

London - Hampstead Research Ethics Committee

Annual Report

01 April 2017 - 31 March 2018



Part 1 – Committee Membership and Training

Name of REC:	London - Hampstead Research Ethics Committee
Type of REC:	Recognised, Type I and Type III
Type of Flag:	Phase I in healthy volunteers, Research involving Children
Chair:	Miss Stephanie Ellis, BEM
Vice-Chair:	Dr Rahul Chodhari
Alternate Vice-Chair:	Mr Paul Hardiman
REC Manager:	Mr Matt Rogerson from 01 April 2017 to 30 November 2017 Miss Ewa Grzegorska from 01 December 2017 to date
REC Assistant:	Miss Nafeesa Khanam
Committee Address:	Barlow House 3rd Floor 4 Minshull Street Manchester M1 3DZ
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Chair's overview of the past year:

This year was my sixth year as Chair of Hampstead REC: how time has flown!

I am as ever grateful to everyone on the committee for their commitment and helpfulness. I continue to be amazed at my good fortune to be working with such a good committee who make the meetings both enjoyable and effective. Although I know members enjoy being on the committee I also know that it involves a fair bit of work and I am always impressed how much time and effort they put in.

We welcome Christine Ellis with her pharmacist background and are pleased that Rahul Choudhury has been appointed as Vice Chair and look forward to seeing him chairing some meetings.

Matt continues to be our very effective Manager supporting us and ensuring we get the work done – although he has just gone on secondment to another job within HRA looking at the future documentation of clinical trials will look and so we are enjoying Ewa Grzegorska's cheerful helpful style that shows that she too is an excellent committee manager. Nafeesa completes our team and has done great work too. We are lucky to have such a pleasant hard working team.

I am particularly pleased with how many researchers come back to us. They clearly find us a friendly helpful committee. We have worked hard to achieve this, and it is good to know that we are helping researchers do good research.

London - Hampstead Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Dr Waheeb Atia	Retired Consultant Physician	Expert	01/11/2010	
Dr Rahul Chodhari	Consultant Paediatrician	Expert	03/04/2008	
Dr Christine Ellis	Clinical Trial Pharmacist	Expert	01/09/2017	
Miss Stephanie Ellis, BEM	Former Civil Servant	Lay Plus	01/04/2012	
Dr Alicia Isabel Etchegoyen Holiday	Psychiatrist	Expert	12/11/2013	
Dr Kanagasabai Ganeshaguru	Retired Scientist	Lay	01/10/2016	
Mr Paul Hardiman	Consultant Gynaecologist/Senior Lecturer in Obstetrics and Gynaecology	Expert	01/09/2010	
Dr Michael Jacobs	Retired Academic Pharmacologist	Lay	14/05/2013	
Miss Monica Jefford	Retired Midwife	Expert	31/08/2011	
Miss Mina Karamshi	Specialist Sister in Radiology	Expert	02/11/2010	
Dr Jane Lees-Millais	General Practitioner	Expert	01/07/2011	
Ms Anna Osadcow	Clinical Trials Research Pharmacist	Expert	01/01/2013	
Ms Ann Rosenthal	Literary Consultant (Retired)	Lay Plus	01/01/2014	
Mrs Arlene Renee Seaton	Retired Medical Publisher	Lay Plus	06/02/2013	
Dr Francesca Silverton	Statistics Teacher	Lay	01/02/2017	
Dr Latha Weston	Consultant Psychiatrist	Expert	14/12/2011	

London - Hampstead Research Ethics Committee: Deputy Members

Name	Profession	Status	Meeting date attended
Dr Victoria Chapman	Consultant Child and Adolescent Psychiatrist	Expert	13/09/2017
Dr Victoria Chapman	Consultant Child and Adolescent Psychiatrist	Expert	14/02/2018
Dr Victoria Chapman	Consultant Child and Adolescent Psychiatrist	Expert	12/07/2017
Dr Victoria Chapman	Consultant Child and Adolescent Psychiatrist	Expert	10/05/2017

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

Name	Declaration of Interest	Date
Dr Waheeb Atia	None	08/11/2017
Dr Victoria Chapman	Consultant Psychiatrist Royal Free CAMS	31/03/2018
Dr Rahul Chodhari	Small shareholder in BT & Vodafone (not aware of any links to medical research). AIR - Asthma Innovation Research Charity - Chairperson (unpaid) - focus is on supporting asthma awareness in school. Member of UCLP Paediatric asthma group. Member of Health London Partnership asthma group. Stakeholder in Camden atopy service. (These roles are aimed at improving service delivery).	05/03/2018
Dr Christine Ellis	None declared - but potential as husband is an employee of GlaxoSmithKline Pharmaceuticals R&D.	01/09/2017
Miss Stephanie Ellis, BEM	None	15/06/2017
Dr Alicia Isabel Etchegoyen Holiday	None	08/11/2017
Dr Kanagasabai Ganeshaguru	None	28/02/2018
Mr Paul Hardiman	None	31/03/2018
Dr Michael Jacobs	None	07/11/2017
Miss Monica Jefford	Shareholdings in British Telecom; Iberdola and SSE Plc. St Andrew's Church, Coulsdon Member. Coulsdon Churches Together, Chair. Croydon Churches Floating Shelter, Volunteer. St Andrew's Church Contact Group Co-ordinator. Croydon Neighbourhood Care Association Affiliation. Croydon Adult Social Services User Panel Member. Croydon Voluntary Action - as above. Bowel Cancer UK, Volunteer. The Royal Marsden (TRM) NHS Foundation Trust: i) Patient and Carer Research Review Panel ii) Clinical Research Facility member and studies co-investigator iii) PPI with the Biomedical Research Centre iv) Patient and Carer Advisory Group member Institute of Cancer Research: Trial Management Group (TMG) member NCRI/N member Colorectal Clinical Studies Group member NIHR, NCRI, TRM various TMGsSE London Consumer Research Panel member NIHR Clinical Research Network - South London member Imperial College PPI sessions with medical students Guy's and St Thomas' NHS Foundation Trust Chaplain	05/03/2018
Miss Mina Karamshi	None	28/02/2018
Dr Jane Lees-Millais	None	31/03/2018
Ms Anna Osadcow	Member of CPAS - Chemotherapy & Pharmacy	14/02/2018

	Advisory Service.(Part of NIHR) - review of cancer services clinical trials & advice given on protocol	
Ms Ann Rosenthal	None	08/11/2017
Mrs Arlene Renee Seaton	Chair of Ethics Committee at IVF Clinic, Lister Hospital, Chelsea	23/01/2018
Dr Francesca Silverton	None	31/03/2018
Dr Latha Weston	PI on Trust Investigations (BEHMHT) - currently PPIP Trial	31/03/2018

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

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

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	26/04/2017	3
May	24/05/2017	3
June	28/06/2017	3
July	26/07/2017	3
November	22/11/2017	3
December	28/12/2017	3
January	25/01/2018	3
March	01/03/2018	3
March	29/03/2018	3

9 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	17/04/2017	2
May	01/05/2017	2
May	15/05/2017	4
May	29/05/2017	2
June	19/06/2017	2
June	29/06/2017	6
July	03/07/2017	2
July	17/07/2017	2
July	31/07/2017	2
August	03/08/2017	3
August	14/08/2017	2
August	28/08/2017	2

September	20/09/2017	2
October	02/10/2017	2
October	16/10/2017	2
October	30/10/2017	2
November	13/11/2017	2
November	27/11/2017	2
December	11/12/2017	2
December	18/12/2017	2
January	02/01/2018	2
January	15/01/2018	2
January	29/01/2018	2
January	31/01/2018	2
February	12/02/2018	2
February	26/02/2018	2
March	12/03/2018	2
March	20/03/2018	2
March	26/03/2018	2

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

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

0

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

Name	Number of Meetings Attended
Dr Waheeb Atia	9
Dr Victoria Chapman	4
Dr Rahul Chodhari	2
Dr Christine Ellis	4
Miss Stephanie Ellis, BEM	10
Dr Alicia Isabel Etchegoyen Holiday	6
Dr Kanagasabai Ganeshaguru	10
Mr Paul Hardiman	5
Dr Michael Jacobs	6
Miss Monica Jefford	7
Miss Mina Karamshi	7
Dr Jane Lees-Millais	5
Ms Anna Osadcow	8
Ms Ann Rosenthal	9
Mrs Arlene Renee Seaton	8
Dr Francesca Silverton	8
Dr Latha Weston	5

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

Name	Number of Meetings Attended
Dr Rahul Chodhari	2
Miss Stephanie Ellis, BEM	9
Dr Alicia Isabel Etchegoyen Holiday	3
Dr Kanagasabai Ganeshaguru	1
Dr Michael Jacobs	1
Miss Monica Jefford	2
Miss Mina Karamshi	1
Dr Jane Lees-Millais	1
Ms Anna Osadcow	1
Ms Ann Rosenthal	1
Mrs Arlene Renee Seaton	2
Dr Francesca Silverton	2
Dr Latha Weston	1

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

Name	Number of Meetings Attended

Dr Waheeb Atia	2
Dr Rahul Chodhari	2
Dr Christine Ellis	1
Miss Stephanie Ellis, BEM	29
Dr Alicia Isabel Etchegoyen Holiday	3
Dr Kanagasabai Ganeshaguru	6
Mr Paul Hardiman	1
Dr Michael Jacobs	3
Miss Monica Jefford	4
Miss Mina Karamshi	2
Dr Jane Lees-Millais	1
Ms Anna Osadcow	2
Ms Ann Rosenthal	2
Mrs Arlene Renee Seaton	2
Dr Francesca Silverton	3
Dr Latha Weston	2

Training 01 April 2017 - 31 March 2018

Name of Member	Date	Event(s) attended
Dr Waheeb Atia	12/04/2017	PPI Workshop
Dr Waheeb Atia	12/04/2017	Northwick Park - The Documentary: Roundtable Discussion
Dr Waheeb Atia	12/04/2017	Improving Information Sheets
Dr Waheeb Atia	12/12/2017	National Members Training Day
Miss Stephanie Ellis, BEM	12/04/2017	HRA Patient & Public Involvement Workshop
Miss Stephanie Ellis, BEM	12/04/2017	Northwick Park the documentary: Roundtable discussion
Miss Stephanie Ellis, BEM	12/04/2017	Improving Information Sheets
Miss Stephanie Ellis, BEM	03/05/2017	National Chair's Day
Miss Stephanie Ellis, BEM	10/05/2017	ShED 22 - Phase 1 review analysis
Miss Stephanie Ellis, BEM	24/11/2017	National Chair's Day
Miss Stephanie Ellis, BEM	12/12/2017	National Members Training Day
Dr Alicia Isabel Etchegoyen Holiday	10/05/2017	ShED 22 - Phase 1 review analysis
Dr Kanagasabai Ganeshaguru	12/04/2017	Improving Information Sheets
Dr Kanagasabai Ganeshaguru	12/04/2017	Northwick Park the documentary: Roundtable discussion
Dr Kanagasabai Ganeshaguru	12/04/2017	HRA Patient & Public Involvement Workshop
Dr Kanagasabai Ganeshaguru	10/05/2017	ShED 22 - Phase 1 review analysis
Dr Kanagasabai Ganeshaguru	12/12/2017	National Members Training Day
Dr Kanagasabai Ganeshaguru	28/02/2018	Ethical Issues in Phase One Research: An Advanced Training Course
Mr Paul Hardiman	12/04/2017	HRA Patient & Public Involvement Workshop
Mr Paul Hardiman	12/04/2017	Northwick Park the documentary: Roundtable discussion
Mr Paul Hardiman	12/04/2017	Improving Information Sheets
Mr Paul Hardiman	10/05/2017	ShED 22 - Phase 1 Review Analysis
Dr Michael Jacobs	10/05/2017	ShED 22 - Phase 1 review analysis
Miss Monica Jefford	12/04/2017	Improving Information Sheets
Miss Monica Jefford	12/04/2017	HRA Patient & Public Involvement Workshop
Miss Monica Jefford	12/04/2017	Northwick Park the documentary: Roundtable discussion
Miss Monica Jefford	10/05/2017	ShED 22 - Phase 1 review analysis
Miss Monica Jefford	23/11/2017	Ethical Issues in Phase One

		Research: An Advanced Training Course
Miss Mina Karamshi	12/04/2017	Northwick Park the documentary: Roundtable discussion
Miss Mina Karamshi	12/04/2017	HRA Patient & Public Involvement Workshop
Miss Mina Karamshi	12/04/2017	Improving Information Sheets
Miss Mina Karamshi	24/04/2017	NIDA Clinical Trials Network GCP Day
Miss Mina Karamshi	10/05/2017	ShED 22 - Phase 1 review analysis
Dr Jane Lees-Millais	10/05/2017	ShED 22 - Phase 1 review analysis
Ms Anna Osadcow	12/04/2017	Improving Information Sheets
Ms Anna Osadcow	12/04/2017	Northwick Park the documentary: Roundtable discussion
Ms Anna Osadcow	12/04/2017	HRA Patient & Public Involvement Workshop
Ms Anna Osadcow	10/05/2017	ShED 22 - Phase 1 review analysis
Ms Ann Rosenthal	12/04/2017	Public & Patient Involvement Workshop
Ms Ann Rosenthal	12/04/2017	Northwick Park: The Documentary: Roundtable Discussion
Ms Ann Rosenthal	12/04/2017	Improving Information Sheets
Mrs Arlene Renee Seaton	12/04/2017	PPI Workshop
Mrs Arlene Renee Seaton	12/04/2017	Northwick Park: The Documentary: Roundtable Discussion
Mrs Arlene Renee Seaton	12/04/2017	Improving Information Sheets
Dr Francesca Silverton	12/04/2017	HRA Patient & Public Involvement Workshop
Dr Francesca Silverton	12/04/2017	Northwick Park the documentary: Roundtable discussion
Dr Francesca Silverton	12/04/2017	Improving Information Sheets
Dr Francesca Silverton	10/05/2017	ShED 22 - Phase 1 review analysis
Dr Francesca Silverton	26/09/2017	Assessing the Consequences (benefits and harms) of Research: a Health Research Authority workshop
Dr Francesca Silverton	05/10/2017	Introduction to Phase 1 Research - Trials & Regulation
Dr Francesca Silverton	12/10/2017	Human Tissue Act (use of Human Samples in Research) An Introduction
Dr Francesca Silverton	12/10/2017	Human Tissue Act (Introduction)
Dr Francesca Silverton	16/11/2017	Committee Members Induction

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	14	35.00
Phase 1	3	7.50
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	1	2.50
Others	22	55.00
Total Applications Reviewed	40	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	8
Number of paediatric applications reviewed	10
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	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	6	15.00
Favourable Opinion with Additional Conditions	13	32.50
Unfavourable Opinion	0	0.00
Provisional Opinion	20	50.00
Provisional Opinion Pending Consultation with Referee	1	2.50
Total	40	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	20	50.00
Further Information Favourable Opinion with Additional Conditions	0	0.00
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	6	15.00
Favourable Opinion with Additional Conditions	13	32.50
Unfavourable Opinion	1	2.50
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	40	100

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

Total Applications Reviewed	20
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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	4
Number of studies withdrawn prior to the meeting	0
Number of student applications reviewed	5
Number of paediatric applications reviewed	3
Number of device applications reviewed	0
Number of qualitative applications reviewed	2

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

Decisions taken at proportionate review sub-committee meetings	Number	%
Favourable Opinion with Standard Conditions	12	60.00
Favourable Opinion with Additional Conditions	4	20.00
No Opinion transfer to full committee for review	2	10.00
Provisional Opinion	1	5.00
Unfavourable Opinion	1	5.00
Total	20	100

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

Average number of applications reviewed per full meeting	4.00
Number of completed applications for full ethical review	40
Number of completed applications for full ethical review over 60 days	0
Number of completed applications over 60 days as a % of total	0.00%
Number of days taken to final decision – average (mean)	23
Number of completed proportionate review applications for ethical review	18
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	6
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	16.67%
Number of SSAs (Phase 1) reviewed	4
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	132
Number of completed substantial amendments over 35 days	1
Number of completed substantial amendments over 35 days as a % of total substantial amendments	0.76%
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	125
Number of substantial amendments received for information	4
Number of substantial amendments received for new sites/PIs	36
Number of annual progress reports received	87
Number of safety reports received	71
Number of Serious Adverse Events received	3
Number of final reports received	16

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/0564	The role of carer- and patient-level characteristics on carer QoL v1.0	30
17/LO/0724	Study assessing long-term safety of bardoxolone methyl in PH patients	22
17/LO/0782	ANB020-004 Placebo controlled study in Adults with Eosinophilic Asthma	23
17/LO/0788	Open-Label study of eteplirsen in Duchenne muscular dystrophy patients	21
17/LO/0976	NI-0501-06	28
17/LO/1134	PrEP Impact Trial	28
17/LO/1139	Fever Pilot Trial	22
17/LO/1146	Effect of Food, Rabeprazole and Formulation on GDC-0853 PK(QCL117979)	22
17/LO/1470	Young males with Asperger's Syndrome (AS) and their peer friendships	21
17/LO/1677	Angular Pregnancy Study, version 1	25
17/LO/1726	Odiparcil in patients with mucopolysaccharidosis (MPS) type VI	19
17/LO/1847	MUK Twelve	26
17/LO/1915	Study to determine the brain biodistribution of UCB0599 using PET	10
17/LO/1919	Shingles Protection (ShiP) Study	10
17/LO/1930	A Study of the Safety of IV Brincidofovir for Adenovirus Infection	28
17/LO/1951	Safety, Tolerability and PK of ABY-039 in Healthy Volunteers	24
17/LO/2021	PPD	27
18/LO/0018	Severe Atopic Disease in the Bangladeshi Population, Version 1	26
18/LO/0217	INSITU study	22
18/LO/0222	Quality of Life following surgery for recurrent rectal cancer	23

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/0550	Educational outcomes after childhood cancer in England (1)	26
17/LO/0977	ICEman	20
17/LO/0998	MAVMET	20
17/LO/1170	SERENADE: Macitentan in HFpEF and Pulmonary Vascular Disease	20
17/LO/1484	Optimal routine use of PROMs in paediatric ophthalmology.	20
18/LO/0168	COMPASS Study: Compassion and motivation in anorexia nervosa	22

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
17/LO/0500	QS-CMR Study	47
17/LO/0542	East London Lupus database	26
17/LO/0719	Flu-shed	21
17/LO/0957	CL04041024: Clinical Rheumatoid Arthritis Development for Olokizumab	20
17/LO/0997	4255 - explorerâ„¢5 efficacy & safety of concizumab in Haem A no inhib	20
17/LO/1485	The Dolphin Primary School Study	20
17/LO/1499	CMR-CPET study	20
17/LO/1568	PIMAT Study	20
17/LO/1755	ATX-TBL-001 Achilles Tx Tissue Research Protocol	15
17/LO/1860	PET-MR imaging iDOSH study	21
18/LO/0001	1199.225 open label extension study of nintedanib in SSc-ILD	22
18/LO/0123	CHESS: CHroniSense National Early Warning Score Study	27
18/LO/0174	Serratus Anterior Block and catheter use in Rib fractures	22

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
17/LO/0969	Biomarkers for chronic venous insufficiency (CVI): A preliminary study	44

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

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
18/LO/0530	Cardiac 31P-MRS at 3T	13

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/0729	Positive Attitudes Concerning Infant Feeding(PACIFY) Study	18
17/LO/0897	Raynaud's phenomenon in patients with peripheral neuropathy	11
17/LO/1102	Autoimmunity in Myalgic Encephalomyelitis/Chronic Fatigue Syndrome	9
17/LO/1105	Spatial Learning in patients with epilepsy and hippocampal sclerosisV1	7
17/LO/1305	Further Insights (Qualitative Stream) into the management of T2DM	12
17/LO/1309	Low risk women's perceptions of birth:an exploratory study. Version 1.	13
17/LO/2037	Time to diagnosis in IPF	13
17/LO/2106	Drug Allergy Labels in the Elective Surgical Population	16

18/LO/0197	Sedentary behaviour and physical activity in psychiatric inpatients	14
18/LO/0373	Evaluation of p16 IHC as a diagnostic tool in diagnosing melanoma.	8
18/LO/0377	Studying presenting symptoms in cancer patients	12
18/LO/0528	NHS Health Check Leaflet	7

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
17/LO/0725	MRI to Identify Changes in Healthy Aging Lungs (MICHAL)	18
17/LO/0898	The Microbiome of Saliva	11
18/LO/0379	Infant CMV Study	4
18/LO/0533	Pain in survivors of paediatric haematological malignancies	21

Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock
18/LO/0534	Exploring primary care and directly employed home care workers	15

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/Q0501/119/AM06	The Investigation of the cause and the mechanism of Immunodeficiency di	6	15/01/2018	28
08/H0720/46/AM05	Healthy Control Samples	Amendment 7	15/01/2018	25
10/H0720/55/AM07	Study of transmission risk between HIV discordant partners	3	13/03/2017	22
10/H0720/82/AM07	EFFORTLESS S-ICD Registry	5	14/07/2017	8
10/H0720/82/AM09	EFFORTLESS S-ICD Registry	6	02/07/2017	9
10/H0720/91/AM03	Anonymous Data Sharing for Small Bowel MRI	Amendment 3	20/12/2017	16
11/LO/0425/AM24	SYCAMORE	20	08/08/2017	17
11/LO/1147/AM02	Predictors 4 New tests for cervical screening Version 1	1	12/06/2017	6
11/LO/1331/AM03	A pilot qualitative study of severe and enduring eating disorders	5	01/11/2016	20
11/LO/2036/AM27	Phase I/II Safety, PK & Efficacy Study of Oral Rucaparib	SA - IB Updates	18/01/2018	12
12/LO/0803/AM39	AZD5363 in patients with advanced or metastatic breast cancer (BEECH)	SA - IB	06/04/2017	20
12/LO/1411/AM08	NeSST2: The development of a non-invasive Short Synacthen Test	6	05/12/2017	9
13/LO/1150/AM03	ROLE OF LEFT ATRIAL SITES THAT TRIGGER PULMONARY VEIN ECTOPY IN PAF	Substantial Amendment 3	20/04/2017	14
13/LO/1150/AM05	ROLE OF LEFT ATRIAL SITES THAT TRIGGER PULMONARY VEIN ECTOPY IN PAF	Amendment 4	14/12/2017	26
13/LO/1321/AM14	GB28547 - Lebrikizumab in patients with idiopathic pulmonary fibrosis	SA08	16/08/2017	20
13/LO/1323/AM08	A study of Ferriprox to see how safe it is and how well it works	7	16/06/2017	20
13/LO/1520/AM14	Study Of Diabetic Nephropathy with Atrasentan	11	08/08/2017	17
14/LO/0120/AM07	Zibotentan better renal scleroderma outcome study (ZEBRA)	6	04/07/2017	20
14/LO/0892/AM10	Phase 1 Study to Evaluate the Safety and Tolerability of MEDI4736 as Monotherapy or in Combination with Tremelimumab with or without Azacitidine in Subjects with Myelodysplastic Syndrome after Treatment with Hypomethylating Agents	Substantial Amendment 8	05/04/2017	21
14/LO/0892/AM12	Phase 1 Study to Evaluate the Safety and Tolerability of MEDI4736 as Monotherapy or in Combination with	10	15/06/2017	21

	Tremelimumab with or without Azacitidine in Subjects with Myelodysplastic Syndrome after Treatment with Hypomethylating Agents			
14/LO/0892/AM15	Phase 1 Study to Evaluate the Safety and Tolerability of MEDI4736 as Monotherapy or in Combination with Tremelimumab with or without Azacitidine in Subjects with Myelodysplastic Syndrome after Treatment with Hypomethylating Agents	SA11	22/02/2018	21
14/LO/1459/AM15	Study of MMXÂ® Mesalamine/Mesalazine in Paediatric Ulcerative Colitis	5	23/06/2017	31
14/LO/2033/AM04	PROVENT	Substantial Amendment 3	24/04/2017	14
14/LO/2033/AM05	PROVENT	009339 SA#3 - Add PIC site	04/09/2017	22
14/LO/2037/AM13	Riociguat in diffuse cutaneous systemic sclerosis (dcSSc)	11	02/05/2017	31
15/LO/0075/AM09	Phase 3 study in treatment-naïve HIV-1 infected subjects	9	31/05/2017	28
15/LO/0273/AM05	Randomised, Phase 3 study for subjects with Early Stage TNBC	Veliparib (ABT-888)	22/06/2017	5
15/LO/0273/AM06	Randomised, Phase 3 study for subjects with Early Stage TNBC	Substantial Amendment 7	02/01/2018	15
15/LO/0278/AM08	Harvoni in Adolescents and Children with HCV	Substantial Amendment 6	05/04/2017	21
15/LO/0278/AM10	Harvoni in Adolescents and Children with HCV	7	09/08/2017	16
15/LO/0278/AM12	Harvoni in Adolescents and Children with HCV	SA08	13/09/2017	13
15/LO/0282/AM06	I1F-MC-RHBE Ixekizumab in patients with active psoriatic arthritis	5	29/06/2017	15
15/LO/0282/AM07	I1F-MC-RHBE Ixekizumab in patients with active psoriatic arthritis	Substantial Amendment 6	04/12/2017	23
15/LO/0315/AM03	Physical Activity Questionnaire for CKD	Substantial Amendment 3	09/04/2017	16
15/LO/0424/AM06	PK of Efavirenz & Lopinavir Nano-Formulations in Healthy Volunteers	Substantial Amendment 6	30/11/2017	24
15/LO/0833/AM11	IBIS 3 Feasibility version 1.0	SA#7	21/03/2017	7
15/LO/0833/AM12	IBIS 3 Feasibility version 1.0	8	08/06/2017	21
15/LO/0833/AM13	IBIS 3 Feasibility version 1.0	Protocol Version 9.0	16/08/2017	9
15/LO/0833/AM15	IBIS 3 Feasibility version 1.0	SA#10	27/11/2017	23

15/LO/0904/AM02	SSAT063- PK of EFV 400mg once daily during pregnancy in HIV+ women	Substantial Amendment 2	03/05/2017	29
15/LO/1077/AM08	ABC-07	Substantial Amendment 6	16/05/2017	17
15/LO/1077/AM09	ABC-07	7	15/06/2017	21
15/LO/1090/AM06	Neutrophil defects and tooth loss in children	3.0	10/08/2017	11
15/LO/1488/AM02	Gift-Surg – Fetal MRI	1	01/06/2017	21
15/LO/1592/AM09	QVA149_Indacaterol maleate/Glycopyrronium bromide_Phase IV_COPD	Substantial Amendment 07	19/04/2017	15
15/LO/1592/AM10	QVA149_Indacaterol maleate/Glycopyrronium bromide_Phase IV_COPD	8	30/06/2017	24
15/LO/1681/AM14	1199.214 Nintedanib vs placebo in scleroderma related lung fibrosis	Substantial Amendment 10	09/05/2017	23
15/LO/1681/AM16	1199.214 Nintedanib vs placebo in scleroderma related lung fibrosis	11	31/05/2017	25
15/LO/1681/AM17	1199.214 Nintedanib vs placebo in scleroderma related lung fibrosis	12	26/07/2017	6
15/LO/1681/AM20	1199.214 Nintedanib vs placebo in scleroderma related lung fibrosis	13	20/11/2017	18
15/LO/1681/AM21	1199.214 Nintedanib vs placebo in scleroderma related lung fibrosis	15	12/01/2018	6
15/LO/1681/AM22	1199.214 Nintedanib vs placebo in scleroderma related lung fibrosis	Substantial Amendment 15	26/02/2018	36
15/LO/1868/AM04	StOP Haemophilia A Study	Substantial Amendment 1	12/12/2017	24
15/LO/1975/AM01	The Effect of Age on Zostavax Vaccine Response	V3 10/6/2017	10/06/2017	13
15/LO/2016/AM02	QOL in dialysis patients and carers	Amendment 2 date 17.05.2017	17/05/2017	22
15/LO/2098/AM10	INTEREST study	IB Ed 17	13/09/2017	18
15/LO/2098/AM11	INTEREST study	Protocol Amendment 5	15/11/2017	26
15/LO/2100/AM08	TAGS	5	31/10/2017	3
16/LO/0017/AM05	Phase I/II study - patients with previously treated solid tumours	Substantial Amendment 4	25/05/2017	9
16/LO/0017/AM06	Phase I/II study - patients with previously treated solid tumours	Substantial Amendment 5	08/12/2017	14

16/LO/0029/AM16	Phase 3 study with GS-9883/F/TAF in HIV-1, treatment naïve subjects	SA - IB Updates	27/09/2017	31
16/LO/0036/AM12	GS-9883/F/TAF versus ABC/DTG/3TC in HIV-1, treatment-naïve subjects	SA - IB Updates	27/09/2017	31
16/LO/0039/AM11	Phase 3 switch study with GS-9883/F/TAF & ABC/DTG/3TC in HIV-1 subject	SA - IB Updates	27/09/2017	31
16/LO/0058/AM06	LAVA- Liver resection surgery versus thermal ablation for CLM	3	03/11/2017	18
16/LO/0141/AM05	INCEPTUS: ATX-MTM-009	5	13/06/2017	18
16/LO/0144/AM04	SHP-GCB-402-effect of Velaglucerase alfa on Bones in Gaucher Disease	5	26/04/2017	8
16/LO/0144/AM07	SHP-GCB-402-effect of Velaglucerase alfa on Bones in Gaucher Disease	Amendment 4	04/05/2017	23
16/LO/0251/AM06	Fetal Atrial Flutter & Supraventricular Tachycardia Therapy Trial	SAM05_AM06	20/09/2017	19
16/LO/0251/AM07	Fetal Atrial Flutter & Supraventricular Tachycardia Therapy Trial	6	12/10/2017	29
16/LO/0251/AM08	Fetal Atrial Flutter & Supraventricular Tachycardia Therapy Trial	SAM08-09	25/10/2017	5
16/LO/0251/AM10	Fetal Atrial Flutter & Supraventricular Tachycardia Therapy Trial	SAM09_AM10	21/03/2018	25
16/LO/0497/AM01	Biomarkers of ageing in serum	1	28/09/2017	14
16/LO/0574/AM07	MERCK - MS200662_0001	7	13/06/2017	23
16/LO/0574/AM08	MERCK - MS200662_0001	SA08 IBv2.0	24/07/2017	8
16/LO/0816/AM03	People with ID moving under Transforming Care	Amendment 2	27/10/2017	7
16/LO/1008/AM04	Phase 2 study in participants with Hepatitis C and liver transplant	SA3	20/04/2017	14
16/LO/1022/AM04	MEDI4736-MM-003 Phase 2 Relapsed and Refractory Multiple Myeloma	SA 4	27/04/2017	32
16/LO/1022/AM05	MEDI4736-MM-003 Phase 2 Relapsed and Refractory Multiple Myeloma	5	30/06/2017	24
16/LO/1022/AM06	MEDI4736-MM-003 Phase 2 Relapsed and Refractory Multiple Myeloma	Temporary halt of study MEDI47	19/09/2017	13
16/LO/1022/AM07	MEDI4736-MM-003 Phase 2 Relapsed and Refractory Multiple Myeloma	7	29/09/2017	25
16/LO/1022/AM08	MEDI4736-MM-003 Phase 2 Relapsed and Refractory Multiple Myeloma	5.0	14/11/2017	25

16/LO/1022/AM09	MEDI4736-MM-003 Phase 2 Relapsed and Refractory Multiple Myeloma	Protocol 2.1, IB and PIS/ICF U	25/01/2018	5
16/LO/1024/AM05	BEAT LUPUS	SA02	28/03/2017	19
16/LO/1024/AM06	BEAT LUPUS	Substantial Amendment #3	11/09/2017	14
16/LO/1222/AM02	ATLANTIS Trial	SA2	10/04/2017	16
16/LO/1226/AM04	Mainstreamed genetic testing: intentions, decision-making and outcomes	3	28/11/2017	14
16/LO/1622/AM04	Investigation of a new diet for the treatment of obesity in the NHS	2	02/08/2017	17
16/LO/1625/AM19	Assessment of real life care (ARIADNE)	SA2	01/09/2017	11
16/LO/1633/AM03	Microbial behaviour and response to polypropylene mesh	No 1	23/08/2017	13
16/LO/1792/AM02	Endoscopic clot lavage in neonatal post-haemorrhagic hydrocephalus	SA01	10/05/2017	22
16/LO/1810/AM06	A Phase 3 - Ublituximab in Combination with TGR-1202	5	05/07/2017	18
16/LO/1810/AM09	A Phase 3 - Ublituximab in Combination with TGR-1202	6	31/10/2017	25
16/LO/1875/AM03	Safety & Efficacy of VX-440 Combination Therapy for Cystic Fibrosis	Substantial Amendment 2	26/05/2017	13
16/LO/2138/AM01	Pirates Assessment Tool	1	29/09/2017	24
16/LO/2186/AM03	IMAT-Neuroblastoma	1.0	15/09/2017	19
16/LO/2203/AM02	POM study of GSK2330811 in diffuse cutaneous systemic sclerosis 201247	Substantial Amendment 1	11/05/2017	22
16/LO/2203/AM04	POM study of GSK2330811 in diffuse cutaneous systemic sclerosis 201247	Protocol Amendment 03, PIS-ICF	28/09/2017	5
17/LO/0040/AM01	PB-102-F30-Open Label Study of PRX-102 in patients with Fabry Disease	SA - Reimbursement Policy	05/01/2018	10
17/LO/0089/AM01	Phase 2 - SOF/VEL in Chronic HCV on Dialysis for Renal Disease	SA#1	25/04/2017	8
17/LO/0179/AM01	Safety & Tolerability of MEDI3506 in SAD/MAD Study	Substantial Amendment 1	18/05/2017	21
17/LO/0179/AM03	Safety & Tolerability of MEDI3506 in SAD/MAD Study	2	15/01/2018	10
17/LO/0179/AM04	Safety & Tolerability of MEDI3506 in SAD/MAD Study	SA 3 –Restart Trial	15/03/2018	13
17/LO/0207/AM01	RIFT (SSCR101)	Substantial Amendment 1	28/03/2017	28

17/LO/0214/AM01	RaNGO	Substantial Amendment 1	14/12/2017	24
17/LO/0249/AM02	CO39385: Study of Atezolizumab + Enzalutamide vs Enzalutamide in mCRPC	SA2	26/04/2017	8
17/LO/0249/AM03	CO39385: Study of Atezolizumab + Enzalutamide vs Enzalutamide in mCRPC	3	05/06/2017	23
17/LO/0249/AM04	CO39385: Study of Atezolizumab + Enzalutamide vs Enzalutamide in mCRPC	Amendment 4	26/09/2017	7
17/LO/0249/AM07	CO39385: Study of Atezolizumab + Enzalutamide vs Enzalutamide in mCRPC	Substantial Amendment 5	13/12/2017	9
17/LO/0500/AM02	QS-CMR Study	01	13/03/2018	21
17/LO/0564/AM01	The role of carer- and patient-level characteristics on carer QoL v1.0	ver 1.2	08/08/2017	14
17/LO/0719/AM01	Flu-shed	1	03/08/2017	15
17/LO/0719/AM02	Flu-shed	2	21/08/2017	11
17/LO/0782/AM02	ANB020-004 Placebo controlled study in Adults with Eosinophilic Asthma	Substantial Amendment 1	17/10/2017	13
17/LO/0782/AM03	ANB020-004 Placebo controlled study in Adults with Eosinophilic Asthma	Substantial Amendment 2	15/01/2018	14
17/LO/0782/AM04	ANB020-004 Placebo controlled study in Adults with Eosinophilic Asthma	Substantial Amendment 3	15/03/2018	19
17/LO/0788/AM01	Open-Label study of eteplirsen in Duchenne muscular dystrophy patients	1	29/06/2017	25
17/LO/0898/AM01	The Microbiome of Saliva	207795161117	16/11/2017	17
17/LO/0997/AM01	4255 - explorer™5 efficacy & safety of concizumab in Haem A no inhib	Substantial Protocol Amendment	14/12/2017	26
17/LO/0998/AM01	MAVMET	#1	15/08/2017	17
17/LO/1134/AM04	PrEP Impact Trial	SA01 - 06 Sep 2017	06/09/2017	6
17/LO/1139/AM01	Fever Pilot Trial	1	06/10/2017	24
17/LO/1170/AM01	SERENADE: Macitentan in HFpEF and Pulmonary Vascular Disease	Mecitentan IB V14 Amdt 1	01/06/2017	24
17/LO/1170/AM02	SERENADE: Macitentan in HFpEF and Pulmonary Vascular Disease	Substantial Amendment 2	04/09/2017	22
17/LO/1170/AM04	SERENADE: Macitentan in HFpEF and Pulmonary Vascular	Substantial	24/11/2017	34

	Disease	Amendment 3		
17/LO/1305/AM01	Further Insights (Qualitative Stream) into the management of T2DM	Amendment 1	27/11/2017	23
17/LO/1499/AM01	CMR-CPET study	Substantial Amendment 01	06/02/2018	30
17/LO/1568/AM01	PIMAT Study	1	29/09/2017	19
17/LO/1755/AM01	ATX-TBL-001 Achilles Tx Tissue Research Protocol	Amendment 01	06/02/2018	27
17/LO/1847/AM01	MUK Twelve	Substantial Amendment 1	10/01/2018	29

Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
15/LO/0441/AM01	Study of Melatonin for treatment of Nocturia in PD	1	26/10/2017	29
16/LO/0141/AM08	INCEPTUS: ATX-MTM-009	Substantial Amendment 6	03/10/2017	35
16/LO/0806/AM03	PPC - Personalised Programmes for Children	Amendment 2	13/11/2017	30

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/0441/AM01/1	Study of Melatonin for treatment of Nocturia in PD	Modified	26/10/2017	2
16/LO/0806/AM03/1	PPC - Personalised Programmes for Children	Formal Letter to REC re: SA2	31/01/2018	1

Unfavourable opinion timeline

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

REC Reference	Title	Number of Days on Clock
17/LO/0732	A PHASE III, MULTICENTER, RAND	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
15/LO/1681/AM22	1199.214 Nintedanib vs placebo in scleroderma related lung fibrosis	Substantial Amendment 15	26/02/2018	36

Modified Amendments over 14 day timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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