Health Research Authority

Research Ethics Service

London - Chelsea Research Ethics Committee

Annual Report

01 April 2017 - 31 March 2018

Part 1 – Committee Membership and Training

Name of REC:	London - Chelsea Research Ethics Committee
Type of REC:	REC recognised to review CTIMPs in Healthy Volunteers – Type I REC recognised to review CTIMPs in Patients - Type III
Type of Flag:	Phase 1 in patients and healthy volunteers
Chair:	Dr Michael Schachter
Vice-Chair:	Mrs Patricia Pank (until 01/12/2017) Mr Roger A'Hern (Acting 01/01/2018 - present)
Alternate Vice-Chair:	Mr Roger A'Hern (until 01/01/2018) Mrs Paula Rogers (01/01/2018 - present)
REC Manager:	Dr Sarah Graves
REC Assistant:	Mr Alex Martin (01/04/2017 – 31/07/2017) Vacant (01/08/2017 – 22/08/2017) Miss Alison Doherty (23/08/2017 – 16/01/2018) Miss Charmaine Orchard (17/01/2018- 14/02/2108) Vacant (15/02/2018 – 06/03/2018) Miss Noorisha Rahman (07/03/2018 – 31/03/2018)
Committee Address:	Research Ethics Committee (REC) Bristol Centre Level 3, Block B Whitefriars Lewins Mead Bristol BS1 2NT
Telephone:	0207 1048055
Email:	nrescommittee.london-chelsea@nhs.net

Chair's overview of the past year:

During the past year 3 colleagues have retired or resigned. Replacements are not yet complete and in particular we are looking to strengthen expertise in pharmacy and pharmacology. We are CTIMPS-accredited committee and we have 2-3 CTIMPs application per meeting. At our request the usual number of applications has been reduced from 6 to 5, with the larger number meetings were very long and maintenance of concentration was sometimes difficult. However, we understand that our committee is well-liked by applicants and there is a waiting list. We hope this reflects our positive approach, wanting to facilitate research and giving advice to improve applications whenever possible and only rejecting a small number outright.
We have consistently had really excellent support from Sarah and her colleagues who have often needed to look after additional committees. We have also had very good support from the Bristol office when needed. One issue which may need consideration is the constantly increasing quantity of documents included in each application, most of them entirely irrelevant from an ethical point of view. I very much doubt that we are unique in these concerns.

Dr Michael Schachter

London - Chelsea Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Mr Roger A'Hern	Medical Statistician	Expert	01/06/2010	
Dr Judy Allfrey	Retired Civil Servant	Lay	01/06/2013	11/12/2017
Dr. Sonya Babu-Narayan	Clinical Senior Lecturer and Consultant Cardiologist	Expert	01/06/2010	
Mrs Christine Gratus	Retired Brand & Communication Consultant	Lay Plus	01/04/2017	
Ms Karen Lipworth	Lead Medical Writer	Lay Plus	01/04/2015	
Mr Serge Miodragovic	Ophthalmology Clinical Research Coordinator	Lay	22/05/2013	
Mrs Patricia Pank	Retired University Lecturer	Lay	01/06/2010	11/12/2017
Mrs Paula Rogers	Cardiology Research Nurse	Expert	01/06/2010	
Ms Cate Savidge	CT Scanning Superintendent	Expert	01/06/2010	
Dr Michael Schachter	Clinical Pharmacologist	Expert	01/12/2010	
Miss Ondine Sherwood	IT Consultant	Lay Plus	01/10/2017	
Dr Mary Taj	Consultant Paediatric Oncologist	Expert	01/06/2010	
Miss Isobel Vass	Magistrate	Lay	19/06/2013	
Ms Mary Watkinson	Teacher	Lay Plus	09/10/2015	
Mr Fraser Wilson	Retired Civil Servant	Lay Plus	05/01/2015	

London - Chelsea Research Ethics Committee: Deputy Members

Name	Profession	Status	Meeting date attended

London - Chelsea Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended
Ms Stephanie Ellis	Retired Civil Servant	Lay Plus	10/04/2017, 10/07/2017

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

Name	Declaration of Interest	Date
Mr Roger A'Hern	Retired as ICRCBU Senior Statistician 30/09/2013 but still active in field part time.	31/03/2018
Dr. Sonya Babu-Narayan	British Heart Foundation funded awardyPeer reviewer for grant applications (Wellcome Trust, MRC, BHF and Academy Medical sciences)	31/03/2018
Mrs Christine Gratus	Reviewer for NIHR, ad-hoc member of award panels as requested and selection of chairs for NIHR funding panels.	10/07/2017
Ms Karen Lipworth	Self- employed healthcare communications consultant and medical writer. Clients include pharma and CROs and from time to time does provide advice and writing support for clinical studies.	10/07/2017
Mr Serge Miodragovic	NED at Central & cecil Housing Trust as well as Clinical Trials Manager Opthalmology Imperial College NHS Trust.	10/07/2017
Mrs Patricia Pank	Trustee: Helen Bamber Foundation. University College Foundation Trust, clinical governance emergency services division	10/07/2017
Mrs Paula Rogers	Research Nurse Manager in NHS Trust, responsible for clinical research delivery.	30/03/2018
Ms Cate Savidge	None	06/03/2018
Dr Michael Schachter	None	30/03/2018
Miss Ondine Sherwood	None	28/09/2017
Dr Mary Taj	Mentor/ member of My Child Matter- charity run by Sanofi Aventis	10/07/2017
Miss Isobel Vass	None	10/07/2017
Ms Mary Watkinson	None	30/03/2018
Mr Fraser Wilson	Member of the Imperial College Research Ethics Committee	02/06/2017

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

Month	Date	Number of Members Present at Meeting
April	10/04/2017	9
May	08/05/2017	12
June	12/06/2017	12
July	10/07/2017	11
September	11/09/2017	10
October	09/10/2017	12
November	13/11/2017	14
December	11/12/2017	10
January	08/01/2018	11
February	12/02/2018	11

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	28/04/2017	4
May	31/05/2017	3
June	30/06/2017	3
September	22/09/2017	3
October	27/10/2017	4
November	24/11/2017	3
December	22/12/2017	3
January	26/01/2018	3
February	23/02/2018	3
March	23/03/2018	3

10 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	07/04/2017	2
April	14/04/2017	2
May	05/05/2017	3
May	05/05/2017	2
May	08/05/2017	2
May	11/05/2017	2
May	26/05/2017	2
June	02/06/2017	2
June	09/06/2017	2
June	16/06/2017	2
June	23/06/2017	3

June	23/06/2017	2
June	30/06/2017	2
July	07/07/2017	2
July	14/07/2017	2
July	21/07/2017	2
July	28/07/2017	2
August	04/08/2017	2
August	14/08/2017	2
August	18/08/2017	2
August	25/08/2017	2
September	01/09/2017	2
September	08/09/2017	2
September	15/09/2017	2
September	22/09/2017	2
September	29/09/2017	2
October	06/10/2017	2
October	13/10/2017	2
October	20/10/2017	2
October	27/10/2017	2
November	03/11/2017	2
November	10/11/2017	2
November	17/11/2017	2
November	24/11/2017	2
December	01/12/2017	2
December	08/12/2017	2
December	15/12/2017	2
January	04/01/2018	2
January	12/01/2018	3
January	19/01/2018	2
January	19/01/2018	2
January	26/01/2018	2
February	02/02/2018	2
February	10/02/2018	2
February	16/02/2018	2
February	23/02/2018	2
February	26/02/2018	2
March	02/03/2018	2
March	09/03/2018	2
March	16/03/2018	2
March	23/03/2018	2
March	30/03/2018	2

52 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
Mr Roger A'Hern	9
Dr Judy Allfrey	6
Dr. Sonya Babu-Narayan	6
Mrs Christine Gratus	9
Ms Karen Lipworth	7
Mr Serge Miodragovic	10
Mrs Patricia Pank	7
Mrs Paula Rogers	7
Ms Cate Savidge	7
Dr Michael Schachter	8
Miss Ondine Sherwood	4
Dr Mary Taj	7
Miss Isobel Vass	7
Ms Mary Watkinson	9
Mr Fraser Wilson	7

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

Name	Number of Meetings Attended
Mr Roger A'Hern	2
Dr Judy Allfrey	1
Dr. Sonya Babu-Narayan	3
Mrs Christine Gratus	2
Ms Karen Lipworth	2
Mr Serge Miodragovic	3
Mrs Paula Rogers	3
Ms Cate Savidge	1
Dr Michael Schachter	10
Dr Mary Taj	1
Miss Isobel Vass	2
Ms Mary Watkinson	2

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

Name	Number of Meetings Attended
Mr Roger A'Hern	22
Dr Judy Allfrey	4
Dr. Sonya Babu-Narayan	4

Mrs Christine Gratus	3
Ms Karen Lipworth	4
Mr Serge Miodragovic	6
Mrs Patricia Pank	24
Mrs Paula Rogers	11
Ms Cate Savidge	6
Dr Michael Schachter	7
Dr Mary Taj	4
Miss Isobel Vass	5
Ms Mary Watkinson	4
Mr Fraser Wilson	3

Training 01 April 2017 - 31 March 2018

Name of Member	Date	Event(s) attended
Mrs Christine Gratus	20/07/2017	Equality & Diversity
Mrs Christine Gratus	25/07/2017	Committee Members Induction.
Mrs Christine Gratus	05/10/2017	Introduction to Phase 1 Research - Trials & Regulation
Mrs Christine Gratus	12/12/2017	National Members Training Day
Ms Karen Lipworth	20/07/2017	Reviewing the research design of clinical trials
Ms Karen Lipworth	07/08/2017	Research involving participants lacking mental capacity
Mr Serge Miodragovic	23/01/2018	Complex Cases
Mrs Paula Rogers	25/08/2017	Introduction to Good Clinical Practice eLearning (PrimaryCare)
Ms Cate Savidge	15/08/2017	Equality, diversity and human rights
Ms Cate Savidge	16/08/2017	medical devices
Ms Cate Savidge	21/03/2018	SDL- 2017/18
Dr Michael Schachter	24/11/2017	HRA National Chairs' Day and Policy Event
Dr Michael Schachter	12/12/2017	National Memeber Training Day
Miss Ondine Sherwood	23/01/2018	Complex Cases
Miss Isobel Vass	27/02/2018	Research involving participants lacking mental capacity
Miss Isobel Vass	29/03/2018	Research Involving Human Tissue
Miss Isobel Vass	29/03/2018	Use of HRA Schedule of Events
Ms Mary Watkinson	23/05/2017	Medical Devices Training Day
Mr Fraser Wilson	12/12/2017	National Members Training Day

PART 2: REC WORKLOAD AND ACTIVITY DURING THE REPORTING PERIOD

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

Applications for full ethical review – Study Type	Number	%
Clinical Trial of Investigational Medicinal Product	24	45.28
Phase 1	1	1.89
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	0	0.00
Others	28	52.83
Total Applications Reviewed	**53**	**100**

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

Number of applications made invalid by the REC Manager	0
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	17
Number of paediatric applications reviewed	11
Number of device applications reviewed	2
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	6

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

Decisions taken at meetings following review of applications	Number	%
Favourable Opinion with Standard Conditions	2	3.77
Favourable Opinion with Additional Conditions	18	33.96
Unfavourable Opinion	2	3.77
Provisional Opinion	30	56.60
Provisional Opinion Pending Consultation with Referee	1	1.89
Total	**53**	**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	30	56.60
Further Information Favourable Opinion with Additional Conditions	1	1.89
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	2	3.77
Favourable Opinion with Additional Conditions	18	33.96
Unfavourable Opinion	2	3.77
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	0	0.00
Total	**53**	**100**

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

Total Applications Reviewed	**24**

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

Number of applications made invalid by the REC Manager	3
Number of studies withdrawn prior to the meeting	2
Number of student applications reviewed	11
Number of paediatric applications reviewed	3
Number of device applications reviewed	0
Number of qualitative applications reviewed	3

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

Decisions taken at proportionate review sub-committee meetings	**Number**	**%**
Favourable Opinion with Standard Conditions	10	41.67
Favourable Opinion with Additional Conditions	7	29.17
No Opinion transfer to full committee for review	1	4.17
Provisional Opinion	6	25.00
Unfavourable Opinion	0	0.00
Total	**24**	**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	5.30
Number of completed applications for full ethical review	53
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	18
Number of completed applications over 40 days as a % of total	33.96%
Number of days taken to final decision – average (mean)	34

Number of completed proportionate review applications for ethical review	23
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	11
Number of completed applications for SSA review over 25 days	1
Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs	9.09%

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	178
Number of completed substantial amendments over 35 days	4
Number of completed substantial amendments over 35 days as a % of total substantial amendments	2.25%
Number of completed substantial amendments over 28 days	49
Number of completed substantial amendments over 28 days as a % of total substantial amendments	27.53%

Number of modified amendments reviewed	2
Number of completed modified amendments over 14 days	0
Number of completed modified amendments over 14 days as a % of total modified amendments	0.00%

Number of non substantial amendments received	121
Number of substantial amendments received for information	3
Number of substantial amendments received for new sites/PIs	39
Number of annual progress reports received	85
Number of safety reports received	123
Number of Serious Adverse Events received	0

Number of final reports received	6

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/0553	Genome Instability in Childhood Obesity (GICO)	42
17/LO/0633	Phase 1 study of IMCY-0098 in Recent Onset Type 1 Diabetes	48
17/LO/0760	Health-related physical fitness of TYA during chemotherapy treatment	34
17/LO/0767	GEMMK	45
17/LO/0787	Supporting BRCA carriers through risk reducing decision making v1.0	46
17/LO/0821	Examining effects of mixed arts programmes on inpatients with dementia	50
17/LO/0848	1943: Safety & Efficacy of SEL in Patients w/ NASH & Bridging Fibrosis	51
17/LO/0849	1944: Safety & Efficacy of SEL in Patients w/ Cirrhosis due to NASH	51
17/LO/0900	BIOPS	59
17/LO/0960	Phase 1b/2a Study of ABI-H0731 in Patients With Chronic Hepatitis B	28
17/LO/1458	ASD-Probiotic V.1	45
17/LO/1473	FRAME: Phase I trial of VS-6063 and RO5126766 (CH5126766)	26
17/LO/1495	Electro-cortical Processing in Anorexia Nervosa: An ERP Study	32
17/LO/1687	The EAT-On Study: Sensitisation, Allergy and Obesity V 2.0	44
17/LO/1690	ASTIClite	35
17/LO/1706	Pilot study to support medication adherence following ACS	40
17/LO/1750	VALENCIA	38
17/LO/1771	Analysis of gait patterns before and after foot arthrodesis surgery	36
17/LO/1811	Study of CHF6366 in healthy subjects and patients with Asthma and COPD	30
17/LO/1888	VIT-D 250	25
17/LO/1928	Social media use, eating disorders and recovery	59
17/LO/1932	Weight management with fitness trackers in CVD prevention v1	45
17/LO/2032	Study to evaluate CORT125281 with Enzalutamide in patients with mCRPC	43
17/LO/2075	Efficacy & Safety of FG-4592 in Anaemia with Lower Risk MDS & RBC LTB	32
18/LO/0014	OpACIN-neo	57
18/LO/0025	What factors break the Scarlet Fever Transmission Chain?	43
18/LO/0040	The LUCIDITY Study	59
18/LO/0126	Phase 1 study of WVE-210201 in patients with DMD	55
18/LO/0170	MK-3475 as neoadjuvant / adjuvant therapy in LA HNSCC	33
18/LO/0171	In-Lab Viability	23

Further Information Favourable Opinion with Additional Conditions		
REC Reference	**Title**	**Number of Days on Clock**
17/LO/0591	First-in-human dose-escalation study of ATR inhibitor BAY 1895344	35

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/0731	PIVOTALBoost	25
17/LO/1494	Chronic Conditions to Education	29

Favourable Opinion with Additional Conditions		
REC Reference	**Title**	**Number of Days on Clock**
17/LO/0497	IMCgp100-202 Phase II Study in Advanced Uveal Melanoma	25
17/LO/0584	HERPET	25
17/LO/0585	Wellbeing Network Mapping: Pilot Study	25
17/LO/0624	Normal lymphoscintigraphy values to unravel breast cancer lymphoedema	25
17/LO/0736	251PP301 Phase IIb Efficacy and Safety Progressive Supranuclear Palsy	25
17/LO/0956	Heart Beat Study – Version 1	24
17/LO/1054	GSK525762 in CRPC	24
17/LO/1088	VX15-770-126 Cystic Fibrosis	24
17/LO/1091	MK-3682B in Hepatitis C Virus (HCV) Genotype 3 (GT3) participants	24
17/LO/1129	An adaptive orthosis for hand osteoarthritis; feasibility & prototype	24
17/LO/1664	The experience of only-eye surgery	24
17/LO/1862	A Phase I/IIa trial of BT1718 in patients with advanced solid tumours	24
17/LO/2068	RCT of RFA vs sham procedure for symptomatic cervical inlet patch	21
17/LO/2101	Concepts of recovery in Chronic Fatigue Syndrome	21
18/LO/0006	C101: Phase I study of GM102 in Gynaelogical Cancer	25
18/LO/0037	Students' experiences of Recovery Colleges. V1.	41
18/LO/0124	ALN-AT3SC-003	18
18/LO/0196	FIRST1D	18

Unfavourable Opinion		
REC Reference	**Title**	**Number of Days on Clock**
17/LO/1120	Clients' viewpoints around chronic-pain acceptance post drop out.	24
17/LO/1721	The Midwives and Mothers Listening Project	22

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

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

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

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

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/0938	"Quantitative tests for binocular vision"	21
17/LO/1122	AMD QoL	19
17/LO/1125	HJHS-VAPS v1.1	19
17/LO/1872	Measuring health status in sarcoidosis	20
17/LO/1884	Impact of malocclusion and orthodontic treatment	14
18/LO/0566	VITAMIN D USE AMONG INFANTS OF AFRICAN AND ASIAN IMMIGRANT IN GLASGOW	18

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/0756	Import of samples from a long-term bed rest study	13
17/LO/2051	Pleural Ultrasound after Pleurodesis for Pneumothorax - A Pilot Study	8
17/LO/2054	The Prevalence of HGD/OAC in Barrett's LGD/IND	7
18/HRA/0229	MIRA	13
18/LO/0210	CLASSIC	18
18/LO/0212	Adherence to secondary prevention in patients with vascular disease	15
18/LO/0384	SENIOR Transplant Registry	12
18/LO/0568	Developing and testing a measure of quality of transition.	8
18/LO/0573	Service user experience of implementing hip precautions following THR	8
18/LO/0574	Exploring patients motivations to participate in health research	9

Favourable Opinion with Additional Conditions		
REC Reference	**Title**	**Number of Days on Clock**
17/LO/0758	EuroEndo	15
17/LO/0942	COALS: Coagulation in Liver Surgery	15
17/LO/1657	Lung Function Indicies and Health Status Score in COPD	12
17/LO/1876	Long term follow up of ECLIPSE trial cohort	10
17/LO/2144	Weight Related Health Behaviours during Pregnancy and Following Birth	13
17/LO/2147	Healthy lifestyle choices in people with severe mental illness	11
18/LO/0357	2nd International closeness survey	12

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**
04/Q0801/60/AM13	Molecular characterisation of hormone refractory prostate cancer	Amendment 15 - Protocol v16 da	06/06/2017	23
06/Q0801/37/AM08	Avoiding Surgery in Rectal Cancer After Pre-Operative Therapy	Amendment No9 VER 18 15/09/201	27/11/2017	14
07/H0801/135/AM04	SEPARATION OF CIRCULATING TUMOUR CELLS USING APHERESIS IN PATIENTS WIT	3	04/05/2017	31
09/H0801/49/AM06	Surveillance Ultrasound of Nodes in Melanoma	Amendment 5 (Protocol Amendmen	02/10/2017	21
10/H0801/45/AM02	The molecular differences between preterm labour phenotypes	Amendment No 1, 27th March, 20	27/03/2017	26
10/H0801/51/AM06	An investigation of knee joint functioning	SA4	12/06/2017	14
11/LO/0003/AM04	Exploratory Analysis of Genomic Signatures of Progression in Melanoma	Amendment 4 08.08.2017	08/08/2017	15
11/LO/0043/AM47	ICON8: Weekly Chemotherapy in Ovarian Cancer v1.0	Substantial Amendment ICON8_SA	02/05/2017	28
11/LO/0043/AM48	ICON8: Weekly Chemotherapy in Ovarian Cancer v1.0	8	10/07/2017	23
11/LO/1563/AM13	Viamet Phase I/II Study VMT-VT-464-CL-001	SA11	24/05/2017	24
11/LO/1563/AM16	Viamet Phase I/II Study VMT-VT-464-CL-001	SA14 - IB 007 and PIS/ICF V12	06/10/2017	24
11/LO/1619/AM20	Comparing safety & efficacy of AI/lapatanib/trastuzumab in HR+HER2 MBC	Substantial Amendment 6 - date	08/03/2017	29
11/LO/1915/AM17	Phase III prostate cancer trial: surgery, radiotherapy, stereotactic	SA10 - 18 July 2017	18/07/2017	26
11/LO/1974/AM08	Extension Study with AMG 145 in Subjects With Hypercholesterolemia	SA8- End of Study PIS	03/08/2017	32
12/LO/0565/AM18	A phaseIb/II study of GDC-0068 or GDC-0980 in patients with CRPC	Protocol V6, Investigator's Br	01/12/2017	32
13/LO/1252/AM14	The MILO Study (MEK Inhibitor in Low-grade Serous Ovarian Cancer)	Substantial Amendment 11	10/05/2017	28

		dated		
13/LO/1265/AM28	First in Human, Dose-Escalating Study of HuMaXÂ®-TF-ADC in solid Tumour	Substantial Amendment 18 - 10.	10/05/2017	28
13/LO/1265/AM31	First in Human, Dose-Escalating Study of HuMaXÂ®-TF-ADC in solid Tumour	Protocol v15.0, IB Ed 14, PIS	09/10/2017	29
13/LO/1730/AM03	Voices over time	Substantial amendment dated 5t	05/05/2017	29
14/LO/0372/AM10	Vertex VX13-970-002	IB Version 6 and IB Version 6	22/06/2017	28
14/LO/0372/AM11	Vertex VX13-970-002	IB v7.0, IB v7.0 Add 1.0, ICF	29/09/2017	10
14/LO/0372/AM12	Vertex VX13-970-002	PI and CI changes	26/09/2017	11
14/LO/0650/AM02	THE BIOLOGICAL BASIS OF REPRODUCTIVE DEPRESSION	AM02_SA2 dated 15 May 2017	15/05/2017	30
14/LO/0650/AM03	THE BIOLOGICAL BASIS OF REPRODUCTIVE DEPRESSION	3	21/08/2017	21
14/LO/0673/AM14	MLN9708 in Multiple Myeloma after Autologous Stem Cell Transplant	AM2 Global AM Pack 8 & 9	21/04/2017	22
14/LO/0673/AM15	MLN9708 in Multiple Myeloma after Autologous Stem Cell Transplant	Global Substantial Amendment P	29/11/2017	34
14/LO/0673/AM16	MLN9708 in Multiple Myeloma after Autologous Stem Cell Transplant	Global Amendment Package 11 JA	28/03/2018	19
14/LO/0712/AM13	Phase 1 Study of GSK2857916 in Subjects with Haematologic Malignancies	SA06 Protocol Amendment 05	22/11/2017	34
14/LO/1053/AM09	(duplicate) Momelotinib vs. Ruxolitinib in subjects with Myelofibrosis	SA7 IB ProtocolPIS/ICF dated 1	14/08/2017	34
14/LO/1068/AM06	Randomised study of Adalimumab in subjects with Ulcerative Colitis.	SA05 - IB v23.1 dated 26 Jun 2	26/06/2017	32
14/LO/1151/AM15	1280.8 - BI 836845 in metastatic castration resistant prostate cancer	SA11 dated 11 August 2017	11/08/2017	27
14/LO/1151/AM18	1280.8 - BI 836845 in metastatic castration resistant prostate cancer	Substantial amendment #12	11/01/2018	27
14/LO/1151/AM20	1280.8 - BI 836845 in metastatic castration resistant prostate	Substantial	06/02/2018	14

	cancer	amendment #13		
14/LO/1163/AM08	Drug-Drug interaction study with ARN509 and abiraterone	56021927PCR1010 Substantial Am	27/10/2017	16
14/LO/1568/AM11	TIER	SA10 dated 18 May 2017	18/05/2017	34
14/LO/1598/AM15	Phase 1 - study of GSK2636771 plus Enzalutamide in mCRProstate Cancer	SA11 - Dose Expansion Phase Di	18/10/2017	9
14/LO/1981/AM05	PIPA: Combination of PI3 kinase inhibitors and PAlbociclib	SA04- dated 18 April 2017	18/04/2017	23
14/LO/1994/AM33	The AMARANTH Study	Sub amend 21	01/08/2017	34
14/LO/1994/AM35	The AMARANTH Study	Amendment 23 – Change in Princ	28/09/2017	19
15/LO/0016/AM08	Monarch 3: Breast Cancer in Postmenopausal Women (JPBM Study)	SA6 - 24.03.2017	24/03/2017	28
15/LO/0016/AM09	Monarch 3: Breast Cancer in Postmenopausal Women (JPBM Study)	IB (15Sep17), ICD V6	11/10/2017	26
15/LO/0165/AM13	56021927PCR3001 - Prostate Cancer Study	UK EC Substantial Amendment #8	11/10/2017	8
15/LO/0165/AM14	56021927PCR3001 - Prostate Cancer Study	UK EC Substantial Amendment #9	02/11/2017	11
15/LO/0165/AM15	56021927PCR3001 - Prostate Cancer Study	SA10 Change in PI	30/01/2018	11
15/LO/0165/AM16	56021927PCR3001 - Prostate Cancer Study	SA11 - Investigator Brochure E	23/02/2018	25
15/LO/0344/AM07	VX-803-001 in Subjects With Advanced Solid Tumours or Lymphoma	Sponsor Change - Protocol v5.0	18/09/2017	14
15/LO/0344/AM08	VX-803-001 in Subjects With Advanced Solid Tumours or Lymphoma	SA#7 IB and ICF's	23/11/2017	11
15/LO/0344/AM09	VX-803-001 in Subjects With Advanced Solid Tumours or Lymphoma	SA#8 Protocol V4	13/03/2018	34
15/LO/0404/AM05	TORCMEK	SA 3.0	10/10/2017	15
15/LO/0548/AM07	The role of Home packs of HIV PEPSE in High Risk Individuals	IMPD Version 3 01 sep 2017 and	11/10/2017	34
15/LO/0638/AM14	PAVE trial v1.0	Substantial amendment 15 13/12	13/12/2017	15

15/LO/0834/AM14	WO29522 - A Study of MPDL3280A and Nab-paclitaxel in Breast Cancer	Amendment 14 (Substantial) - A	27/07/2017	19
15/LO/0834/AM15	WO29522 - A Study of MPDL3280A and Nab-paclitaxel in Breast Cancer	Amendment 15	28/11/2017	6
15/LO/0834/AM16	WO29522 - A Study of MPDL3280A and Nab-paclitaxel in Breast Cancer	Amendment 16 substantial amend	29/03/2018	8
15/LO/0958/AM08	AZD1775 in patients with Ovarian, Fallopian Tube, or Peritoneal Cancer	AM08_CSP v7 dated 20/01/17	20/01/2017	28
15/LO/0958/AM09	AZD1775 in patients with Ovarian, Fallopian Tube, or Peritoneal Cancer	Amendment 7	12/09/2017	11
15/LO/0958/AM10	AZD1775 in patients with Ovarian, Fallopian Tube, or Peritoneal Cancer	D6010C00004 Substantial Amendm	17/11/2017	18
15/LO/0958/AM13	AZD1775 in patients with Ovarian, Fallopian Tube, or Peritoneal Cancer	Substantial Amendment 11 - CSP	09/03/2018	17
15/LO/1132/AM08	A Phase II Study of Pembrolizumab in Subjects with Triple-Negative Breast Cancer	SA06 Main PIS/ICF update dated	16/08/2017	22
15/LO/1132/AM09	A Phase II Study of Pembrolizumab in Subjects with Triple-Negative Breast Cancer	SA07 - IBV15	01/11/2017	12
15/LO/1132/AM10	A Phase II Study of Pembrolizumab in Subjects with Triple-Negative Breast Cancer	SA08 - Protocol 02, PIS/CF 8.0	26/02/2018	16
15/LO/1166/AM14	Efficacy and Safety of RTH258 versus Aflibercept	5	22/01/2018	19
15/LO/1174/AM09	Open label ISIS 420915-CS3	SA 2017/02/22	22/02/2017	25
15/LO/1174/AM10	Open label ISIS 420915-CS3	updated patient dosing diary 1	16/06/2017	35
15/LO/1175/AM10	RPC01-3101 True North study	SA11 Protocol Amendment	30/10/2017	13
15/LO/1175/AM12	RPC01-3101 True North study	Protocol V4, ICFv5.0	07/02/2018	27
15/LO/1364/AM01	CHEER	AM01_Amendment 1 dated 03/05/2	03/05/2017	32
15/LO/1478/AM02	The PEAR Study	SA2 dated 13 April 2017	13/04/2017	34
15/LO/1502/AM04	Phase I study of IPH4102 treatment in patients with CTCL	Substantial	11/05/2017	28

		amendment 4 - Prot		
15/LO/1502/AM05	Phase I study of IPH4102 treatment in patients with CTCL	Substantial 5 - dated 25 July	25/07/2017	18
15/LO/1502/AM07	Phase I study of IPH4102 treatment in patients with CTCL	SA7- dated 2 October 2017	02/10/2017	14
15/LO/1502/AM09	Phase I study of IPH4102 treatment in patients with CTCL	SA08 - Stop of recruitment	13/02/2018	14
15/LO/1512/AM12	RPC01-3102 Open-label extension study	SA11 Protocol Amendment	31/10/2017	13
15/LO/1512/AM13	RPC01-3102 Open-label extension study	SA12	30/01/2018	11
15/LO/1668/AM01	Gut Hormones after Oesophagectomy and Gastrointestinal Symptoms	AM01- substantial amendment 1	13/11/2016	28
15/LO/2207/AM01	Assessing Circulating Tumour Cells as biomarkers for colorectal cancer	Substantial amendment 1 dated	18/07/2017	21
16/LO/0180/AM02	Role of avastin and 5-fluorouracil in trabeculectomy surgery (RAFTS)	AM02- SA1 dated 23 May 2017	23/05/2017	27
16/LO/0396/AM08	PHysical activity Implementation Study In Community-dwelling AduLts	AM08_Amendment 6, SA0317, dat	25/03/2017	27
16/LO/0585/AM03	NeoART version 1.0	SAM02_AM03	28/07/2017	32
16/LO/0585/AM11	NeoART version 1.0	SAM06_AM09	15/11/2017	4
16/LO/0586/AM10	Multiple Sclerosis Study Using Ocrelizumab	SA07 Update to docs (validated	16/08/2017	23
16/LO/0586/AM11	Multiple Sclerosis Study Using Ocrelizumab	SA08 - Protocol v4, IB V15 Add	22/11/2017	8
16/LO/0586/AM13	Multiple Sclerosis Study Using Ocrelizumab	SA09 - Ocrelizumab Investigato	11/01/2018	24
16/LO/0595/AM06	monarcHER: Phase 2, 3-Arm, Study in Women with Advanced Breast Cancer	am06_Substantial 5,updated IB,	07/04/2017	26
16/LO/0595/AM08	monarcHER: Phase 2, 3-Arm, Study in Women with Advanced Breast Cancer	IB 15Sep17, ICF V7	27/10/2017	24
16/LO/0610/AM02	Prematurity and the Lipid Profiles of Newborns	Amendment 2	12/10/2017	14
16/LO/0610/AM03	Prematurity and the Lipid Profiles of Newborns	Amendment 3	08/02/2018	35
16/LO/0682/AM03	The Reproductive Life Course Project V1.0	Substantial	12/01/2017	25

		Amendment 1.4 12/0		
16/LO/0994/AM01	A phase 1/2 study of DTX-SPL8783 in advanced solid tumours or in NSCLC	Substantial Amendment 1 dated	05/04/2017	28
16/LO/0994/AM02	A phase 1/2 study of DTX-SPL8783 in advanced solid tumours or in NSCLC	AM02_UK02 dated 30 May 2017	30/05/2017	35
16/LO/1083/AM04	QuANTUM-First	2	28/06/2017	24
16/LO/1083/AM05	QuANTUM-First	SA3 - ProtV2 IBV10 Updated ICF	15/08/2017	35
16/LO/1083/AM06	QuANTUM-First	SA4: Main ICFv7.0 and FLT3-ITD	21/11/2017	9
16/LO/1133/AM04	MK-3475 in the Treatment of Recurrent/Metastatic Head and Neck Cancer	AM04_SA05 - Protocol amendment	09/05/2017	28
16/LO/1169/AM02	Determining the effects of gut content on satiety	Amendment number: 2, 12/06/201	12/06/2017	31
16/LO/1169/AM03	Determining the effects of gut content on satiety	Amendment number: 3, 12/02/201	12/02/2018	15
16/LO/1209/AM01	Peer Support for Late Presenters	SA1	30/03/2017	31
16/LO/1272/AM02	IntellO2 vs Manual Control for Optimizing Oxygenation in Infants	Amendment #2 11 September 2017	11/09/2017	20
16/LO/1424/AM04	Clearing Lungs With ENaC Inhibition in Primary Ciliary Dyskinesia	PS-G202_Sub Am 003_Patient Doc	26/09/2017	25
16/LO/1424/AM05	Clearing Lungs With ENaC Inhibition in Primary Ciliary Dyskinesia	PS-G202_Sub Am 004_Ivacaftor I	01/09/2017	10
16/LO/1424/AM06	Clearing Lungs With ENaC Inhibition in Primary Ciliary Dyskinesia	PS-G202_Sub Am 005_VX-371 IB V	21/11/2017	35
16/LO/1514/AM09	Phase III Study of MK-3475 + Best Supportive Care in Subjects with HCC	SA04 - main PIS/ICF update dat	07/08/2017	33
16/LO/1514/AM10	Phase III Study of MK-3475 + Best Supportive Care in Subjects with HCC	SA06 - IB Edition 15	11/10/2017	33
16/LO/1514/AM11	Phase III Study of MK-3475 + Best Supportive Care in Subjects with HCC	SA07 - Protocol 03 & ICF 6.0	02/03/2018	18
16/LO/1566/AM03	KORTUC	AM03_AM1704/08	11/05/2017	33

16/LO/1566/AM04	KORTUC	AM1707/42 - 20 July 2017	20/07/2017	26
16/LO/1566/AM05	KORTUC	AM1710/48	27/10/2017	17
16/LO/1566/AM06	KORTUC	AM1711/83 1.0	28/12/2017	36
16/LO/1686/AM03	BARCODE 2	BARCODE 2 Substantial Amendmen	29/06/2017	26
16/LO/1735/AM02	The Mini Linguistic State Examination (MLSE)	2.0 - 24.04.2017	24/04/2017	25
16/LO/1735/AM03	The Mini Linguistic State Examination (MLSE)	5.0 - 08/12/2017	20/12/2017	27
16/LO/1753/AM03	Education delivery for the low FODMAP diet	2	23/01/2018	13
16/LO/1782/AM06	Phase Ib/II Trial of Pembrolizumab (MK-3475) in Combination Therapies	SA03 Protocol and Main PIS/ICF	09/08/2017	17
16/LO/1782/AM07	Phase Ib/II Trial of Pembrolizumab (MK-3475) in Combination Therapies	SA07 - IB15 & PIS/CF update	01/11/2017	12
16/LO/1782/AM08	Phase Ib/II Trial of Pembrolizumab (MK-3475) in Combination Therapies	SA08 – Protocol 04 + PIS/ICF 8	19/02/2018	29
16/LO/1785/AM01	MRI Pouchography	SA1 dated 16/05/17	16/05/2017	35
16/LO/2128/AM05	PANORAMA V1.0 15Aug2016	UK SubAM01 Change of CI and PI	13/09/2017	24
16/LO/2137/AM02	A Phase 1 Study of Durvalumab & IPH2201 in Adults with advance tumours	Substantial Amendment 2 dated	31/03/2017	32
16/LO/2137/AM03	A Phase 1 Study of Durvalumab & IPH2201 in Adults with advance tumours	SA3 - 32.05.2017	23/05/2017	30
16/LO/2137/AM04	A Phase 1 Study of Durvalumab & IPH2201 in Adults with advance tumours	Substantial Amendment 4	14/07/2017	27
16/LO/2137/AM05	A Phase 1 Study of Durvalumab & IPH2201 in Adults with advance tumours	REC Substantial Amendment 5 (M	22/08/2017	30
16/LO/2137/AM07	A Phase 1 Study of Durvalumab & IPH2201 in Adults with advance tumours	Investigator's Brochure for Du	13/03/2018	13
16/LO/2148/AM03	Intraprostatic PRX302 injection to treat localised prostate cancer /2b	AM03- Intro of PIL, SA dated 0	05/04/2017	28
16/LO/2150/AM02	OCTOVA	002	10/07/2017	19
16/LO/2150/AM05	OCTOVA	SubAmend003 dated 18 August 20	18/08/2017	30

16/LO/2150/AM08	OCTOVA	SubAmend004	20/02/2018	20
16/LO/2157/AM01	An efficacy,safety and tolerability study of Fosmetpantotenate in PKAN	AM01_ Substantial amendment	02/06/2017	24
16/LO/2157/AM02	An efficacy,safety and tolerability study of Fosmetpantotenate in PKAN	PIS & ICF-Related Travel thr G	31/07/2017	32
16/LO/2157/AM03	An efficacy,safety and tolerability study of Fosmetpantotenate in PKAN	Dosing Instructions, v2.0 date	13/09/2017	26
16/LO/2157/AM04	An efficacy,safety and tolerability study of Fosmetpantotenate in PKAN	PIS ICF and recruitment materi	15/02/2018	31
16/LO/2261/AM01	Platelet-rich plasma and fat graft for diabetic ulcer	Amendment No.1 21/04/2017	21/04/2017	25
16/LO/2261/AM02	Platelet-rich plasma and fat graft for diabetic ulcer	no2 dated 3 Aug 2017	03/08/2017	13
16/LO/2261/AM03	Platelet-rich plasma and fat graft for diabetic ulcer	1.3	08/01/2018	17
17/LO/0005/AM01	The PAPAYA Study	SA1 - 24.05.24	24/05/2017	26
17/LO/0011/AM02	VEROnA	Substantial Amendment 2 dated	18/07/2017	28
17/LO/0017/AM04	Open-label Extension Study for Participants with Prostate Cancer	AM04_Substantial amendemnt 4 d	30/05/2017	14
17/LO/0064/AM01	Study of Mirvetuximab Soravtansine vs standard cancer treatments	Substantial Amendment 1 - 25 M	25/05/2017	31
17/LO/0064/AM02	Study of Mirvetuximab Soravtansine vs standard cancer treatments	Protocol 8 dated 8 May 2017	08/05/2017	27
17/LO/0145/AM01	A Study of CA-170 in participants with Advanced Tumours and Lymphomas	Substantial Amendment: #1 – Pr	15/06/2017	30
17/LO/0145/AM02	A Study of CA-170 in participants with Advanced Tumours and Lymphomas	Substantial Amendment 2	28/02/2018	25
17/LO/0272/AM04	Extension Study of UTX-TGR-304	sa#02 dated 8 December 2017	08/12/2017	33
17/LO/0497/AM01	IMCgp100-202 Phase II Study in Advanced Uveal Melanoma	Substantial Amendment 1 - 11.0	11/07/2017	31
17/LO/0497/AM03	IMCgp100-202 Phase II Study in Advanced Uveal Melanoma	IMCgp100-202 -	21/12/2017	27

		Amendment 19Dec		
17/LO/0585/AM01	Wellbeing Network Mapping: Pilot Study	1 - 27.02.2018	27/02/2018	15
17/LO/0591/AM01	First-in-human dose-escalation study of ATR inhibitor BAY 1895344	SA1 Protocol update v2.0	08/06/2017	31
17/LO/0591/AM04	First-in-human dose-escalation study of ATR inhibitor BAY 1895344	SA03 Protocol update v5.0	16/11/2017	44
17/LO/0624/AM01	Normal lymphoscintigraphy values to unravel breast cancer lymphoedema	1	20/07/2017	12
17/LO/0633/AM01	Phase 1 study of IMCY-0098 in Recent Onset Type 1 Diabetes	SA1 - 29.05.2017	29/05/2017	27
17/LO/0633/AM04	Phase 1 study of IMCY-0098 in Recent Onset Type 1 Diabetes	Protocol amendment	30/01/2018	27
17/LO/0731/AM01	PIVOTALBoost	Amendment 01 dated 17th Octobe	16/11/2017	14
17/LO/0736/AM05	251PP301 Phase IIb Efficacy and Safety Progressive Supranuclear Palsy	Substantial Amendment #2	15/12/2017	39
17/LO/0758/AM02	EuroEndo	2	15/08/2017	27
17/LO/0848/AM02	1943: Safety & Efficacy of SEL in Patients w/ NASH & Bridging Fibrosis	SA#2 dated 15 Aug 2017	15/08/2017	23
17/LO/0848/AM04	1943: Safety & Efficacy of SEL in Patients w/ NASH & Bridging Fibrosis	Site Specific PIS ICF (Dr Sher	26/09/2017	13
17/LO/0849/AM02	1944: Safety & Efficacy of SEL in Patients w/ Cirrhosis due to NASH	SA02 Dated 15 August 2017	15/08/2017	23
17/LO/0849/AM04	1944: Safety & Efficacy of SEL in Patients w/ Cirrhosis due to NASH	Site Specific PIS ICF (Dr Sher	26/09/2017	13
17/LO/0960/AM01	Phase 1b/2a Study of ABI-H0731 in Patients With Chronic Hepatitis B	1	26/09/2017	12
17/LO/0960/AM02	Phase 1b/2a Study of ABI-H0731 in Patients With Chronic Hepatitis B	002	01/11/2017	11
17/LO/1054/AM01	GSK525762 in CRPC	Recruitment Materials	19/09/2017	35
17/LO/1088/AM01	VX15-770-126 Cystic Fibrosis	SA01 Patient Materials	21/08/2017	21
17/LO/1088/AM02	VX15-770-126 Cystic Fibrosis	2	27/10/2017	18
17/LO/1088/AM03	VX15-770-126 Cystic Fibrosis	SA03 Patient Materials	26/02/2018	11
17/LO/1458/AM01	ASD-Probiotic V.1	1 15/01/18	15/01/2018	15

17/LO/1687/AM01	The EAT-On Study: Sensitisation, Allergy and Obesity V 2.0	1, dated 19th December 2017	19/12/2017	29
17/LO/1687/AM02	The EAT-On Study: Sensitisation, Allergy and Obesity V 2.0	Substantial Amendment 2	22/02/2018	27
17/LO/1690/AM01	ASTIClite	ASTIClite Substantial Amendmen	03/01/2018	31
17/LO/1750/AM01	VALENCIA	1 2017/11/22	20/12/2017	28
17/LO/1862/AM01	A Phase I/IIa trial of BT1718 in patients with advanced solid tumours	CTA Amendment 01, dated 07 Dec	20/12/2017	27
17/LO/2032/AM01	Study to evaluate CORT125281 with Enzalutamide in patients with mCRPC	SA - 001 - protocol amendment	09/01/2018	5
17/LO/2075/AM01	Efficacy & Safety of FG-4592 in Anaemia with Lower Risk MDS & RBC LTB	Open Label Phase, Open Label I	26/03/2018	20
17/LO/2101/AM01	Concepts of recovery in Chronic Fatigue Syndrome	Amendment 1 05/01/2018	09/01/2018	26
18/LO/0006/AM01	C101: Phase I study of GM102 in Gynaelogical Cancer	UK Substantial Amendment 1	06/02/2018	19
18/LO/0210/AM02	CLASSIC	One 9th March 2018	09/03/2018	21
18/LO/0357/AM01	2nd International closeness survey	SA1 dated 21/03/18	21/03/2018	19

Unfavourable opinion				
Amendment REC Reference	**Title**	**Version**	**Date**	**Number of Days on Clock**
15/LO/0304/AM05	Bubble	05	18/10/2017	27
15/LO/1636/AM08	Effect of Serelaxin on cardiac troponin I release in patients with CHF	AM08 -Second Temporary halt of	28/03/2017	55
16/LO/2137/AM06	A Phase 1 Study of Durvalumab & IPH2201 in Adults with advance tumours	REC SA 6 _ incorporating MHRA	01/02/2018	26
17/LO/0591/AM03	First-in-human dose-escalation study of ATR inhibitor BAY 1895344	SA02 Protocol update v4.0	12/09/2017	35

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**
15/LO/1636/AM08/1	Effect of Serelaxin on cardiac troponin I release in patients with CHF	Re-submission-Second Temporary	02/06/2017	6
17/LO/0591/AM03/1	First-in-human dose-escalation study of ATR inhibitor BAY 1895344	SA02 Protocol update v4.0 - Mo	07/11/2017	2

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**
17/LO/0968	Development, validation and cl	63

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**
15/LO/1636/AM08	Effect of Serelaxin on cardiac troponin I release in patients with CHF	AM08 -Second Temporary halt of	28/03/2017	55
16/LO/1566/AM06	KORTUC	AM1711/83 1.0	28/12/2017	36
17/LO/0591/AM04	First-in-human dose-escalation study of ATR inhibitor BAY 1895344	SA03 Protocol update v5.0	16/11/2017	44
17/LO/0736/AM05	251PP301 Phase IIb Efficacy and Safety Progressive Supranuclear Palsy	Substantial Amendment #2	15/12/2017	39

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