6
11/LO/1033/AM01	Effects of laparoscopic sacrocolpopexy on defecatory dysfunction	SA01	23/08/2017	27
11/LO/2019/AM20	TOPARP	MREC15MHRA5	30/01/2018	12
12/LO/0105/AM03	Blood Donation	SA2	14/12/2017	19
12/LO/1407/AM06	Phase I trial of RO5126766, a dual RAF/MEK inhibitor	AM09	09/08/2017	6
12/LO/1606/AM07	MPD-RC 112 (Pegasys)	SA5 Protocol AM09	11/10/2016	25
13/LO/0826/AM28	C diffense	SA17	02/05/2017	23
13/LO/0826/AM32	C diffense	SA19	30/11/2017	29
13/LO/0826/AM33	C diffense	SA20	30/01/2018	12
13/LO/0867/AM18	1199.93 - Nintedanib in mesothelioma	SA12	20/07/2017	17
13/LO/0867/AM20	1199.93 - Nintedanib in mesothelioma	SA13	17/01/2018	28
13/LO/0935/AM10	A Phase I trial of ONX-0801	SA08	16/08/2017	7
13/LO/0983/AM08	GO28625 - Phase II study of MPDL3280A for non-small cell lung cancer	SA08	06/10/2017	32
13/LO/1081/AM11	PROSPER:MDV3100-14 Phase 3,Enzalutamide,non-metastatic CRPC patients	07	02/05/2017	29
13/LO/1081/AM12	PROSPER:MDV3100-14 Phase 3,Enzalutamide,non-metastatic CRPC patients	SA09	30/08/2017	29
13/LO/1081/AM14	PROSPER:MDV3100-14 Phase 3,Enzalutamide,non-metastatic CRPC patients	SA09 - Radiation update	11/01/2018	16
13/LO/1303/AM02	InfeCtion respONse through vIrus genomiCs (ICONIC)	2	22/12/2017	3
13/LO/1320/AM17	STUDY OF FAI INSERT IN SUBJECTS WITH CHRONIC NON-INFECTIOUS UVEITIS	AM17 26/06/2017	26/06/2017	11
13/LO/1320/AM18	STUDY OF FAI INSERT IN SUBJECTS WITH CHRONIC NON-INFECTIOUS UVEITIS	IBv9.0	05/12/2017	34

13/LO/1352/AM16	GO28753 Anti-PDL1 in NSCLC	Amendment 10 (substantial) - updated PIS & ICF 2017/05/24	24/05/2017	6
13/LO/1352/AM17	GO28753 Anti-PDL1 in NSCLC	SA11	01/08/2017	15
13/LO/1352/AM18	GO28753 Anti-PDL1 in NSCLC	IBv9.0	19/12/2017	30
13/LO/1616/AM22	Phase 1 study of MEDI4736 in Subjects With Advanced Solid Tumours	SA15	29/03/2017	6
13/LO/1616/AM23	Phase 1 study of MEDI4736 in Subjects With Advanced Solid Tumours	SA16	26/05/2017	20
13/LO/1616/AM24	Phase 1 study of MEDI4736 in Subjects With Advanced Solid Tumours	SA#17	18/12/2017	10
14/LO/0080/AM13	Luster PCI32765FLR3001	NOSA for Ibrutinib IB ed 11, Addendum 1 to IB ed 11 & PIS / ICF Addendum 2.0	24/01/2018	34
14/LO/0080/AM14	Luster PCI32765FLR3001	NOSA 9 New PI Swansea	01/02/2018	10
14/LO/1064/AM17	BYM338D2201 A Possible Treatment for Muscle Wasting after Hip Fracture	SA15	29/06/2017	27
14/LO/1064/AM18	BYM338D2201 A Possible Treatment for Muscle Wasting after Hip Fracture	Substantial Amendment IB Update Ed10	01/02/2018	13
14/LO/1425/AM11	CHM for RUTIs	AM11	30/03/2017	153
14/LO/1485/AM07	A study to evaluate SYD985 in advanced or metastastic solid tumours	SA6	06/04/2017	14
14/LO/1485/AM09	A study to evaluate SYD985 in advanced or metastastic solid tumours	SA07	30/08/2017	23
14/LO/1485/AM10	A study to evaluate SYD985 in advanced or metastastic solid tumours	8	24/11/2017	32
14/LO/1617/AM10	Type I DM Study	SA06	23/06/2017	30
14/LO/1633/AM07	Case-control study of inherited women's cancer	V3 (22 December 2015)	21/04/2017	20
14/LO/1633/AM09	Case-control study of inherited women's cancer	5	29/01/2018	11
14/LO/2156/AM16	A phase II study of VSN16R for Multiple Sclerosis related spasticity	SA12	09/06/2017	9

14/LO/2188/AM03	K-07 Physica KR Fluoroscopy study	AM03	15/03/2017	13
15/LO/0241/AM03	Children Innovative Debridement Study (CIDS) MW2012-01-01	V01	09/11/2017	12
15/LO/0263/AM09	CDI-CS-002: Oral BAL101553 in Patients with Advanced Solid Tumors	SA08	30/05/2017	9
15/LO/0263/AM10	CDI-CS-002: Oral BAL101553 in Patients with Advanced Solid Tumors	SA09	26/06/2017	10
15/LO/0843/AM09	Feasibility and efficacy of resistance training in CP. Version 1.	AM04	24/03/2017	10
15/LO/1118/AM11	BET115521: GSK525762 in Subjects with Solid Tumours	BET115521 Substantial Amendment 05	25/04/2017	22
15/LO/1118/AM12	BET115521: GSK525762 in Subjects with Solid Tumours	SA06	31/05/2017	13
15/LO/1118/AM13	BET115521: GSK525762 in Subjects with Solid Tumours	SA07	27/06/2017	13
15/LO/1500/AM08	1199.229 Drug-drug interaction study with nintedanib and pirfenidone	7	21/03/2017	14
15/LO/1500/AM09	1199.229 Drug-drug interaction study with nintedanib and pirfenidone	SA05	22/05/2017	8
15/LO/1825/AM04	Open label Phase 1b Qt/QTc study of ARN-509 in CR Prostate Cancer	SA03	26/05/2017	15
15/LO/1825/AM06	Open label Phase 1b Qt/QTc study of ARN-509 in CR Prostate Cancer	SA04	06/10/2017	29
15/LO/1825/AM08	Open label Phase 1b Qt/QTc study of ARN-509 in CR Prostate Cancer	5	26/01/2018	17
15/LO/1836/AM06	TRIGGER Trial Version 1.0	AM5	04/12/2017	28
15/LO/2017/AM07	Testing the usability of the eRAPID system in surgery	SA04	17/07/2017	21
15/LO/2017/AM09	Testing the usability of the eRAPID system in surgery	5	27/02/2018	34
15/LO/2028/AM09	TAS3681 in Metastatic Castration Resistant Prostrate Cancer	3	30/11/2017	32
15/LO/2039/AM07	PET scanning in evaluation of vaccine reactogenicity; v1	SA06	17/07/2017	15
16/LO/0401/AM01	Parents' experience of decision making in PICU	SA01 - Protocol Version 2	01/07/2017	6
16/LO/0422/AM10	A Phase 1/2 trial of oral SRA737 given in combination	SA7	10/11/2017	28
16/LO/0422/AM13	A Phase 1/2 trial of oral SRA737 given in combination	SA10	01/02/2018	26
16/LO/0423/AM07	A Phase 1/2 trial of SRA737 in subjects with advanced cancer	SA05	26/05/2017	7
16/LO/0423/AM09	A Phase 1/2 trial of SRA737 in subjects with advanced cancer	SA08	13/10/2017	33
16/LO/0423/AM13	A Phase 1/2 trial of SRA737 in subjects with advanced cancer	SA11	01/02/2018	10
16/LO/0677/AM07	CQVM149B2302 to compare QVM149 with QMF149 in patients with asthma	SA4 Protocol Amendment 05	04/04/2017	16

16/LO/0677/AM08	CQVM149B2302 to compare QVM149 with QMF149 in patients with asthma	SA05	12/07/2017	12
16/LO/0677/AM11	CQVM149B2302 to compare QVM149 with QMF149 in patients with asthma	SA 06 Amended Protocol v06	22/01/2018	12
16/LO/0708/AM05	Evaluating TAS-116 in patients with advanced solid tumours	8	28/03/2017	24
16/LO/0708/AM08	Evaluating TAS-116 in patients with advanced solid tumours	SA04	14/06/2017	14
16/LO/0708/AM10	Evaluating TAS-116 in patients with advanced solid tumours	6	08/11/2017	16
16/LO/0708/AM11	Evaluating TAS-116 in patients with advanced solid tumours	11.0	20/11/2017	16
16/LO/0708/AM12	Evaluating TAS-116 in patients with advanced solid tumours	v6.0	22/01/2018	35
16/LO/1032/AM03	Phase 3 open label study with nab-Paclitaxel in patients with NSCLC	AM03	04/09/2017	32
16/LO/1032/AM04	Phase 3 open label study with nab-Paclitaxel in patients with NSCLC	03	16/11/2017	21
16/LO/1032/AM05	Phase 3 open label study with nab-Paclitaxel in patients with NSCLC	Amendment 4	19/01/2018	40
16/LO/1034/AM05	Phase II Trial of MK-3475 in Subjects with mCRPC	SA04	31/03/2017	28
16/LO/1034/AM07	Phase II Trial of MK-3475 in Subjects with mCRPC	SA06	08/08/2017	33
16/LO/1034/AM08	Phase II Trial of MK-3475 in Subjects with mCRPC	SA08	16/11/2017	22
16/LO/1034/AM09	Phase II Trial of MK-3475 in Subjects with mCRPC	SA09	21/02/2018	35
16/LO/1051/AM01	CHAP study	SA01	05/05/2017	31
16/LO/1211/AM06	JHL-CLIN-1101-01: JHL1101 versus MabThera in RA	Substantial Amendment #4	09/01/2018	16
16/LO/1240/AM01	DHEA in Poor Responders (1)	SA01	11/07/2017	13
16/LO/1240/AM02	DHEA in Poor Responders (1)	SA02	13/10/2017	33
16/LO/1240/AM03	DHEA in Poor Responders (1)	SA03	09/02/2018	34
16/LO/1502/AM03	CTC-STOP	SA03	13/06/2017	5
16/LO/1502/AM07	CTC-STOP	5	20/02/2018	37
16/LO/1552/AM01	INITIATE	SA01	20/06/2017	11
16/LO/1605/AM01	HyPeR: Phase1 - combination of pembrolizumab with guadecitabine	1	30/11/2017	32
16/LO/1679/AM02	A Microneurography Test-Retest Study	SA02	17/03/2017	20
16/LO/1779/AM07	MDV3800-06 Talazoparib in Men with MCRPC	SA04	17/05/2017	28
16/LO/1779/AM08	MDV3800-06 Talazoparib in Men with MCRPC	SA06	20/07/2017	17
16/LO/1779/AM09	MDV3800-06 Talazoparib in Men with MCRPC	SA07	14/12/2017	29
16/LO/1871/AM01	SSAT073 PK of Dolutegravir and Darunavir/Cobicistat	01	02/11/2017	18
16/LO/2220/AM01	EP differences in the South Asian heart	SA01	25/10/2017	34

16/LO/2243/AM01	BCCs Ultrasound Vs Histology Version 6.0	7.0	09/01/2018	20
17/LO/0018/AM03	Phase 1/1b study of Medi3726 for castration resistant prostate cancer	2	27/04/2017	19
17/LO/0018/AM04	Phase 1/1b study of Medi3726 for castration resistant prostate cancer	SA03	24/07/2017	14
17/LO/0018/AM05	Phase 1/1b study of Medi3726 for castration resistant prostate cancer	4	27/12/2017	35
17/LO/0082/AM02	PuraStatÂ®; Post Market Performance during Vascular Surgery	1	07/12/2017	18
17/LO/0262/AM01	PDR001 in Advanced or Metastatic Non-Functional NeuroendocrineTumours	SA01	23/05/2017	7
17/LO/0262/AM02	PDR001 in Advanced or Metastatic Non-Functional NeuroendocrineTumours	2	22/02/2018	40
17/LO/0263/AM01	ACE: A PhaseI/II trial of AZD5069 in combination with enzalutamide	Amdt01	22/02/2018	34
17/LO/0381/AM02	ESMI	SA01	06/10/2017	21
17/LO/0441/AM01	Phase 3 trial of etoposide/platinum with or without pembrolizumab	As per HARP AM01	05/05/2017	6
17/LO/0441/AM03	Phase 3 trial of etoposide/platinum with or without pembrolizumab	SA03	09/08/2017	21
17/LO/0441/AM04	Phase 3 trial of etoposide/platinum with or without pembrolizumab	SA04	11/09/2017	25
17/LO/0441/AM05	Phase 3 trial of etoposide/platinum with or without pembrolizumab	SA06	01/11/2017	22
17/LO/0444/AM04	M13-576: Follow-up for 2nd Gen DAA in previous HCV studies	3	14/11/2017	33
17/LO/0603/AM01	Optimal: Effectiveness of discharge advocate to reduce readmission	1	10/11/2017	22
17/LO/0605/AM01	Combined Novel 3D Cell Culture and Biospectroscopy: Osteoporosis	SA01	14/06/2017	14
17/LO/0625/AM03	Within-participant predictors of adherence to oral HIV PrEP	SA01	29/08/2017	15
17/LO/0627/AM02	Study of VAL-1221 in Patients with Pompe Disease (VAL-1221-201-16)	6.0	09/11/2017	22
17/LO/0627/AM03	Study of VAL-1221 in Patients with Pompe Disease (VAL-1221-201-16)	7.0 (UK-specific) 15/12/2017	20/12/2017	32
17/LO/0627/AM04	Study of VAL-1221 in Patients with Pompe Disease (VAL-1221-201-16)	v8 Protocol & IB Amendment	28/02/2018	35

17/LO/0629/AM01	Use of MRI-Enema in the Assessment of Colorectal Anastomotic Integrity	SA01	20/10/2017	29
17/LO/0660/AM01	A Phase 1 study of E7386 in patients with advanced Neoplasms	2	22/11/2017	29
17/LO/0825/AM01	Filgotinib, GS-9876, GS-4059 in Adults with Active Sjogren's Syndrome	SA01	19/07/2017	33
17/LO/0825/AM04	Filgotinib, GS-9876, GS-4059 in Adults with Active Sjogren's Syndrome	SA03	04/10/2017	6
17/LO/0825/AM05	Filgotinib, GS-9876, GS-4059 in Adults with Active Sjogren's Syndrome	SA04	18/12/2017	25
17/LO/0825/AM06	Filgotinib, GS-9876, GS-4059 in Adults with Active Sjogren's Syndrome	SA05	13/02/2018	34
17/LO/0994/AM01	The use of novel measures to detect Accelerated Long-Term Forgetting	SA01	08/09/2017	7
17/LO/0994/AM02	The use of novel measures to detect Accelerated Long-Term Forgetting	2	03/11/2017	16
17/LO/1022/AM01	Phase III study to evaluate efficacy and safety of C1-INH	Protocol Amendment 1 - 28/11/17	28/11/2017	27
17/LO/1043/AM01	ECHO 206:epacadostat in combination with pembrolizumab and azacitadine	SA01	21/07/2017	31
17/LO/1071/AM01	Self-Binding Advance Directives in Bipolar: Phase 1	SA01	14/09/2017	29
17/LO/1174/AM04	Phase 2 of Filgotinib in patients with active non-infectious uveitis	SA02	23/10/2017	31
17/LO/1174/AM05	Phase 2 of Filgotinib in patients with active non-infectious uveitis	Substantial Amendment 3	08/12/2017	26
17/LO/1218/AM01	ASD Arrhythmia Study	1	13/11/2017	18
17/LO/1432/AM02	A Study of MGA012 in Patients with Advanced Solid Tumors	1	22/12/2017	34
17/LO/1527/AM01	Investigating Pain in Inflammatory Bowel Disease	SA01	13/10/2017	34
17/LO/1746/AM01	ObeSity related Colorectal Adenoma Risk	1	01/12/2017	19

Unfavourable opinion				
Amendment REC Reference	**Title**	**Version**	**Date**	**Number of Days on Clock**
16/LO/1679/AM03	A Microneurography Test-Retest Study	SA03	07/06/2017	35
17/LO/0075/AM02	Validation of two measures for growth hormone deficiency in	2	12/12/2017	58

	children			
17/LO/0271/AM02	The BEACON study	SA01	03/08/2017	32

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**
16/LO/1679/AM03/1	A Microneurography Test-Retest Study	SA03	08/09/2017	4

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**

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

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

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

Substantial Amendments over 35 day timeline				
Amendment REC Reference	**Title**	**Version**	**Date**	**Number of Days on Clock**
14/LO/1425/AM11	CHM for RUTIs	AM11	30/03/2017	153
16/LO/1032/AM05	Phase 3 open label study with nab-Paclitaxel in patients with NSCLC	Amendment 4	19/01/2018	40
16/LO/1502/AM07	CTC-STOP	5	20/02/2018	37
17/LO/0075/AM02	Validation of two measures for growth hormone deficiency in children	2	12/12/2017	58
17/LO/0262/AM02	PDR001 in Advanced or Metastatic Non-Functional NeuroendocrineTumours	2	22/02/2018	40

Modified Amendments over 14 day timeline				
Amendment REC Reference	**Title**	**Version**	**Date**	**Number of Days on Clock**