

London - Bloomsbury Research Ethics Committee

Annual Report

01 April 2015 - 31 March 2016



Part 1 – Committee Membership and Training

Name of REC:	London - Bloomsbury Research Ethics Committee
Type of REC:	Recognised, Type I and Type III
Type of Flag:	Phase 1 studies in healthy volunteers, Paediatric
Chair:	Reverend Jim Linthicum
Vice-Chair:	Vacant
Alternate Vice-Chair:	Professor Faith Gibson
REC Manager:	Dr Ashley Totenhofer from April 2015 to Sept 2015 Ms Rachel Eltringham from Sept 2015 to Nov 2015 No REC Manager from Nov 2015 to March 2016 Mrs Kieran Hall from March 2016
REC Assistant:	Ms Amber Ecclestone from April 2015 to March 2016 Miss Ewa Grzegorska from March 2016
Committee Address:	HRA RES Centre Manchester Barlow House 3rd Floor 4 Minshull Street Manchester M1 3DZ
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Chair's overview of the past year:

The Bloomsbury Research Ethics Committee continues to be a dynamic group of lay people and experts committed to the importance of research and yet, at the same, seeking to always ensure that it takes place in an ethically responsible manner. Having been one of the committees that piloted the application review and advice, the number of favourable reviews (albeit some in need of further information) has increased. The continuing success of this process is demonstrated in, among other places, Section 2: Table 4. The commitment by lead reviewers and full committee alike demonstrates scrutiny that is thorough and at the same time looks at issues that can clearly be articulated as *ethical*.

As attendance and membership have been challenging at times, the ability of the REC managers has also been challenged, but never been found wanting. In fact, the strengths of the Committee are in the main attributable to excellent management. Nowhere has this been more apparent than during a period in which three moves within management resulted in a degree of uncertainty. Good choices of REC managers, both temporary and permanent, managed to give direction in the uncertain times. The Committee is now delighted with Kieran coming on in this role and the support given by Ewa.

Difficulties have also arisen minimally in the lack of a vice chair for so much of the year and the alternate vice chair's study leave. Once again, the Committee, aided primarily by the REC manager, made it through and anxiously awaits our newly appointed vice chair.

Looking forward to next year, the Bloomsbury REC is looking at the opportunity to be flagged for Qualitative Research. Efforts will continue to be made as we recruit and appoint to ensure that the right balance is represented in both committee membership and attendance. It has been a privilege to be able to participate in this committee and I look forward to our continued work together to celebrate research and ensure its safety

London - Bloomsbury Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Dr Joe Brierley	Consultant Intensivist	Expert	12/05/2005	12/05/2015
Ms Sally Doganis	Executive Producer and Media Consultant	Lay Plus	23/03/2011	
Mrs Gila Falkus	Retired Team Leader for Early Years Speech & Language Therapy	Lay	01/09/2015	
Dr Rashmi Gandhi	Neonatal registrar	Expert	24/09/2012	
Professor Faith Gibson	Clinical Professor of Children and Young People's Cancer Care	Expert	12/05/2005	Had break in service which extended membership to August 2015 and then a years extension
Mrs Sally Gordon Boyd	Medical Ethicist	Lay Plus	01/10/2015	
Ms Zara Grant	Clinical Trial Manager	Expert	01/03/2016	
Ms Claire Khalil	Pharmacist	Expert	31/07/2009	20/05/2015
Dr Leah Li	Statistician	Lay Plus	07/01/2013	
Dr Vincenzo Libri	Consultant in Clinical Pharmacology	Expert	24/09/2012	
Reverend Jim Linthicum	Lay member - Hospital Chaplain	Lay Plus	30/05/2007	
Ms Clare Madin	Semi-Retired Clinical Data Management Manager	Lay	01/10/2014	
Ms Michelle McPhail	Lecturer in Management Studies	Lay Plus	17/04/2013	
Dr Katie Elizabeth Myers Smith	Health Psychologist	Expert	11/06/2013	Currently on Break in Service since 01/05/2015
Dr Reecha Sofat	Senior Clinical Lecturer - Clinical Pharmacology	Expert	01/10/2015	
Dr Nabila Youssouf	Research Fellow in Clinical Trials	Expert	01/12/2011	

London - Bloomsbury Research Ethics Committee: Deputy Members

Name	Profession	Status	Meeting date attended
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London - Bloomsbury Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended
Mr Simon Eaton	Senior Lecturer in Paediatric Surgery and Metabolic biochemistry	Expert	06/05/2015
Ms Stephanie Cooper	Retired Solicitor	Lay Plus	02/09/2015
Miss Stephanie Ellis (as Acting Chair)	Former Civil Servant	Lay Plus	01/04/2015 07/10/2015
Dr Katie Harron	Statistician	Expert	03/06/2015
Dr Lorraine Ludman	Chartered Psychologist	Lay	02/09/2015
Ms Anne Rosenthal	Literary Consultant	Lay	01/07/2015
Mrs Christine Holly	Retired Librarian	Lay Plus	PR SC - 15/04/2015

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

Name	Declaration of Interest	Date
Ms Sally Doganis	None	01/04/2015
Mrs Gila Falkus	None	09/09/2015
Dr Rashmi Gandhi	None	01/04/2015
Mrs Sally Gordon Boyd	Holdings of small shareholding and joint-shareholding together with husband in GlaxoSmithKline and AstraZeneca. Fellowship, including transient committee memberships of Royal Society of Medicine	07/08/2015
Ms Zara Grant	Progress Educational Trust (PET) - Involved in Research for Corporate Funding Full Time Employment in Bio-Pharma Industry, Responsible for Project Management of Clinical Trials of Medicinal Products/Devices. Potential Education, Sales or Business Development Roles. ZG will declare any potential conflict of interest if project is presented for review to REC from a company she is employed by.	01/03/2016
Dr Leah Li	Senior Lecturer in Medical Statistics and Epidemiology. Life Course and Statistics Section . Population, Policy, and Practice Programme. UCL Institute of Child Health. Trial Oversight Committee for an NIHR PHR-funded study and a HTA study. Statistician on the MCRN/BSPED Diabetes and Endocrine Clinical Studies Group. Regular peer reviewer for NIHR Health Technology Assessment reports.	01/04/2015
Dr Vincenzo Libri	GSK shares received while employed by GSK between 2004 and 2009. No shares received since termination of employment (March 2009).	01/04/2015
Ms Clare Madin	None	01/04/2015
Ms Michelle McPhail	20 UniLever shares Member of Parkinsons UK. Lay reviewer for NIHR Member of 2 ethics Committees with delegated authority (ECDA) for University of Hertfordshire Member of Public Health England Research Governance Committee Ad hoc panel member for NIHR as public contributor/lay member	01/04/2015
Dr Katie Elizabeth Myers Smith	Is the director of own professional company – MyHealth Consultancy Limited. Is a research fellow and manager of an academic unit at Queen Mary University of London but has no role in local R&D management.	01/04/2015
Dr Reecha Sofat	I peer review grants for charities and research councils and I am a clinical academic conducting my own research	01/04/2015
Dr Nabila Youssouf	None	01/04/2015
Reverend James Linthicum	No declarations of interest	01/04/2015

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

Month	Date	Number of Members Present at Meeting
April	01/04/2015	9
May	06/05/2015	9
June	03/06/2015	7
July	01/07/2015	8
September	02/09/2015	8
October	07/10/2015	8
November	04/11/2015	8
December	02/12/2015	9
February	03/02/2016	12
March	02/03/2016	10

10 full committee meetings were held during the reporting period.

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

Month	Date	Number of Members Present at Meeting
April	15/04/2015	3
October	05/10/2015	3
November	09/11/2015	3
January	18/01/2016	3
February	17/02/2016	3
March	16/03/2016	3

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

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

Month	Date	Number of Members Present at Meeting
April	10/04/2015	2
April	14/04/2015	2
April	16/04/2015	3
April	23/04/2015	2
May	20/05/2015	2
May	20/05/2015	2
May	22/05/2015	2
May	26/05/2015	3
May	27/05/2015	2
May	29/05/2015	3
June	05/06/2015	2
June	17/06/2015	5
June	24/06/2015	3
July	02/07/2015	2

July	13/07/2015	3
July	16/07/2015	4
July	23/07/2015	4
August	04/08/2015	3
August	17/08/2015	3
August	24/08/2015	3
September	01/09/2015	2
September	15/09/2015	2
September	25/09/2015	2
October	09/10/2015	2
October	23/10/2015	2
November	06/11/2015	2
November	20/11/2015	2
December	04/12/2015	2
December	18/12/2015	2
January	04/01/2016	2
January	13/01/2016	2
January	15/01/2016	3
January	29/01/2016	2
February	12/02/2016	2
February	24/02/2016	3
February	26/02/2016	3
March	09/03/2016	3
March	11/03/2016	2
March	14/03/2016	2
March	25/03/2016	4

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

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

None

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

Name	Number of Meetings Attended
Ms Sally Doganis	7
Mrs Gila Falkus	3
Dr Rashmi Gandhi	6
Professor Faith Gibson	4
Mrs Sally Gordon Boyd	5
Ms Zara Grant	1
Dr Leah Li	6
Dr Vincenzo Libri	8
Reverend Jim Linthicum	8
Ms Clare Madin	8
Ms Michelle McPhail	9
Dr Katie Elizabeth Myers Smith	1
Dr Reecha Sofat	3
Dr Nabila Youssouf	10

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

Name	Number of Meetings Attended
Dr Rashmi Gandhi	2
Professor Faith Gibson	2
Mrs Sally Gordon Boyd	5
Reverend Jim Linthicum	4
Dr Nabila Youssouf	3

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

Name	Number of Meetings Attended
Dr Joe Brierley	2
Ms Sally Doganis	3
Mrs Gila Falkus	1
Dr Rashmi Gandhi	10
Professor Faith Gibson	14
Mrs Sally Gordon Boyd	5
Dr Leah Li	2
Dr Vincenzo Libri	7
Reverend Jim Linthicum	28
Ms Clare Madin	1
Ms Michelle McPhail	3
Dr Reecha Sofat	1
Dr Nabila Youssouf	19

Training 01 April 2015 - 31 March 2016

Name of Member	Date	Event(s) attended
Mrs Gila Falkus	10/03/2016	Committee Members Induction
Dr Rashmi Gandhi	16/04/2015	Quantitative Research
Dr Rashmi Gandhi	01/07/2015	Equality & Diversity
Mrs Sally Gordon Boyd	01/04/2015	Equality and Diversity
Reverend Jim Linthicum	10/05/2015	Presented Life Death and Paediatric Care
Ms Clare Madin	13/07/2015	Equality and Diversity (elearning module)
Ms Clare Madin	24/09/2015	Committee Member Induction
Ms Clare Madin	26/11/2015	REC Members Training Day
Ms Michelle McPhail	08/04/2015	Ethics and GCP_08.04.2015
Ms Michelle McPhail	14/07/2015	Telehealth Development and Evaluation Project
Ms Michelle McPhail	25/02/2016	NIHR Review and Refresh Open Competition - Selection Panel
Ms Michelle McPhail	27/03/2016	Research and human tissue legislation
Ms Michelle McPhail	27/03/2016	Good Research Practice
Dr Nabila Youssouf	26/11/2015	REC 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	20	38.46
Phase 1	2	3.85
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	0	0.00
Others	30	57.69
Total Applications Reviewed	52	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	10
Number of device applications reviewed	4
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	0
Number of applications reviewed that are funded by the US DHHS	0
Number of qualitative applications reviewed	1

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

Decisions taken at meetings following review of applications	Number	%
Favourable Opinion with Standard Conditions	5	9.62
Favourable Opinion with Additional Conditions	9	17.31
Unfavourable Opinion	1	1.92
Provisional Opinion	37	71.15
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	52	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	35	67.31
Further Information Favourable Opinion with Additional Conditions	1	1.92
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	5	9.62
Favourable Opinion with Additional Conditions	9	17.31
Unfavourable Opinion	1	1.92
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	1.92
Total	52	100

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

Total Applications Reviewed	17
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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	0
Number of student applications reviewed	9
Number of paediatric applications reviewed	0
Number of device applications reviewed	1
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	6	35.29
Favourable Opinion with Additional Conditions	4	23.53
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	7	41.18
Unfavourable Opinion	0	0.00
Total	17	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	5.20
Number of completed applications for full ethical review	51
Number of completed applications for full ethical review over 60 days	1
Number of completed applications over 60 days as a % of total	1.92%
Number of completed applications for full ethical review over 40 days	10
Number of completed applications over 40 days as a % of total	19.23%
Number of days taken to final decision – average (mean)	31
Number of completed proportionate review applications for ethical review	17
Number of completed proportionate review applications for ethical review over 14 days	5
Number of completed proportionate review applications over 14 days as a % of total	29.41%
Number of SSAs (non-Phase 1) reviewed	5
Number of completed applications for SSA review over 25 days	0
Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs	0.00%
Number of SSAs (Phase 1) reviewed	1
Number of completed applications for SSA review over 14 days	0
Number of completed applications for SSA review over 14 days as % of all Phase 1 SSAs	0.00%
Number of substantial amendments reviewed	145
Number of completed substantial amendments over 35 days	7
Number of completed substantial amendments over 35 days as a % of total substantial amendments	4.83%
Number of completed substantial amendments over 28 days	37
Number of completed substantial amendments over 28 days as a % of total substantial amendments	25.52%
Number of modified amendments reviewed	10
Number of completed modified amendments over 14 days	1
Number of completed modified amendments over 14 days as a % of total modified amendments	10.00%
Number of minor amendments received	92
Number of substantial amendments received for information	0
Number of substantial amendments received for new sites/PIs	43
Number of annual progress reports received	105
Number of safety reports received	32
Number of Serious Adverse Events received	17

Number of final reports received	25
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Table 9.1: Breakdown of current status of all full applications reviewed within the reporting period

Further Information Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
15/LO/0495	FTC/RPV/TAF switch from FTC/RPV/TDF in HIV-1 positive	23
15/LO/0496	EFV/FTC/TDF switch to FTC/RPV/TAF in HIV-1 Patients	23
15/LO/0522	Effect of heart rate modulation in Fontan circulation	48
15/LO/0523	Efficacy & safety of PT003, PT005 and PT001 in moderate to severe COPD	32
15/LO/0705	Early Drug Use and Later Dependence Outcomes	31
15/LO/0715	The internet as a support for acute ward inpatients with psychosis	28
15/LO/0718	MEPO PK-PD Paediatric Study in Severe Eosinophilic Asthma	29
15/LO/0957	Observational study: effect of Pirfenidone on cough in IPF patients	22
15/LO/0965	Exhaled hydrogen sulphide in ventilated neonates and children.	19
15/LO/1074	4159 Explorera,,ç3 safety, PK and PD of concizumab in haemophilia A	25
15/LO/1341	Ultrasound prediction in operative vaginal deliveries.	35
15/LO/1372	Understanding the nature of inhibitors in haemophilia	33
15/LO/1378	The Use of MRE in the Diagnosis of Nodular Regenerative Hyperplasia	31
15/LO/1382	Delivering primary health care to homeless people	47
15/LO/1596	SSAT067 PK of atazanavir/cobicistat and darunavir/cobicistat	23
15/LO/1608	Oral Tolvaptan in patients with Euvolemic or Hypervolemic Hyponatremia	41
15/LO/1637	The WATER Study	28
15/LO/1644	Exploring collateral influences in multivessel coronary artery disease	20
15/LO/1817	The REACT Study	47
15/LO/1824	Cardiac Output optimisation following Liver Transplantation (COLT) Trial	55
15/LO/1829	Study Reference CLS001-CO-PR-005	36
15/LO/1838	RAVICTI and NaPBA in Patients with Urea Cycle Disorders	42
15/LO/1959	NI-0501 in Primary HLH	60
15/LO/1978	Investigating the microenvironment in SSc patients with severe sepsis	26
15/LO/1990	A Study of Single Agent Pembrolizumab vs Single Agent Chemotherapy for	30
15/LO/2057	EBUS-TBNA vs Flex 19G EBUS-TBNA	63
16/LO/0083	A Phase 3 Study of Luspatercept versus Placebo in Beta-Thalassemia	35
16/LO/0110	MLN0002SC-3030 Vedolizumab SC Long-Term, Open-Label, Extension Study	34
16/LO/0136	STARTRK-2 Open Label Phase 2 of Entrectinib in Solid Tumours	35
16/LO/0138	Study of Lenalidomide and Dexamethasone with or without Pembrolizumab	49
16/LO/0173	MRI catheterization for congenital heart disease (v 1.0)	40
16/LO/0248	Personalising examination after death for bereaved parents	41

16/LO/0330	LEO 32731 - DDI Study with LEO 32731 and Midazolam in healthy males	32
16/LO/0361	Peanut allergy study in children and adults	36
16/LO/0363	In vivo investigations of familial Parkinson's disease	34

Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/LO/1632	The DESiGN Trial - Detection of small for gestational age fetus (SGA)	24

Further Information Unfavourable Opinion

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

REC Reference	Title	Number of Days on Clock
15/LO/0677	Quality of life for children with intractable epilepsy	22
15/LO/0691	Nivolumab monotherapy in patients with Non-Small Cell Lung Cancer	22
15/LO/0907	Ob-AKI feasibility study	19
15/LO/1087	Phase 4 study of Voncento in Subjects with Von Willebrand Disease	20
15/LO/1093	Test And Detect Antibodies in HPV unvaccinated women Study-2	20

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/LO/0576	Stress in Inflammatory Bowel disease	29
15/LO/0964	Barriers to weight management in patients with Rheumatoid Arthritis.	19
15/LO/1022	Predictors of outcome in vein of Galen malformation	20
15/LO/1060	Gastrointestinal metabolomics study	20
15/LO/1086	OPeRa	20
15/LO/1375	The effect of mood and appetite in obese and non-obese subjects	27
15/LO/1951	Renoprotective effects of Ursodeoxycholic acid	23
16/LO/0198	Diagnosis of CLAD using EIT	28
16/LO/0431	Multisystemic therapy in adoptive families	27

Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock
15/LO/0505	To determine the emotional impact of Molar Pregnancy on women	29

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
15/LO/1777	OMS721 in Adults with Thrombotic Microangiopathies	28

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
15/LO/1789	Are ketones raised after prolonged pre-operative fasting?	18
15/LO/1791	Small gas bubble tamponade in retinal detachment surgery. version 1	21
16/LO/0169	Exploring father's attitudes to Infant Feeding.	24
16/LO/0364	Measurement of sodium pump inhibitor in plasma	17
16/LO/0508	Neuropathology of disorders of movement and cognition	13
16/LO/0509	NRAS-BRAF Clinical Performance Evaluation Study	13

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
15/LO/0697	Parental experiences of administering treatments to allergic children	10

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
15/LO/0698	CBT Pain Management in Primary Care	7
15/LO/1784	Far Infra-Red and the Cardiovascular System	12
15/LO/1788	Nevisense Evaluation in Southampton	12
15/LO/1984	The use of estimating height in lung function assessment (1)	14
16/LO/0174	Anxiety and Pain Expectation: Effects on Day Surgery Recovery	15
16/LO/0184	Survey of Dental Patients taking Bisphosphonate medication: Version 1	14

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
15/LO/0700	Study of foetal muscle contraction	8
15/LO/0701	OXford Knee OsteoArthritis Cohort (OXKOAC) Version 1.0	8
16/LO/0506	Patient experience survey for ambulatory emergency care	5
16/LO/0517	Difficulties of life and medication adherence in ulcerative colitis	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
05/Q0508/6/AM06	Identification of genes involved in renal and electrolyte disorders	Amendment Number 5	14/05/2015	20
06/Q0508/58/AM04	Hypoglycaemia in childhood	Amendment 4	29/06/2015	23
07/Q0508/58/AM06	Inflammation and endothelial injury in childhood CNS vasculitis	Substantial Amendment 4	30/04/2015	21
08/H0713/44/AM07	GCaPPS Version-1_20_April-2008	Version F2.7_01.10.15, 01 Octo	30/12/2015	36
09/H0713/50/AM10	Optigrow Infant Feeding Study	Substantial Amendment 9	10/03/2015	31
10/H0713/16/AM04	The sensorimotor system in children with CP assessed by DTI	Amendment 3.0	14/05/2015	26
10/H0713/16/AM05	The sensorimotor system in children with CP assessed by DTI	Amendment 4.0	08/07/2015	19
10/H0713/16/AM07	The sensorimotor system in children with CP assessed by DTI	Amendment 5.0, date 23/10/2015	23/10/2015	25
10/H0713/54/AM14	GeDDiS	Amendment 14	28/07/2015	21
10/H0713/57/AM02	RCT on the effectiveness of a fixed versus removable retention regime	Amendment 2	05/02/2016	31
10/H0713/88/AM12	Phase II Ponatinib in Refractory CML and Ph+ALL Version 2.0 27Oct2010	ICF amendment 6.1, 11 June 201	01/07/2015	22
11/H0713/12/AM08	IDEA	6	24/09/2015	37
11/LO/0489/AM08	A molecular and genetic analysis of otosclerosis	4	11/09/2015	17
11/LO/1164/AM15	Eculizumab in antibody-mediated rejection in LD kidney transplant	UK-EC-SA-patient contact EoT	23/11/2015	35
11/LO/1313/AM08	Cetuximab with chemoradiotherapy in bladder cancer (TUXEDO)	Amendment 6 - protocol and pat	17/08/2015	17
11/LO/1455/AM09	Gilead HCV Registry 0122 - Responders	Participant Number Increase +	05/05/2015	20
11/LO/1456/AM09	Gilead HCV Registry 0123 - Non-Responders	Participant Number Increase +	20/05/2015	20
11/LO/1540/AM07	GWAS in children with DDH	Amendment 7	05/06/2015	26
11/LO/1718/AM27	The 2012 TYA Cancer Cohort Study	Substantial Amendment to	11/03/2015	11

		Substantial Amendment 4		
11/LO/1718/AM28	The 2012 TYA Cancer Cohort Study	Substantial Amendment 12	16/06/2015	17
11/LO/1718/AM29	The 2012 TYA Cancer Cohort Study	13	03/07/2015	24
11/LO/1718/AM30	The 2012 TYA Cancer Cohort Study	Substantial Amendment 14	24/07/2015	21
12/LO/0144/AM01	Mitochondrial Research Biobank [MitoBank], Version 1	V2 February 2016	11/02/2016	32
12/LO/0858/AM14	M13-101: DAAs and pegIFN/RBV for treatment failure in chronic Hep C	M13-101 Amendment 10	26/06/2015	14
12/LO/0858/AM15	M13-101: DAAs and pegIFN/RBV for treatment failure in chronic Hep C	10	26/06/2015	34
12/LO/0864/AM09	FIESTA	MO11/9803/P/V6.0/12052015	12/05/2015	21
12/LO/1201/AM14	UK Haplo v1.0	UCL/10/0411 - (10) - Protocol	16/02/2015	22
12/LO/1319/AM05	A Phase 2 study for older adults with Acute Lymphoblastic Leukaemia	Substantial Amendment 2	29/05/2015	24
12/LO/1319/AM06	A Phase 2 study for older adults with Acute Lymphoblastic Leukaemia	3 05.02.2016	05/02/2016	20
12/LO/1836/AM02	Protection of erosive tooth wear	2	24/07/2015	20
13/LO/0004/AM02	CREATE (EORTC 90101)	UK02	29/09/2015	35
13/LO/0125/AM13	Selumetinib in combination with 1st line chemotherapy in NSCLC	D1532C000070 Protocol Amendment	23/03/2015	22
13/LO/0326/AM18	9090-14: A Study of Ganetespib in advanced lung cancer	Urgent safety measure Safety L	02/10/2015	17
13/LO/0395/AM05	Aneurysm CaRe Trial - Cardiac rehabilitation after aneurysm repair 1.0	Number 3	10/06/2015	15
13/LO/0418/AM11	Sildenafil in neonates with persistent pulmonary hypertension	Summary Parent ICF V1.0 07-May	21/05/2015	20
13/LO/0418/AM13	Sildenafil in neonates with persistent pulmonary hypertension	3	14/09/2015	17
13/LO/0440/AM05	Airway Cells and Air Pollution (ACAP)	Amendment 2.0	03/03/2015	32
13/LO/0440/AM06	Airway Cells and Air Pollution (ACAP)	3.0	15/04/2015	28
13/LO/0440/AM07	Airway Cells and Air Pollution (ACAP)	4.0	01/06/2015	13

13/LO/0450/AM01	Enhancing Viability of Mononuclear Cells from the Female Genital Tract	No. 1	21/05/2015	20
13/LO/0563/AM10	The TREATCASP study	Substantial Amendment 04	28/04/2015	21
13/LO/0563/AM12	The TREATCASP study	Substantial Amendment 05	25/06/2015	8
13/LO/1229/AM05	Assessing the palliative care needs of people with cancer	Substantial Amendment 1	20/02/2015	22
13/LO/1229/AM07	Assessing the palliative care needs of people with cancer	Substantial amendment 2, 01.09	11/09/2015	25
13/LO/1272/AM12	Phase 1/2 study of nab-paclitaxel in children with solid tumours	Protocol Amendment 4 PIS/ICFs	25/03/2015	17
13/LO/1272/AM15	Phase 1/2 study of nab-paclitaxel in children with solid tumours	Permanent Transfer of PI/CI	10/06/2015	22
13/LO/1444/AM05	Safety, Effectiveness Study of RP103 in Patients with Cystinosis	Three	25/02/2016	9
13/LO/1600/AM07	Extension study of LUM001 in Alagille Syndrome paediatric patients.	Amendment 3	22/09/2015	27
13/LO/1600/AM08	Extension study of LUM001 in Alagille Syndrome paediatric patients.	Amendment 4	02/02/2016	8
13/LO/1608/AM04	Study of efficacy and safety of nilotinib in paediatric CML patients	CAMN107A2203	04/05/2015	16
13/LO/1798/AM07	Sotatercept (ACE-011) in Subjects with End-Stage Kidney Disease	ACE011 IBv10.0, Updated Risk B	04/08/2015	20
13/LO/1798/AM08	Sotatercept (ACE-011) in Subjects with End-Stage Kidney Disease	Updated ICF	31/08/2015	28
13/LO/1830/AM02	Diffusion Tensor Imaging of the myocardium	Substantial Amendment 1	29/06/2015	16
13/LO/1830/AM04	Diffusion Tensor Imaging of the myocardium	Substantial Amendment 2	13/10/2015	25
13/LO/1830/AM05	Diffusion Tensor Imaging of the myocardium	Substantial Amendment 3 06.01	21/01/2016	31
14/LO/0009/AM02	Study to investigate CSL689 in subjects with haemophilia (A or B)	AM 1 - Protocol Amendment 1	04/02/2015	34

14/LO/0009/AM03	Study to investigate CSL689 in subjects with haemophilia (A or B)	AM 2 - E Diary	24/03/2015	5
14/LO/0226/AM02	Growing bladders in the laboratory	Substantial Amendment 1	01/02/2015	35
14/LO/0344/AM05	BMN 673 in patients with metastatic breast cancer and a BRCA mutation	Patient Pre-Screening Consent	24/02/2015	21
14/LO/0344/AM06	BMN 673 in patients with metastatic breast cancer and a BRCA mutation	Embraca FactSheet	15/04/2015	33
14/LO/0344/AM07	BMN 673 in patients with metastatic breast cancer and a BRCA mutation	Investigator's Brochure	08/04/2015	13
14/LO/0344/AM08	BMN 673 in patients with metastatic breast cancer and a BRCA mutation	Protocol Version: 2.0	10/02/2016	33
14/LO/0378/AM02	Paediatric MS patients - Fingolomid versus interferon	Substantial Amendment 2	08/04/2015	6
14/LO/0378/AM04	Paediatric MS patients - Fingolomid versus interferon	3	08/09/2015	16
14/LO/0452/AM03	Generic EORTC QL Phases I-III	2	08/10/2015	18
14/LO/0452/AM04	Generic EORTC QL Phases I-III	Substantial Amendment 3	09/10/2015	24
14/LO/0452/AM05	Generic EORTC QL Phases I-III	Substantial Amendment 4_PIS and Consent	15/02/2016	20
14/LO/0453/AM01	EORTC QL Cut-Off Scores	1st July 2015	17/08/2015	22
14/LO/0565/AM06	Lubiprostone for the treatment of paediatric functional constipation	SAG/0211PFC113 1 SA5	14/04/2015	16
14/LO/0565/AM09	Lubiprostone for the treatment of paediatric functional constipation	SAG/0211PFC113 1 SA6	14/04/2015	22
14/LO/0565/AM13	Lubiprostone for the treatment of paediatric functional constipation	SAG/0211PFC113 1 SA7	06/10/2015	19
14/LO/0565/AM14	Lubiprostone for the treatment of paediatric functional constipation	SAG/0211PFC113 1 SA08	03/03/2016	21
14/LO/0664/AM02	RCT of a web-based alcohol treatment programme	Amendment 2	12/06/2015	27
14/LO/0807/AM07	TARVA: Total Ankle Replacement versus Arthrodesis Trial	3	30/06/2015	22
14/LO/0807/AM08	TARVA: Total Ankle Replacement versus Arthrodesis Trial	4	06/09/2015	23

14/LO/0807/AM09	TARVA: Total Ankle Replacement versus Arthrodesis Trial	5 03 Feb 2016	04/02/2016	32
14/LO/0816/AM07	Long term efficacy of Lubiprostone for paed. functional constipation	11S1-SA1 (protocol v.4.0, 19 N	10/12/2015	22
14/LO/0816/AM08	Long term efficacy of Lubiprostone for paed. functional constipation	SAG/0211PFC11S 1 SA 006	01/02/2016	24
14/LO/1035/AM02	Extension study to investigate CSL627 in Subjects with Haemophilia A	AM02 Protocol Amendment No.02	05/06/2015	28
14/LO/1045/AM01	Language Therapy in British Sign Language v1	Amendment 1	27/03/2015	22
14/LO/1045/AM02	Language Therapy in British Sign Language v1	Amendment 2 080116	18/01/2016	31
14/LO/1113/AM06	Risky Beginnings: A 3-year longitudinal study of expectant parents	Amendment 3	24/07/2015	21
14/LO/1162/AM02	Brain Functioning in Typically-Developing and At-Risk Teens	Amendment 2	27/03/2015	30
14/LO/1509/AM01	FM systems on children with Auditory Processing Disorders	Substantial Amendment 1	01/10/2015	19
14/LO/1509/AM02	FM systems on children with Auditory Processing Disorders	2	09/11/2015	30
14/LO/1565/AM03	MYPAN	3	22/12/2015	36
14/LO/1602/AM09	UCON	AM02	21/05/2015	26
14/LO/1678/AM01	Decision Making with Teenagers, Parents and Clinicians	Substantial Amendment 1	10/04/2015	28
14/LO/1910/AM04	CLEFT-Q Fieldtest	Substantial Amendment 1	24/06/2015	21
14/LO/1910/AM05	CLEFT-Q Fieldtest	Substantial Amendment 2	29/07/2015	21
14/LO/2148/AM01	Illness beliefs, quality of life and clinical outcome in persistent AF	Amendment 1.0 March 2015	18/03/2015	26
14/LO/2148/AM03	Illness beliefs, quality of life and clinical outcome in persistent AF	Substantial Amendment 2	15/03/2016	15
14/LO/2150/AM01	Pfizer B1371013 - Phase 2 PF-04449913 for Myelofibrosis	B1371013 Protocol Amendment 2	19/02/2015	26
14/LO/2150/AM02	Pfizer B1371013 - Phase 2 PF-04449913 for Myelofibrosis	B1371013 Amendment 3 - IB Apri	28/08/2015	34
14/LO/2308/AM01	A feasibility study of patient navigation in Bowel Scope Screening	Version 2: 11.03.15 Version 3:	11/03/2015	27

14/LO/2308/AM03	A feasibility study of patient navigation in Bowel Scope Screening	Version 3: 21.07.2015 (Protocol	21/07/2015	24
14/LO/2308/AM04	A feasibility study of patient navigation in Bowel Scope Screening	Substantial Amendment 3	14/10/2015	18
15/LO/0014/AM01	Factor X in the prophylaxis of bleeding in Children <12yrs	Ten02	22/04/2015	21
15/LO/0014/AM04	Factor X in the prophylaxis of bleeding in Children <12yrs	Ten02	24/08/2015	34
15/LO/0014/AM06	Factor X in the prophylaxis of bleeding in Children <12yrs	Ten 02 Version 6	24/11/2015	35
15/LO/0017/AM02	MYK 461-001 Safety and tolerability of MYK 461 in HV & Patients	Substantial Amendment - Protocol	27/04/2015	14
15/LO/0017/AM03	MYK 461-001 Safety and tolerability of MYK 461 in HV & Patients	Substantial Amendment IB	22/07/2015	11
15/LO/0017/AM04	MYK 461-001 Safety and tolerability of MYK 461 in HV & Patients	Substantial Amendment - Patient Liaison Form and Medical History Referral Form	07/08/2015	17
15/LO/0031/AM02	SSAT066 Renal Integrase Study	Substantial Amendment 02	04/03/2015	19
15/LO/0031/AM03	SSAT066 Renal Integrase Study	3	21/12/2015	14
15/LO/0084/AM01	Simvastatin in sight threatening Uveitis trial (SU)	SA 1	20/01/2016	35
15/LO/0084/AM02	Simvastatin in sight threatening Uveitis trial (SU)	SA2	02/03/2016	16
15/LO/0141/AM03	Bimatoprost SR in Open-angle Glaucoma or Ocular Hypertension	Amendment 3	25/11/2015	37
15/LO/0246/AM01	LUM001 in patients with Primary Sclerosing Cholangitis (CAMEO study)	01	10/02/2015	13
15/LO/0246/AM02	LUM001 in patients with Primary Sclerosing Cholangitis (CAMEO study)	02	16/04/2015	28
15/LO/0246/AM03	LUM001 in patients with Primary Sclerosing Cholangitis (CAMEO study)	03	03/06/2015	19
15/LO/0246/AM05	LUM001 in patients with Primary Sclerosing Cholangitis (CAMEO study)	Addition of Flyer at Dr Thorburn's Site	17/07/2015	17
15/LO/0246/AM07	LUM001 in patients with Primary Sclerosing Cholangitis (CAMEO study)	Substantial Amendment Investigator	29/09/2015	23

		Brochure change to risk/benefit section		
15/LO/0385/AM01	Study to Evaluate the Long-term Safety of Zorblisa in Patients with Epidermolysis Bullosa	SA 001 (Protocol Version 1.1,	01/04/2015	12
15/LO/0385/AM03	Study to Evaluate the Long-term Safety of Zorblisa in Patients with Epidermolysis Bullosa	Substantial Amendment 002	01/03/2016	17
15/LO/0495/AM02	FTC/RPV/TAF switch from FTC/RPV/TDF in HIV-1 positive	Substantial Amendment 2 - Updated IB, updated IDMC Charter & Change of PI at 1 site (Dr Gilson)	16/07/2015	17
15/LO/0495/AM04	FTC/RPV/TAF switch from FTC/RPV/TDF in HIV-1 positive	Substantial Amendment 3 Protocol Amendment 2, ICF v2.0_9 Sep 2015 & Closure of 1 site (Dr Hay)	07/10/2015	19
15/LO/0496/AM04	EFV/FTC/TDF switch to FTC/RPV/TAF in HIV-1 Patients	Substantial Amendment 3 updated - updated IB, updated IMDC Charter & Change of PI at 1 site (Dr Gilson)	16/07/2015	18
15/LO/0496/AM06	EFV/FTC/TDF switch to FTC/RPV/TAF in HIV-1 Patients	Substantial Amendment 4 Protocol Amendment 2 (9 Sep 2015), Summary of Changes (28 Sep 2015), Clarification Letter (12 Oct 2015) & Closure of	21/10/2015	28

		4 nonrecruiting sites (Hay, Pozniak, Schembri & Taylor)		
15/LO/0523/AM01	Efficacy & safety of PT003, PT005 and PT001 in moderate to severe COPD	Sub Amt 1	01/05/2015	28
15/LO/0523/AM07	Efficacy & safety of PT003, PT005 and PT001 in moderate to severe COPD	Amendment 3 23/11/2015	23/11/2015	24
15/LO/0691/AM03	Nivolumab monotherapy in patients with Non-Small Cell Lung Cancer	03 Nivolumab IB Addendums 2 &	29/06/2015	24
15/LO/0691/AM04	Nivolumab monotherapy in patients with Non-Small Cell Lung Cancer	04	19/08/2015	34
15/LO/0697/AM01	Parental experiences of administering treatments to allergic children	Participant information sheets,	05/05/2015	16
15/LO/0718/AM01	MEPO PK-PD Paediatric Study in Severe Eosinophilic Asthma	SA01-Protocol Amendment 01	18/06/2015	21
15/LO/0718/AM03	MEPO PK-PD Paediatric Study in Severe Eosinophilic Asthma	SA03addition Alder Hey hospital	15/10/2015	28
15/LO/0964/AM01	Barriers to weight management in patients with Rheumatoid Arthritis.	Substantial Amendment 1	22/06/2015	19
15/LO/1060/AM01	Gastrointestinal metabolomics study	2.0	12/10/2015	32
15/LO/1060/AM02	Gastrointestinal metabolomics study	3.0 02/02/16	02/02/2016	20
15/LO/1086/AM01	OPeRa	Substantial Amendment 1 Protoc	21/07/2015	11
15/LO/1087/AM01	Phase 4 study of Voncento in Subjects with Von Willebrand Disease	Substantial Amendment 1	27/10/2015	25
15/LO/1596/AM01	SSAT067 PK of atazanavir/cobicistat and darunavir/cobicistat	Substantial Amendment 1	29/10/2015	34
15/LO/1637/AM01	The WATER Study	Substantial Amendment 1	27/11/2015	29
15/LO/1824/AM01	Cardiac Output optimisation following Liver Transplantation (COLT) Trial	1 04/02/2016	05/02/2016	28
15/LO/1829/AM02	Study Reference CLS001-CO-PR-005	Substantial Amendment Code Number 2.0	07/01/2016	48
16/LO/0136/AM01	STARTRK-2 Open Label Phase 2 of Entrectinib in Solid	Substantial	09/03/2016	21

	Tumours	Amendment 1		
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Unfavourable opinion				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
11/LO/1898/AM04	Huntington's Phenocopy Genetics Study	Substantial Amendment 1.0	20/02/2015	13
14/LO/1113/AM08	Risky Beginnings: A 3-year longitudinal study of expectant parents	Amendment 4 14/12/15	14/12/2015	45
14/LO/1162/AM03	Brain Functioning in Typically-Developing and At-Risk Teens	3	01/10/2015	35
14/LO/1509/AM03	FM systems on children with Auditory Processing Disorders	3 20Nov15	24/11/2015	33
14/LO/2079/AM01	Empowerment in Parkinson's Disease	Amendment 1 14 Dec 2015	15/01/2016	30
15/LO/0718/AM09	MEPO PK-PD Paediatric Study in Severe Eosinophilic Asthma	SA06- Information for schools	26/01/2016	30
15/LO/0907/AM02	Ob-AKI feasibility study	Amendment 1	09/11/2015	34
15/LO/1074/AM02	4159 Explorer, 3 safety, PK and PD of concizumab in haemophilia A	Substantial protocol amendment	11/11/2015	32
15/LO/1608/AM01	Oral Tolvaptan in patients with Euvolemic or Hypervolemic Hyponatremia	Investigator's Brochure Version	20/01/2016	36

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
11/LO/1898/AM04/1	Huntington's Phenocopy Genetics Study	2.0 April 2015	08/06/2015	2
11/LO/1898/AM04/2	Huntington's Phenocopy Genetics Study	3.0, May 2015	09/06/2015	5
14/LO/1162/AM03/1	Brain Functioning in Typically-Developing and At-Risk Teens	Amendment 3 (modification), 01	17/12/2015	4
14/LO/1509/AM03/2	FM systems on children with Auditory Processing Disorders	3 20Nov15	15/01/2016	11
14/LO/2079/AM01/1	Empowerment in Parkinson's Disease	Amendment 1 14	14/12/2015	10

		Dec 2015		
15/LO/0907/AM02/1	Ob-AKI feasibility study	Minor Amendment 1	10/02/2016	17
15/LO/1074/AM02/1	4159 Explorerâ„¢3 safety, PK and PD of concizumab in haemophilia A	Substantial protocol amendment	09/02/2016	13
15/LO/1608/AM01/1	Oral Tolvaptan in patients with Euvolemic or Hypervolemic Hyponatremia	Investigator's Brochure _ Modi	10/03/2016	11

Unfavourable opinion timeline				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
14/LO/1113/AM08/1	Risky Beginnings: A 3-year longitudinal study of expectant parents	Amendment 5	04/03/2016	12
14/LO/1509/AM03/1	FM systems on children with Auditory Processing Disorders	Modified Amendment to (3 20 No	30/12/2015	13

Table 11: Items exceeding timelines**Full applications for ethical review over 60 day timeline**

REC Reference	Title	Number of Days on Clock
15/LO/2057	EBUS-TBNA vs Flex 19G EBUS-TBNA	63

Proportionate review applications for ethical review over 14 day timeline

REC Reference	Title	Number of Days on Clock
15/LO/1789	Are ketones raised after prolonged pre-operative fasting?	18
15/LO/1791	Small gas bubble tamponade in retinal detachment surgery. version 1	21
16/LO/0169	Exploring father's attitudes to Infant Feeding.	24
16/LO/0174	Anxiety and Pain Expectation: Effects on Day Surgery Recovery	15
16/LO/0364	Measurement of sodium pump inhibitor in plasma	17

SSAs (non Phase 1) over 25 day timeline

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

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

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
08/H0713/44/AM07	GCaPPS Version-1_20_April-2008	Version F2.7_01.10.15, 01 Octo	30/12/2015	36
11/H0713/12/AM08	IDEA	6	24/09/2015	37
14/LO/1113/AM08	Risky Beginnings: A 3-year longitudinal study of expectant parents	Amendment 4 14/12/15	14/12/2015	45
14/LO/1565/AM03	MYPAN	3	22/12/2015	36
15/LO/0141/AM03	Bimatoprost SR in Open-angle Glaucoma or Ocular Hypertension	Amendment 3	25/11/2015	37

15/LO/1608/AM01	Oral Tolvaptan in patients with Euvolemic or Hypervolemic Hyponatremia	Investigator's Brochure Versio	20/01/2016	36
15/LO/1829/AM02	Study Reference CLS001-CO-PR-005	Substantial Amendment Code Num	07/01/2016	48

Modified Amendments over 14 day timeline				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
15/LO/0907/AM02/1	Ob-AKI feasibility study	Substantial Amendment 1	10/02/2016	17