

London - Stanmore Research Ethics Committee

Annual Report

01 April 2017 - 31 March 2018



Part 1 – Committee Membership and Training

Name of REC:	London - Stanmore Research Ethics Committee
Type of REC:	Authorised
Type of Flag:	Medical Devices and Qualitative
Chair:	Mrs Rosemary Hill
Vice-Chair:	Mr Anthony Gilbert until 30 June 2017 Mrs Sunder Chita from 21 August 2017
Alternate Vice-Chair:	Dr Anthony Kaiser
REC Manager:	Mr Patrick Walsh
REC Assistant:	Stephan Ramey; previously Asha Jama
Committee Address:	Ground Floor NRES/HRA 80 London Road London SE1 6LH
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Chair's overview of the past year:

The Committee had another interesting and worthwhile year. The whole committee is enthusiastic and very willing to do what they can.

We are flagged for medical devices and for qualitative research. In addition to the qualitative research detailed in the report much of the student applications were qualitative work.

The Committee has specialists in a wide variety of fields, including medical device studies and qualitative research. Quite a few of the members have conducted research themselves and are in a position to give advice to applicants from their own experience.

The Committee is grateful for the help we receive from the manager and assistants.

London - Stanmore Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Mrs Sunder Chita	Health Service Research Manager	Lay	21/08/2017	
Mr Gordon Coleman	Retired - Justice of Peace	Lay Plus	26/06/2009	
Mrs Marion Cumbers	Retired Librarian	Lay Plus	16/06/2009	
Dr Geraldine Edge	Consultant Anaesthetist	Expert	16/06/2009	
Miss Elizabeth Eldridge	Freelance Senior Corporate Producer	Lay	17/11/2017	
Mr Anthony Gilbert	Therapies Research Co-ordinator	Expert	21/06/2009	
Dr Lisa Griffiths	Neurophysiology Technician	Lay Plus	05/01/2017	
Mrs Rosemary Hill	Statistician	Lay	18/06/2009	
Dr Anthony Kaiser	Consultant Neonatologist	Expert	01/12/2013	
Mrs Elayne Nasr	Retired School Matron	Lay Plus	17/06/2009	
Dr Carol Pellowe	Senior Lecturer - Infection Control - retired	Lay	17/06/2009	
Mrs Susan Ruben	Pharmacist / Pharmacy Manager	Expert	09/12/2011	
Mrs Yasmin Shaik	Administrative	Lay	09/08/2016	
Mr George Verghese	Orthopaedic Surgeon	Expert	01/07/2011	
Mrs Shirley Williams	Retired Nurse	Lay	17/06/2009	07/12/2017

London - Stanmore Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended
Mrs Sunder Chita	Research Manager	Lay	01/06/2017
Mr Nicholas Harper	Project Manager	Lay	01/06/2017
Mrs Monica Jefford	Retired Nurse	Expert	01/06/2017
Mrs Stephanie Ellis	Retired Civil Servant	Expert	01/02/2018
Dr Michael Schachter	Senior Lecturer	Expert	01/03/2018

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

Name	Declaration of Interest	Date
Mrs Sunder Chita	None	05/10/2017
Mrs Marion Cumbers	Lay Representative, TARVA ankle research project, RNOH Lay Representative, Statins and Pragmatic Trials research projects, Farr Institute, (Tjeerd van Staa) Lay representative, Neonatal Clinical Studies Group, Medicines for Children Research Network, Public representative, Member of RNOH Patient Group JAG Lay Assessor, Royal College of Physicians, London (in training), Use My Data Member, CLL Support Ambassador	15/03/2018
Dr Geraldine Edge	None	31/03/2018
Miss Elizabeth Eldridge	None	05/12/2017
Mr Anthony Gilbert	HVIVO shares	15/03/2018
Dr Lisa Griffiths	Research Lead for Clinical Neurophysiology department at RNOH, may be involved in future research.	15/03/2018
Mrs Rosemary Hill	Astra Zeneca shares	15/03/2018
Dr Anthony Kaiser	None	15/03/2018
Mrs Elayne Nasr	None	01/03/2018
Dr Carol Pellowe	Member of infection prevention society (retired section) Lay member of the Royal College of Anaesthetists' Committee	15/03/2018
Mrs Susan Ruben	None	01/03/2018
Mrs Yasmin Shaik	None	15/03/2018

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

Month	Date	Number of Members Present at Meeting
April	06/04/2017	9
May	04/05/2017	9
June	01/06/2017	8
July	06/07/2017	9
September	07/09/2017	11
October	05/10/2017	10
December	07/12/2017	13
February	01/02/2018	8
March	01/03/2018	7

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	27/04/2017	3
May	24/05/2017	3
July	24/07/2017	3
August	21/08/2017	3
October	24/10/2017	3

5 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	27/04/2017	2
May	15/05/2017	2
May	31/05/2017	2
June	15/06/2017	2
June	30/06/2017	3
July	31/07/2017	2
August	15/08/2017	3
August	29/08/2017	3
August	31/08/2017	4
September	15/09/2017	3
October	15/10/2017	2
October	31/10/2017	2
November	15/11/2017	2
November	30/11/2017	2
December	15/12/2017	2
January	15/01/2018	2
January	31/01/2018	2

February	28/02/2018	2
March	15/03/2018	2
March	30/03/2018	2

20 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
Mrs Sunder Chita	5
Mr Gordon Coleman	5
Mrs Marion Cumbers	7
Dr Geraldine Edge	8
Miss Elizabeth Eldridge	3
Dr Anthony Gilbert	2
Dr Lisa Griffiths	8
Mrs Rosemary Hill	8
Dr Anthony Kaiser	6
Mrs Elayne Nasr	8
Dr Carol Pellowe	4
Mrs Susan Ruben	6
Mrs Yasmin Shaik	3
Mr George Verghese	5
Mrs Shirley Williams	4

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

Name	Number of Meetings Attended
Mrs Sunder Chita	1
Mrs Marion Cumbers	1
Dr Geraldine Edge	1
Mrs Rosemary Hill	4
Dr Anthony Kaiser	3
Mrs Elayne Nasr	1
Dr Carol Pellowe	1
Mrs Susan Ruben	1
Mrs Yasmin Shaik	2

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

Name	Number of Meetings Attended
Mrs Sunder Chita	6
Mrs Marion Cumbers	4
Dr Geraldine Edge	3
Dr Lisa Griffiths	3
Mrs Rosemary Hill	14
Dr Anthony Kaiser	4
Mrs Elayne Nasr	3
Dr Carol Pellowe	2
Mrs Susan Ruben	4
Mrs Yasmin Shaik	2
Mr George Verghese	1

Training 01 April 2017 - 31 March 2018

Name of Member	Date	Event(s) attended
Mrs Sunder Chita	06/11/2017	REC Chair Meeting
Mrs Marion Cumbers	15/11/2017	Medical devices training
Mrs Marion Cumbers	08/03/2018	Local Member Training Day
Miss Elizabeth Eldridge	04/09/2017	Introduction to GCP
Mr Anthony Gilbert	15/11/2017	Medical Devices Training
Dr Lisa Griffiths	23/05/2017	Medical Devices training
Dr Lisa Griffiths	04/10/2017	Equality and Diversity
Mrs Rosemary Hill	03/05/2017	REC Chairs Meeting
Dr Anthony Kaiser	01/08/2017	HTA
Dr Anthony Kaiser	15/11/2017	Medical Devices training
Mrs Elayne Nasr	15/11/2017	Medical devices training
Dr Carol Pellowe	15/11/2017	Medical devices training
Mrs Susan Ruben	04/01/2018	Statistics in Research
Mrs Susan Ruben	10/01/2018	Child Protection Training
Mrs Yasmin Shaik	12/11/2017	Online 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	0	0.00
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	40	100.00
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	1
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	13
Number of paediatric applications reviewed	6
Number of device applications reviewed	12
Number of prisoner applications reviewed	1
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	12

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	1	2.50
Favourable Opinion with Additional Conditions	4	10.00
Unfavourable Opinion	2	5.00
Provisional Opinion	33	82.50
Provisional Opinion Pending Consultation with Referee	0	0.00
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	26	65.00
Further Information Favourable Opinion with Additional Conditions	7	17.50
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	1	2.50
Favourable Opinion with Additional Conditions	4	10.00
Unfavourable Opinion	2	5.00
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	0	0.00
Total	40	100

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

Total Applications Reviewed	8
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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	2
Number of paediatric applications reviewed	1
Number of device applications reviewed	2
Number of qualitative applications reviewed	1

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	1	12.50
Favourable Opinion with Additional Conditions	1	12.50
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	6	75.00
Unfavourable Opinion	0	0.00
Total	8	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	4.44
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)	37
Number of completed proportionate review applications for ethical review	8
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	1
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	0
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	46
Number of completed substantial amendments over 35 days	2
Number of completed substantial amendments over 35 days as a % of total substantial amendments	4.35%
Number of modified amendments reviewed	0
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	82
Number of substantial amendments received for information	0
Number of substantial amendments received for new sites/PIs	0
Number of annual progress reports received	35
Number of safety reports received	0
Number of Serious Adverse Events received	6
Number of final reports received	4

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/0668	SAMBUCA version1	59
17/LO/0772	East London Project (Component A)	34
17/LO/0907	PRIMER V1.1	55
17/LO/0919	Return to work with Individualised Supported Employment (RISE)	37
17/LO/1031	Non-invasive neuromodulation for bladder suppression following SCI	44
17/LO/1092	The school experiences of transgender young people in the UK	27
17/LO/1101	CONVERGE IDE Study VAL-1200D	34
17/LO/1110	Families Experiences of Positive Behaviour Support	25
17/LO/1145	Mutation profile of Low grade Uterine Cancer of poor prognosis	30
17/LO/1416	Assessment of bone graft substitute in high tibial osteotomy	48
17/LO/1454	East London Project (Component B; version 1)	55
17/LO/1672	Melanoma Detection System (MDS) Clinical Utility Study	36
17/LO/1691	TOLERANCE AND ACCEPTABILITY OF AYMES 'MONACO'	31
17/LO/1705	Sexual health, risk and attitudes among men who have sex with men	41
17/LO/2050	Pilot Study Gait Rehabilitation	47
17/LO/2073	Protective Factors Preventing Admissions in Anorexic Patients	45
17/LO/2094	Exploring the relationship UK male gamblers have with money.	39
17/LO/2102	Rethinking Strategies for Positive Newborn Screening Result Delivery	29
18/LO/0048	Biological mechanisms associated with anxiety in very preterm children	60
18/LO/0069	ReAT Project	39
18/LO/0070	MR guided focused ultrasound treatment of Parkinson's disease	59
18/LO/0135	Rapid AssessMent of prostAte caNcer - RAMAN Study	31
18/LO/0252	Pilot study of AS OCT in Paediatric Uveitis	57
18/LO/0366	A Pilot Study: Cognitive Behavioural Therapy for Alopecia Areata	31
18/LO/0375	Lived experiences for potential IAC. Version number 1.0	32
18/LO/0378	The PIONEER III Study, SIN-US-001	54

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
17/LO/0457	The Bio-inspired Artificial Pancreas for the Home	39
17/LO/0472	Stimulation Headset for the Prevention of Migraine Headache	34

17/LO/0577	The effect of cannabis use on brain function in early psychosis	27
17/LO/0759	POP KD. Version 1.0	35
17/LO/0839	The impact on the family when one member has a label of dementia	31
17/LO/0929	Implantable Sensor in Severe Aortic Stenosis (ISAS study) Version 1.0	32
17/LO/1467	Exploring Advance Care Planning	33

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
18/LO/0163	SMS Reminders to Reduce Was Not Brought Rates in Paediatric Outpatient	24

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
17/LO/0576	The artificial pancreas in very young children with T1D-pilot-KidsAP01	26
17/LO/1341	Ultrasound in Forearm Fractures	28
17/LO/1474	Experience of Neuropsychological Ax in Neurodegenerative Conditions v1	28
17/LO/1684	Measurement on Our Terms (MOT)	28

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
17/LO/1685	Catric Study (Version 2)	27
17/LO/2117	Reduce Rates of Dislocation after THR- Use of Kinesio Tape	24

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
17/LO/0739	Pilot Study Comparing Leg Wound Complications From Vein Harvest	21
17/LO/0752	Co-designing a cardiac rehabilitation programme for South Asians	19
17/LO/1854	Prognostic value of histological grade in Medullary Thyroid Cancer	14
17/LO/1856	Breast Cancer Feasibility	9

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
17/LO/0895	Intraoral Tongue Stimulation for Treatment of Snoring and Sleep Apnoea	20
17/LO/1435	Overlap	17

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/1437	Seqirus EPSS 2017	10

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
17/LO/1296	SURPASS Registry	11

Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock

Provisional Opinion		
REC Reference	Title	Number of Days on Clock

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

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

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

Favourable opinion				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
08/H0724/34/AM18	Non-invasive Assessment of Human Bone Quality	SubAM May 17	01/05/2017	18
10/H0724/38/AM05	SCD	4	15/09/2017	25
11/LO/0922/AM04	OVATION Post Market Study	3	03/07/2017	8
12/LO/0491/AM09	Surgical Replacement & Transcatheter Aortic Valve Implantation SURTAVI	7	06/09/2017	28
12/LO/0837/AM04	Association of human papillomavirus (HPV) and breast tumours	3	20/03/2017	16
13/LO/0451/AM06	The UK TAVI Trial (version 1.0)	08	21/07/2017	17
13/LO/1832/AM03	SAFETY AND EFFICACY EVALUATION OF HAIRSTETICS' HAIR IMPLANT	7	06/07/2017	20
13/LO/1837/AM07	Radiocyst 01	3	06/09/2017	18
14/LO/0663/AM05	Brain connectivity in ASD: a biomarker to predict treatment response	5	27/03/2017	10
14/LO/0677/AM06	Preterm birth and executive attention	5	07/06/2017	27
14/LO/0677/AM07	Preterm birth and executive attention	SA6	18/12/2017	28
14/LO/0843/AM07	Beyond TME version 1.2	4	31/07/2017	29
14/LO/1264/AM03	Image guidance with image overlay for laparoscopic surgery	2	16/11/2017	12
15/LO/0900/AM09	630-0012 Pulmonx LIBERATE Study	5	14/08/2017	29
15/LO/1051/AM03	NEST: NMDA-receptors in Epilepsy, Stroke and TBI.	2	26/04/2017	28
15/LO/1051/AM06	NEST: NMDA-receptors in Epilepsy, Stroke and TBI.	4	18/01/2018	35
15/LO/1348/AM01	MyLifeHub: Internet of Things in Ophthalmic Care	2	24/08/2017	8
15/LO/1597/AM03	RejuvenAir™ System Chronic Bronchitis Version 2	3	16/06/2017	25
16/LO/0104/AM02	International validation of the EORTC QLQ-CAX24	2	26/01/2018	13
16/LO/0118/AM05	Valiant Evo International Clinical Trial	4	06/10/2017	19
16/LO/0645/AM07	Equality for CYP with learning disabilities (LD) - Phases 2-4	4	24/10/2017	19
16/LO/0645/AM09	Equality for CYP with learning disabilities (LD) - Phases 2-4	9	20/12/2017	37
16/LO/0671/AM05	CAPT OE	3	26/07/2017	35
16/LO/0878/AM04	everlinQ endoAVF EU Study v1.0	3	30/03/2017	2
16/LO/0878/AM05	everlinQ endoAVF EU Study v1.0	4	06/06/2017	21
16/LO/1044/AM12	DETECT II	3	29/06/2017	33
16/LO/1091/AM04	Ealing geko VLU study	2	11/08/2017	31

16/LO/1245/AM02	The HeartSpare Plus 1B Trial	6	11/05/2017	27
16/LO/1325/AM03	faecal bile acid study	2	22/09/2017	25
16/LO/1336/AM01	Tocilizumab mono therapy versus other biologic mono therapy in RA	1	01/09/2017	23
16/LO/1551/AM02	Abnormal Patient Test Results Study	1	17/10/2017	34
16/LO/1796/AM02	CONTOUR (A4062)	2	22/05/2017	12
16/LO/1805/AM01	Vitamin D to resolve inflammation after tuberculosis (Resolved-TB)V5.1	1	03/10/2017	16
17/LO/0166/AM01	The Effects of Whole Body Unloading on Physiological Function	1	10/05/2017	7
17/LO/0366/AM01	ROBIN, V2	4	22/05/2017	13
17/LO/0366/AM02	ROBIN, V2	2	21/02/2018	41
17/LO/0577/AM02	The effect of cannabis use on brain function in early psychosis	1.0	07/11/2017	10
17/LO/0919/AM02	Return to work with Individualised Supported Employment (RISE)	1	08/09/2017	13
17/LO/0919/AM03	Return to work with Individualised Supported Employment (RISE)	2	19/12/2017	31
17/LO/0919/AM04	Return to work with Individualised Supported Employment (RISE)	4	21/03/2018	23
17/LO/1101/AM01	CONVERGE IDE Study VAL-1200D	1 - VAL-1200(E)	02/10/2017	10
17/LO/1110/AM01	Families Experiences of Positive Behaviour Support	Amendment 1	22/01/2018	18
17/LO/1296/AM01	SURPASS Registry	1	10/11/2017	32
17/LO/1435/AM01	Overlap	1	09/02/2018	32
17/LO/1467/AM01	Exploring Advance Care Planning	1	12/12/2017	35
17/LO/1672/AM01	Melanoma Detection System (MDS) Clinical Utility Study	01	21/12/2017	35

Unfavourable opinion				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock

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

Unfavourable opinion timeline				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock

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

REC Reference	Title	Number of Days on Clock
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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
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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
16/LO/0645/AM09	Equality for CYP with learning disabilities (LD) - Phases 2-4	9	20/12/2017	37
17/LO/0366/AM02	ROBIN, V2	2	21/02/2018	41

Modified Amendments over 14 day timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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