

**London - Dulwich Research Ethics Committee**

**Annual Report**

**01 April 2017 - 31 March 2018**



## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	London - Dulwich Research Ethics Committee
<b>Type of REC:</b>	Recognised to review CTIMPs in Patients Type III
<b>Type of Flag:</b>	Medical Devices
<b>Chair:</b>	Dr Michael Philpot
<b>Vice-Chair:</b>	Mr Colin Standfield
<b>Alternate Vice-Chair:</b>	Dr Thomas Kabir
<b>REC Manager:</b>	Mr Patrick Walsh
<b>REC Assistant:</b>	Stephan Ramey; previously Asha Jama and Charlotte Ferris
<b>Committee Address:</b>	Health Research Authority Skipton House 80 London Road London SE1 6LH
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<b>Email:</b>	nrescommittee.london-dulwich@nhs.net

## Chair's overview of the past year:

During the past year, two long-standing members of the REC left us. I would like to thank Mrs. Catherine Walton for her 11 years of service during which her particular expertise in midwifery and nursing has been a great help to the Committee. I would also like to thank our statistician member Dr Traiani Stari who was with us for 3 years but has moved to live and work away from London. Unfortunately, no new members joined so we need to recruit more experts in the forthcoming year.

Subjectively, workload appears to have increased over the past year although there has been a fall in the number of new studies reviewed at full meetings (41 - compared to 47 in 2016-7). Perhaps the impression that the work is more difficult is due to increasing study complexity: 30% were CTIMPs, and 32% medical devices. All but one study was given a provisional opinion. However, an informal review of the provisional decisions suggested that about a third were limited to changes of wording in the PIS or consent form.

Substantial amendments remained stable compared to previous years. Proportionate review activity varied depending on availability of REC staff but 19 studies were reviewed and 37% received a favourable decision. I would like to thank Dr Joanne Lawson and Anna Ramberg for their invaluable assistance in helping with the PR sub-committee over the last 2 years.

Targets have, on the whole, been met although the average time to final decision for new studies is creeping up again (37 days compared to 29 days in 2016-7).

With regard to training, details are given in the report, but I would like to highlight two events: a medical devices training day held jointly with London-Surrey Borders in November 2017, and a local training day organised by the London Office in March 2018 touching on ethical issues relating to Big Data, the new Clinical Trials Regulation and improving trial participation in young people. In March the REC began reviewing CTIMP applications as part of the EU CT Pilot project.

Lastly, I would like to thank REC Manager Patrick Walsh and his various assistants during the year – Asha Jama and Charlotte Ferris (both promoted within the HRA) and Stephan Ramey, and my fellow officers Colin Standfield (Vice-Chair) and Thomas Kabir (Alternate Vice-Chair).

## London - Dulwich Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Dr Urmi Bapat	Pharmaceutical Physician	Expert	17/07/2014	
Mrs Sophie Bulmer	Programme Manager	Lay Plus	01/09/2016	
Mrs Humra Chadwick	Trial Manager	Expert	01/05/2016	
Mr Stuart Chandler	Pharmacy Clinical Trials Team Leader	Expert	01/06/2016	
Dr Jiafeng Feng	Research Assistant	Lay Plus	01/09/2015	
Mr Kenny Ip	Clinical Trials Specialist	Lay	01/09/2014	
Dr Thomas Kabir	Public Involvement in Research Manager	Lay	10/02/2010	
Dr Martin Keech	Clinical Project Manager	Lay	22/09/2014	
Dr Edward Lavender	GP (retired)	Expert	03/12/2014	
Dr Joanne Lawson	Civil Servant	Lay Plus	11/02/2014	
Dr Michael Philpot	Consultant Psychiatrist	Expert	30/12/2007	
Ms Anna Ramberg	Research Governance & Integrity Manager	Lay Plus	01/10/2010	
Mr Colin Standfield	Charity Worker	Lay	01/02/2012	
Dr Traiani Stari	Associate Director - Biostatistics	Expert	01/09/2015	14/03/2018
Ms Catherine Walton	Consultant Midwife	Expert	30/06/2006	30/06/2017

## London - Dulwich Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended
Ms Stephanie Ellis	Retired Civil Servant	Lay Plus	14/02/2018

## London - Dulwich Research Ethics Committee: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Dr Urmi Bapat	Substantively employed by the Health Foundation, an independent grant-making charity which funds improvement projects in health care. Hold shares in Bristol-Myers Squibb Pharmaceuticals.	07/02/2018
Mrs Sophie Bulmer	Substantively employed by the Health Foundation, an independent grant-making charity which funds improvement projects in health care.	07/02/2018
Mrs Humra Chadwick	Trial Manager in cardiovascular research at Guys and St Thomas Hospital.	07/02/2018
Mr Stuart Chandler	None	15/03/2018
Dr Jiafeng Feng	Support the Department of Cardiovascular Imaging, King's College London, we have clinicians, clinical research fellows working on research projects on devices/technologies on heart diseases.	23/06/2017
Mr Kenny Ip	I am currently working in a global CRO company – PAREXEL as Associate Director in Business development. PAREXEL conducted clinical trial and provides consultation for pharmaceutical companies across the globe.	01/03/2018
Dr Thomas Kabir	Co-applicant on several NIHR funded research studies. I am the Public Involvement in Research Manager at a mental health research charity called the McPin Foundation. My job brings me into contact with many people in the field of health research. Public Involvement in Research Manager at a mental health research charity called the McPin Foundation. My job brings me into contact with many people in the field of health research. I have honorary contracts as a visiting researcher with Kings College London, Cambridge University, and Oxford University. Full corporate member of the Institute of Physics. Member of the trial steering committees of the NIHR funded ENRICH and ECLIPSE studies	01/03/2018
Dr Martin Keech	Shares in GSK and Astra Zeneca	15/03/2018
Dr Edward Lavender	Member of PPI group at Guys St Thomas'	01/02/2018
Dr Joanne Lawson	None	31/03/2018
Dr Michael Philpot	None	15/03/2018
Ms Anna Ramberg	Research Governance & Integrity Manager at City, University of London	07/02/2018
Mr Colin Standfield	Lay member of NICE Appeals Panel	21/02/2018

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

Month	Date	Number of Members Present at Meeting
April	12/04/2017	9
June	14/06/2017	12
July	12/07/2017	11
September	13/09/2017	11
October	11/10/2017	12
December	13/12/2017	11
January	10/01/2018	11
February	14/02/2018	8
March	14/03/2018	9

9 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	20/04/2017	3
May	18/05/2017	4
June	29/06/2017	4
July	28/07/2017	3
August	25/08/2017	3
September	22/09/2017	4
October	27/10/2017	4

7 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	06/04/2017	2
May	10/05/2017	2
May	15/05/2017	2
May	31/05/2017	2
June	14/06/2017	2
June	28/06/2017	2
July	06/07/2017	2
July	17/07/2017	3
July	31/07/2017	2
August	15/08/2017	2
August	31/08/2017	2
September	15/09/2017	2
September	30/09/2017	3
October	02/10/2017	2
October	15/10/2017	2

October	18/10/2017	2
October	31/10/2017	2
November	15/11/2017	2
December	07/12/2017	2
December	22/12/2017	3
January	12/01/2018	2
January	26/01/2018	2
February	09/02/2018	2
February	23/02/2018	2
March	09/03/2018	2
March	16/03/2018	2
March	23/03/2018	2

27 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
Dr Urmi Bapat	5
Mrs Sophie Bulmer	7
Mrs Humra Chadwick	5
Mr Stuart Chandler	7
Dr Jiafeng Feng	6
Mr Kenny Ip	7
Dr Thomas Kabir	7
Dr Martin Keech	7
Dr Edward Lavender	7
Dr Joanne Lawson	5
Dr Michael Philpot	9
Ms Anna Ramberg	7
Mr Colin Standfield	8
Dr Traiani Stari	6

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

Name	Number of Meetings Attended
Dr Edward Lavender	5
Dr Joanne Lawson	7
Dr Michael Philpot	7
Ms Anna Ramberg	5
Mr Colin Standfield	1

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

Name	Number of Meetings Attended
Mr Stuart Chandler	5
Dr Thomas Kabir	10
Dr Martin Keech	12
Dr Joanne Lawson	1
Dr Michael Philpot	25
Ms Anna Ramberg	1
Mr Colin Standfield	1
Dr Traiani Stari	1

## Training 01 April 2017 - 31 March 2018

Name of Member	Date	Event(s) attended
Dr Urmi Bapat	15/11/2017	Medical Devices
Dr Urmi Bapat	12/12/2017	National Members training day
Dr Urmi Bapat	28/02/2018	Phase one research
Mrs Sophie Bulmer	15/11/2017	Medical Devices
Mrs Humra Chadwick	15/11/2017	Medical Devices
Mr Stuart Chandler	15/11/2017	Medical Devices
Dr Jiafeng Feng	08/06/2017	Seminar with case study on PPI in clinical research
Dr Jiafeng Feng	11/06/2017	Emanuel Ezekiel J, Wendler David, Killen Jack, and Grady Christine, Perspective, What Makes Clinical Research in Developing Countries Ethical
Mr Kenny Ip	01/09/2017	"Research ethics for emerging trial designs: does equipoise need to adapt?"
Mr Kenny Ip	02/10/2017	I read the following paper from work as part of the professional training - Phase I MHRA Accreditation Requirements
Mr Kenny Ip	03/10/2017	MHRA GCP which included research ethics updates
Mr Kenny Ip	01/12/2017	PAREXEL - Regulatory Authorities and Ethics Committees
Dr Thomas Kabir	08/03 2017	Regional Members Training day
Dr Thomas Kabir	03/05/2017	REC Chair Meeting
Dr Martin Keech	12/12/2017	National Members training day
Dr Edward Lavender	15/11/2017	Medical Devices
Dr Edward Lavender	18/01/2018	Quantitative research
Dr Joanne Lawson	15/11/2017	Medical Devices
Dr Michael Philpot	15/11/2017	Medical Devices training
Dr Michael Philpot	24/11/2017	National Chair's Training Day
Ms Anna Ramberg	12/12/2017	National Members training day
Ms Anna Ramberg	07/02/2018	Introduction to Phase one research
Ms Anna Ramberg	13/02/2018	The Ethical Issues of Research Involving Children
Mr Colin Standfield	15/11/2017	Medical Devices training
Mr Colin Standfield	08/03/2018	Regional 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:**

<b>Applications for full ethical review – Study Type</b>	<b>Number</b>	<b>%</b>
Clinical Trial of Investigational Medicinal Product	12	29.27
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	0	0.00
Others	29	70.73
<b>Total Applications Reviewed</b>	<b>41</b>	<b>100</b>

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

Number of applications made invalid by the REC Manager	2
Number of applications withdrawn prior to the meeting	2
Number of student applications reviewed	7
Number of paediatric applications reviewed	3
Number of device applications reviewed	13
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**

<b>Decisions taken at meetings following review of applications</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	1	2.44
Unfavourable Opinion	0	0.00
Provisional Opinion	40	97.56
Provisional Opinion Pending Consultation with Referee	0	0.00
<b>Total</b>	<b>41</b>	<b>100</b>
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**

<b>Status of applications at date of generation of report</b>	<b>Number</b>	<b>%</b>
Further Information Favourable Opinion with Standard Conditions	38	92.68
Further Information Favourable Opinion with Additional Conditions	1	2.44
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	1	2.44
Unfavourable Opinion	0	0.00
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	1	2.44
<b>Total</b>	<b>41</b>	<b>100</b>

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

<b>Total Applications Reviewed</b>	<b>19</b>
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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	3
Number of studies withdrawn prior to the meeting	1
Number of student applications reviewed	6
Number of paediatric applications reviewed	4
Number of device applications reviewed	1
Number of qualitative applications reviewed	2

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

<b>Decisions taken at proportionate review sub-committee meetings</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	3	15.79
Favourable Opinion with Additional Conditions	4	21.05
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	12	63.16
Unfavourable Opinion	0	0.00
<b>Total</b>	<b>19</b>	<b>100</b>

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

<b>Average number of applications reviewed per full meeting</b>	4.56
<b>Number of completed applications for full ethical review</b>	40
<b>Number of completed applications for full ethical review over 60 days</b>	0
<b>Number of completed applications over 60 days as a % of total</b>	0.00%
<b>Number of days taken to final decision – average (mean)</b>	37
<b>Number of completed proportionate review applications for ethical review</b>	19
<b>Number of completed proportionate review applications for ethical review over 21 days</b>	1
<b>Number of completed proportionate review applications over 21 days as a % of total</b>	5.26%
<b>Number of SSAs (non-Phase 1) reviewed</b>	3
<b>Number of completed applications for SSA review over 25 days</b>	1
<b>Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs</b>	33.33%
<b>Number of SSAs (Phase 1) reviewed</b>	0
<b>Number of completed applications for SSA review over 14 days</b>	0
<b>Number of completed applications for SSA review over 14 days as % of all Phase 1 SSAs</b>	0.00%
<b>Number of substantial amendments reviewed</b>	100
<b>Number of completed substantial amendments over 35 days</b>	1
<b>Number of completed substantial amendments over 35 days as a % of total substantial amendments</b>	1.00%
<b>Number of modified amendments reviewed</b>	1
<b>Number of completed modified amendments over 14 days</b>	0
<b>Number of completed modified amendments over 14 days as a % of total modified amendments</b>	0.00%
<b>Number of non substantial amendments received</b>	102
<b>Number of substantial amendments received for information</b>	2
<b>Number of substantial amendments received for new sites/PIs</b>	9
<b>Number of annual progress reports received</b>	64
<b>Number of safety reports received</b>	27
<b>Number of Serious Adverse Events received</b>	2
<b>Number of final reports received</b>	25

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

<b>Further Information Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
17/LO/0417	INTERVAL - MCRPC v3.0	34
17/LO/0590	RELIEF-1	47
17/LO/0593	Phase 2B Study of Bimekizumab in Active Ankylosing Spondylitis	36
17/LO/0606	SPEAKS focus groups	40
17/LO/0797	ABRE Study	34
17/LO/0859	ReLEx SMILE Hyperopia	34
17/LO/0909	i-PROGNOSIS	29
17/LO/0950	BARI-LIFESTYLE Version 1	39
17/LO/1051	The Lived Experience of positive risk management of self-harm	33
17/LO/1095	DOMINO trial	38
17/LO/1127	A Study of Dinutuximab and Irinotecan for Small Cell Lung Cancer	28
17/LO/1149	Phase 3 study of Maribavir vs Valganciclovir in CMV infection in HSCT	33
17/LO/1160	Mental Health and Behaviour in Childhood Dystonia	30
17/LO/1261	SOLVE-CRT (v1.3)	30
17/LO/1433	WATS3D to detect oesophageal high grade dysplasia and adenocarcinoma	48
17/LO/1501	AccuCinch	35
17/LO/1519	The Leaflex™ Performer Feasibility Study	38
17/LO/1560	105SAR301: TRC105 and pazopanib vs pazopanib in advanced angiosarcoma	40
17/LO/1673	Switch 2	38
17/LO/1678	Lateral Flow Assay and Reader for Malaria Detection version 1.0	33
17/LO/1693	iNDiGO	33
17/LO/1698	Emergency Advanced Clinical Practitioners: Quality and Acceptability	38
17/LO/1914	Left ventricular flow dynamics	41
17/LO/1964	PERSONALISED COGNITIVE REMEDIATION THERAPY (pCRT)	38
17/LO/2024	LUCY	43
17/LO/2093	HEPMARC Study	31
18/LO/0022	Understanding intention and agency in psychosis	59
18/LO/0030	BARI-OPTIMISE Version 1	49
18/LO/0031	Treatment-Resistant Depression (54135419DEP4001)	43
18/LO/0035	ONYX-one study	42
18/LO/0076	Bodytrak Feasibility Study BT01	46
18/LO/0140	SpectraCure P18 Study	27

18/LO/0190	Clinical investigation of the eyeWatch glaucoma drainage device	21
18/LO/0227	A feasibility study of ACT for people with MND (Phase 1) v1	44
18/LO/0326	DISRUPT CAD II POST-MARKET STUDY (Version number B - 29 Nov 2017)	45
18/LO/0362	Early Youth Engagement in first episode psychosis (EYE-2) RCT	37
18/LO/0383	Pilot Study for the validation of the Psy-PD Rater-Administered Scale	42
18/LO/0398	Phase 3 Study of A4250 in Children with PFIC (PEDFIC 1)	52

#### Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
17/LO/0616	Identifying biomarkers of deterioration and relapse in schizophrenia	27

#### 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
18/LO/0225	CaPSulAR (version 2.0)	27

#### Unfavourable Opinion

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

REC Reference	Title	Number of Days on Clock
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#### 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
17/LO/0594	Phase 2B Study of Bimekizumab in Active Psoriatic Arthritis	27

**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/0695	Use of Intracellular Calcium Influx as Marker on Allergy Testing Ver 1	14
17/LO/0696	Developing a toothbrushing intervention for pregnant women	20
17/LO/0698	VIP Signature Study	26
17/LO/0863	Da Vinci	20
17/LO/1117	Lectin expression in Cystic Fibrosis	13
17/LO/1315	The association between pain and poor function after knee replacement	14
17/LO/1318	Levosert PASS 010-100	18
17/LO/1462	Oximetry parameters in children with cyanotic congenital heart disease	21
17/LO/1463	RICO: Risk COmmunication in NHS Health Checks_v1	21
17/LO/1465	EARLY EXPERIENCE WITH A NEW HEXAPOD IN TREATMENT OF TIBIAL FRACTURES	17
17/LO/1870	Talking Therapies Research Resource V1	20
17/LO/1882	HR-CRT in Heart Failure Patients	10

**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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<b>Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
17/LO/1652	First-Line Advanced Melanoma Chart Review Study, Version 1.0	11
17/LO/1658	AV - Almac TP53 Next Generation Sequencing CTA for BI	7
17/LO/1877	The study of immune cell interactions in blood from healthy subjects	13

<b>Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
17/LO/0694	Kidney recipient donor risk choices	11
17/LO/0866	Paediatric Type 2 diabetes: Experiences/views of children & families	14
17/LO/1321	Physical activity among adolescents with cystic fibrosis	13
17/LO/1651	Analysis of peripheral blood ILC2s/Th2 cells in response to ANB020	14

<b>Unfavourable Opinion</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>

<b>Provisional Opinion</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>

<b>Further information response not complete</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>

<b>Withdrawn after the meeting</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>

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

<b>Favourable opinion</b>				
<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>
06/Q0703/40/AM19	PEG-IFN ± Lamivudine for chronic HBV infection in children	17 (Our AM19)	12/05/2017	22
07/Q0703/24/AM08	Improving outcomes in robotic prostate surgery using AR guidance	Am08	01/08/2017	23
09/H0808/98/AM06	Cartiva MOTION Study	Our AM06	19/06/2017	31
10/H0808/135/AM11	Psychological risk factors for fatigue in Rheumatoid Arthritis	12	18/05/2017	33
10/H0808/141/AM03	Longitudinal study non motor symptoms PD: treatment effect/tolerability	2	05/04/2017	16
11/LO/1243/AM06	Childhood blindness: genetic diagnosis for clinical management	SA04	20/02/2018	34
11/LO/1596/AM07	A RCT of PCI versus no PCI prior to TAVI	7	24/11/2017	26
12/LO/1473/AM08	Cardiovascular function in hypertension	5	03/07/2017	21
12/LO/2017/AM10	Brain Imaging in Babies (BIBS)	9	01/08/2017	34
13/LO/1468/AM04	Patients perception of anticoagulation therapy	Amendment 2, Feb 2017	01/02/2017	21
13/LO/1651/AM08	Evaluation of the NSPCC UK Minding the Baby Programme	8	01/08/2017	29
14/LO/0020/AM04	Neurofeedback for Stroke Rehabilitation	3	18/05/2017	7
14/LO/0020/AM06	Neurofeedback for Stroke Rehabilitation	Amendment 4	16/01/2018	16
14/LO/0052/AM09	MASTER SL clinical study	2	02/01/2018	11
14/LO/0353/AM06	PERIGON Pivotal Trial	Change in Chief Investigator	30/06/2017	6
14/LO/0353/AM08	PERIGON Pivotal Trial	Our AM08	19/09/2017	5
14/LO/1559/AM01	Sorin Universal REgistry on Aortic Valve Replacement	1	21/03/2017	6
14/LO/1588/AM11	D-fend – Vitamin D First Episode Neuroprotection Design. Version 1	8	02/06/2017	12
14/LO/1588/AM13	D-fend – Vitamin D First Episode Neuroprotection Design. Version 1	9	23/08/2017	20
14/LO/1615/AM06	Naltrexone Enhanced Addiction Treatment (NEAT)	5	20/06/2017	33
14/LO/1966/AM02	SSAT065 Dean Street HIV Cohort Study	2	23/11/2017	18
14/LO/2129/AM04	The VIOLET study	3 (Overall amendment 4)	22/05/2017	14
15/LO/0041/AM05	Uptake and implementation of CBT for psychosis: Phase 1	Am2	02/03/2017	7

15/LO/0047/AM03	Intrinsic PEEP and laryngeal aperture in COPD	3	13/10/2017	24
15/LO/0436/AM03	The PREDICT Study	001/2017	15/05/2017	22
15/LO/0646/AM02	The development of a Youth Mental Health Help Seeking decision aid	1	26/07/2017	10
15/LO/0928/AM03	Mitral Valve Repair Clinical Trial (MAVERIC Trial)	2	20/03/2017	14
15/LO/1002/AM03	Tendinopathy: Treatment effects and mechanisms 1 (Tendinopathy TEAM 1)	SA02	04/12/2017	34
15/LO/1640/AM05	SPYRAL HTN-ON MED Study	5	29/11/2017	16
15/LO/1700/AM02	Care.Know.Do Pilot: Version 1	2	30/03/2017	14
15/LO/1827/AM01	Evaluating a web-based intervention for maternal postpartum anxiety	1	02/05/2017	23
15/LO/1923/AM01	The Twelve TMVR Pilot Study	001	03/05/2017	28
15/LO/1950/AM17	A Phase IIb/III study of ABT-414 for newly diagnosed glioblastoma	5	18/08/2017	35
15/LO/1950/AM18	A Phase IIb/III study of ABT-414 for newly diagnosed glioblastoma	6	02/01/2018	11
15/LO/1998/AM01	DEFINING IMMUNE PATHWAYS DRIVING GUT INFLAMMATION	AMD 1	15/01/2018	20
15/LO/1999/AM02	FATTY LIVER DISEASE IN HIV	2.0	24/04/2017	14
16/LO/0026/AM13	Phase 3 open-label switch study with GS-9883/F/TAF in HIV-1 subjects	2	15/12/2016	24
16/LO/0026/AM14	Phase 3 open-label switch study with GS-9883/F/TAF in HIV-1 subjects	our ref AM14	23/02/2017	9
16/LO/0026/AM15	Phase 3 open-label switch study with GS-9883/F/TAF in HIV-1 subjects	our ref AM15	07/11/2017	17
16/LO/0194/AM01	WiCS-LV Post Market Surveillance Registry	1	20/04/2017	28
16/LO/0240/AM10	Prose - Cosentyx®/Secukinumab/AIN457	6	02/03/2017	6
16/LO/0409/AM02	Safety and Performance of IRIS V2 System	2	03/07/2017	12
16/LO/0409/AM03	Safety and Performance of IRIS V2 System	3	29/09/2017	22
16/LO/0414/AM03	Randomised trial of LightPath Imaging in breast cancer surgery	3	04/07/2017	34
16/LO/0436/AM07	APRICOT_V1	Am04	03/04/2017	23
16/LO/0436/AM09	APRICOT_V1	4.1	09/06/2017	31
16/LO/0436/AM10	APRICOT_V1	6	14/11/2017	19
16/LO/0547/AM01	Novel vascular manifestations of COPD, part 3	1	19/06/2017	9
16/LO/0603/AM02	Mild to Moderate Acne Study with IPL (CD3061_FINAL_V2.0)	2	08/08/2016	23
16/LO/0986/AM01	Characterising safe walking aid use	1	21/06/2017	11

16/LO/0986/AM02	Characterising safe walking aid use	Substantial Amendment 2, 25/01/18	06/02/2018	24
16/LO/1064/AM04	PHNA study to assess the peripheral immune system in NOT1D pts	2	15/03/2017	22
16/LO/1086/AM06	CNT0136 sirukumab	5 version 1	20/04/2017	30
16/LO/1086/AM08	CNT0136 sirukumab	SA#07	09/11/2017	26
16/LO/1086/AM10	CNT0136 sirukumab	V 1.0 (8 - Update to the Patient Information Sheet and protocol amendment 5)	01/02/2018	15
16/LO/1242/AM02	Predicting outcome from adrenalectomy	Version 3	30/11/2017	21
16/LO/1577/AM01	Portable manometry (Anopress THD): a pilot study	no 1	03/04/2017	9
16/LO/1610/AM01	Pacing in Heart Failure Study	1	28/11/2017	10
16/LO/1648/AM04	Pembrolizumab+axitinib.vs.sunitinib monotherapy in mRCC	3	28/03/2017	40
16/LO/1648/AM05	Pembrolizumab+axitinib.vs.sunitinib monotherapy in mRCC	Am05	24/04/2017	22
16/LO/1648/AM07	Pembrolizumab+axitinib.vs.sunitinib monotherapy in mRCC	7	14/09/2017	5
16/LO/1648/AM08	Pembrolizumab+axitinib.vs.sunitinib monotherapy in mRCC	9	28/09/2017	26
16/LO/1648/AM09	Pembrolizumab+axitinib.vs.sunitinib monotherapy in mRCC	10	17/10/2017	17
16/LO/1648/AM10	Pembrolizumab+axitinib.vs.sunitinib monotherapy in mRCC	SA11	01/12/2017	33
16/LO/1648/AM11	Pembrolizumab+axitinib.vs.sunitinib monotherapy in mRCC	SA12	01/03/2018	25
16/LO/1755/AM04	Fractyl Laboratories inc REVITA-2 Study C-30000	2	18/05/2017	8
16/LO/1755/AM05	Fractyl Laboratories inc REVITA-2 Study C-30000	3	12/07/2017	35
16/LO/1755/AM08	Fractyl Laboratories inc REVITA-2 Study C-30000	4	04/10/2017	18
16/LO/1755/AM09	Fractyl Laboratories inc REVITA-2 Study C-30000	5	09/11/2017	11
16/LO/1755/AM11	Fractyl Laboratories inc REVITA-2 Study C-30000	Amendment-6	31/01/2018	12
16/LO/1776/AM02	TIPSÅ microspheres for perianal fistula	2	05/02/2018	29
16/LO/1808/AM03	Trial of sitagliptin for depressive symptoms in type 2 diabetes	3.0	14/02/2018	34
16/LO/1812/AM03	FANCONI-TAF (FANTA) study	2	20/01/2017	22
16/LO/1812/AM04	FANCONI-TAF (FANTA) study	2.0	20/01/2017	22
16/LO/1984/AM06	MK-3682 + Ruzasvir for 12 weeks in Subjects with HCV GT1-6 Infection	SA05	14/11/2017	10
16/LO/1990/AM02	Characterising Cognitive Decline	2	03/08/2017	8
16/LO/2002/AM06	Study 4045-301: Phase 3 of SRP-4045 and SRP-4053 in DMD Patients	Protocol Amendment 5	06/04/2017	12

16/LO/2002/AM08	Study 4045-301: Phase 3 of SRP-4045 and SRP-4053 in DMD Patients	7	08/02/2018	22
16/LO/2002/AM09	Study 4045-301: Phase 3 of SRP-4045 and SRP-4053 in DMD Patients	Version 7_GB1 (Amendment 6),	12/03/2018	31
16/LO/2153/AM04	Affirm-AHF	2.0	25/04/2017	21
16/LO/2196/AM01	Post static cold storage normothermic machine liver perfusion	1	28/05/2017	14
17/LO/0054/AM01	PROSPECTS	1	27/12/2017	31
17/LO/0232/AM03	Sunovion CTH-302	3	06/09/2017	28
17/LO/0339/AM05	Pembrolizumab/placebo in combination with CRT- locally advanced HNSCC	SA05	08/02/2018	10
17/LO/0396/AM02	Fathers' and health professionals' views of paternal perinatal support	2	12/10/2017	12
17/LO/0590/AM01	RELIEF-1	1	13/07/2017	20
17/LO/0590/AM02	RELIEF-1	2	08/12/2017	26
17/LO/0696/AM01	Developing a toothbrushing intervention for pregnant women	1	10/07/2017	34
17/LO/0859/AM01	ReLEx SMILE Hyperopia	1	06/09/2017	12
17/LO/0950/AM01	BARI-LIFESTYLE Version 1	1	01/08/2017	14
17/LO/0950/AM02	BARI-LIFESTYLE Version 1	2	23/11/2017	21
17/LO/1127/AM01	A Study of Dinutuximab and Irinotecan for Small Cell Lung Cancer	1	07/09/2017	14
17/LO/1127/AM02	A Study of Dinutuximab and Irinotecan for Small Cell Lung Cancer	2	10/10/2017	10
17/LO/1127/AM04	A Study of Dinutuximab and Irinotecan for Small Cell Lung Cancer	SA003	19/12/2017	27
17/LO/1127/AM05	A Study of Dinutuximab and Irinotecan for Small Cell Lung Cancer	SA004	17/01/2018	22
17/LO/1149/AM01	Phase 3 study of Maribavir vs Valganciclovir in CMV infection in HSCT	3	01/09/2017	13
17/LO/1160/AM01	Mental Health and Behaviour in Childhood Dystonia	1	21/08/2017	12
17/LO/1160/AM02	Mental Health and Behaviour in Childhood Dystonia	2	05/01/2018	24
17/LO/1519/AM02	The Leaflexâ„¢ Performer Feasibility Study	SA01	13/02/2018	32

#### Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
15/LO/1641/AM05	SPYRAL HTN-OFF MED Study	5	13/06/2017	35

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

<b>Favourable opinion timeline</b>				
<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>

<b>Unfavourable opinion timeline</b>				
<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>
15/LO/1641/AM05/1	SPYRAL HTN-OFF MED Study	6	22/09/2017	14

**Table 11: Items exceeding timelines**

**Full applications for ethical review over 60 day timeline**

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

REC Reference	Title	Number of Days on Clock
17/LO/0698	VIP Signature Study	26

**SSAs (non Phase 1) over 25 day timeline**

REC Reference	Title	Number of Days on Clock
17/LO/2160	INTense Exercise foR surVivAL	28

**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
16/LO/1648/AM04	Pembrolizumab+axitinib.vs.sunitinib monotherapy in mRCC	3	28/03/2017	40

**Modified Amendments over 14 day timeline**

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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