

**South Central - Oxford C Research Ethics
Committee**

Annual Report

01 April 2017 - 31 March 2018



Part 1 – Committee Membership and Training

Name of REC:	South Central - Oxford C Research Ethics Committee
Type of REC:	REC recognised to review CTIMPs in patients -Type III
Type of Flag:	Adults Lacking Capacity Phase 1 in Patients Research Database Research Tissue Bank Qualitative Research
Chair:	Professor Nigel Wellman
Vice-Chair:	Mrs Susan Lousada
Alternate Vice-Chair:	Dr Lee Potiphar
REC Manager:	Ms Helen Sivey (09/01/2017 – 25/01/2018) Miss Lucy Roberts (26/01/2018 to present)
REC Assistant:	Ms Amy Peters (09/01/2017 – 01/11/2017) Miss Alison Doherty (18/01/2018 to present)
Committee Address:	Level 3, Block B Whitefriars Building Lewins Mead Bristol BS1 2NT
Telephone:	0207 104 8049
Email:	nrescommittee.southcentral-oxfordc@nhs.net

Chair's overview of the past year:

As always, Oxford C has been very busy over the last year, reviewing a wide range of studies. Through this time both the full committee and the sub-committee systems have continued to work well and the committee has continued to support researchers attempting to address vital but sometimes controversial and ethically challenging research questions, delivering sensible and pragmatic decisions which have ensured both the protection of the public and the promotion of high quality research for the public good. We have continued to welcome observers and we allocate three places per meeting for people from within clinical, educational and research communities to attend and observe the REC in action. This opportunity has proven to be highly valued by the local research community and observers have often provided interesting feedback to the committee.

As inevitably happens, valued members have retired or otherwise moved on from the committee and we have welcomed new members in their place. The Vice-Chair Mrs Susan Lousada and the Alternate Vice-Chair Dr Lee Potiphar have very ably managed the proportionate review work allowing the chair to focus on the sub-committee work arising from the full REC meetings and on chair's business, the provision of advice to researchers and other elements of work for the research and REC communities. As chair, I continue to feel very privileged to have had the support of Mrs Lousada and Dr Potiphar and our very committed group of lay and expert members. We have experienced changes of staff as REC managers and assistants have been promoted or moved on to other roles. For most of the current reporting period the committee was managed by Helen Sivey and her assistant Amy Peters. Helen and Amy have recently been replaced by Lucy Roberts and Alison Doherty who like their predecessors have been extremely efficient in managing all aspects of the business of this busy REC.

I would like to thank the officers, members and staff of the committee for their commitment, diligence and hard work. I am convinced that the committee will continue to deliver a prompt, courteous and efficient service to the research community over the next twelve months.

South Central - Oxford C Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Dr Leonard Brookes	Consultant to the Pharmaceutical Industry	Lay	01/04/2010	
Dr Linda Cartwright	Retired Consultant Epidemiologist	Expert	16/06/2017	
Dr Ben Caswell	Accountant	Lay Plus	15/09/2016	
Dr Alessandro Di Nicola	Lecturer in Philosophy	Lay Plus	12/09/2016	09/02/2018
Mrs Rebekah Howe	Farmer	Lay Plus	15/09/2016	
Mrs Vivienne Laurie	Barrister	Lay Plus	15/11/2012	
Dr Simon Lord	Honorary Consultant in Medical Oncology and Senior Clinical Researcher in Experimental Cancer Therapeutics	Expert	01/01/2016	24/11/2017
Mrs Susan Lousada	Company Director (Property) & Non-legal member of first-tier tax tribunal	Lay Plus	01/04/2010	
Mr Barry Muir	NHS Management Consultant (Retired)	Lay	01/05/2006	07/10/2016
Dr Lee Potiphar	Lecturer in Adult Nursing (Evidence Based Practice)	Expert	26/03/2015	
Mr Chris Pratt	Specialist Cancer Pharmacist	Expert	25/07/2016	31/05/2017
Ms Anna Rathmell	Medical Manager - GI	Lay	01/02/2016	
Dr Sabeena Sharma	Consultant Anaesthetist	Expert	23/05/2011	
Dr Surjeet Singh	Clinical Trials Coordinator	Expert	17/01/2013	
Ms Kayleigh Stanbury	Trial Coordinator and Developmental Assessor	Lay	29/01/2015	
Professor Nigel Wellman	Professor of Health and Human Sciences	Expert	01/09/2010	

South Central - Oxford C Research Ethics Committee: Deputy Members

Name	Profession	Status	Meeting date attended
------	------------	--------	-----------------------

South Central - Oxford C Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended
Dr Karen Pulford	Freelance medical/scientific writer and the honorary title of Emeritus Reader of Immunodiagnosics, NDCLS	Lay Plus	28/04/2017
Professor Ron King	Mathematician (Retired)	Lay Plus	23/03/2018

Miss Jennifer Lawson	Trials Manager	Lay	23/03/2018
----------------------	----------------	-----	------------

South Central - Oxford C Research Ethics Committee: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Dr Leonard Brookes	None	31/03/2018
Dr Linda Cartwright	None	26/06/2017
Dr Ben Caswell	None	31/03/2018
Mrs Rebekah Howe	None	28/04/2017
Mrs Vivienne Laurie	Share holding with Astra Zeneca	31/03/2018
Dr Simon Lord	Consultant Oncologist running several early phase cancer trials in Oxford.	01/06/2017
Mrs Susan Lousada	None	31/03/2018
Dr Lee Potiphar	None	31/03/2018
Ms Anna Rathmell	Gilead Sciences EMEAC- Senior Manager, Learning and Development, Medical Affairs- effective 5th March 2018	31/01/2018
Dr Sabeena Sharma	None	24/05/2017
Dr Surjeet Singh	Works for a surgical trials unit at the University of Oxford as CI/PI; might apply to the REC from this department. Works for the university of Oxford, which has a joint research office that initially reviews applications to the REC/MHRA and agrees to act as sponsor.	23/06/2017
Ms Kayleigh Stanbury	Works within the Clinical Trial Unit at University of Oxford who work on a variety of research and clinical trials which all require ethical review.	31/03/2018
Professor Nigel Wellman	None	26/05/2017

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

Month	Date	Number of Members Present at Meeting
April	28/04/2017	8
May	26/05/2017	9
June	30/06/2017	12
August	25/08/2017	13
September	29/09/2017	10
October	27/10/2017	11
November	24/11/2017	9
January	26/01/2018	9
February	23/02/2018	9
March	23/03/2018	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
August	23/08/2017	3
September	19/09/2017	4
September	27/09/2017	3
October	25/10/2017	3
November	22/11/2017	3
December	27/12/2017	3
February	19/02/2018	3
March	28/03/2018	3

12 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	10/04/2017	5
April	14/04/2017	2
April	21/04/2017	2
April	28/04/2017	2
May	05/05/2017	2
May	12/05/2017	2
May	19/05/2017	2
May	23/05/2017	3
May	26/05/2017	2

June	02/06/2017	2
June	07/06/2017	3
June	09/06/2017	2
June	16/06/2017	2
June	23/06/2017	2
June	30/06/2017	2
July	07/07/2017	2
July	14/07/2017	2
July	28/07/2017	2
August	04/08/2017	2
August	11/08/2017	2
August	18/08/2017	2
August	25/08/2017	2
September	01/09/2017	2
September	08/09/2017	2
September	15/09/2017	2
September	22/09/2017	2
September	29/09/2017	2
October	06/10/2017	2
October	13/10/2017	2
October	27/10/2017	3
November	03/11/2017	2
November	10/11/2017	2
November	17/11/2017	2
November	24/11/2017	2
December	01/12/2017	2
December	08/12/2017	3
December	08/12/2017	2
December	15/12/2017	2
December	20/12/2017	3
January	05/01/2018	2
January	12/01/2018	2
January	19/01/2018	2
January	26/01/2018	2
February	02/02/2018	2
February	09/02/2018	2
February	16/02/2018	2
February	23/02/2018	2
March	02/03/2018	2
March	02/03/2018	2
March	09/03/2018	2
March	16/03/2018	2
March	23/03/2018	2
March	30/03/2018	2
March	30/03/2018	2

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

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

None

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

Name	Number of Meetings Attended
Dr Leonard Brookes	9
Dr Linda Cartwright	7
Dr Ben Caswell	9
Dr Alessandro Di Nicola	2
Mrs Rebekah Howe	6
Mrs Vivienne Laurie	7
Dr Simon Lord	5
Mrs Susan Lousada	6
Dr Lee Potiphar	8
Mr Chris Pratt	3
Ms Anna Rathmell	8
Dr Sabeena Sharma	6
Dr Surjeet Singh	8
Professor Nigel Wellman	10

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

Dr Leonard Brookes	4
Dr Linda Cartwright	1
Dr Ben Caswell	1
Dr Alessandro Di Nicola	1
Mrs Rebekah Howe	2
Mrs Vivienne Laurie	2
Dr Simon Lord	5
Mrs Susan Lousada	7
Dr Lee Potiphar	6
Mr Chris Pratt	1
Ms Anna Rathmell	2
Dr Sabeena Sharma	1
Dr Surjeet Singh	2

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

Name	Number of Meetings Attended
Dr Leonard Brookes	10
Dr Linda Cartwright	3
Dr Ben Caswell	6
Dr Alessandro Di Nicola	2
Mrs Rebekah Howe	7
Mrs Vivienne Laurie	6

Dr Simon Lord	3
Mrs Susan Lousada	3
Dr Lee Potiphar	6
Mr Chris Pratt	3
Ms Anna Rathmell	8
Dr Surjeet Singh	5
Professor Nigel Wellman	54

Training 01 April 2017 - 31 March 2018

Name of Member	Date	Event(s) attended
Dr Leonard Brookes	19/06/2017	Equality and Diversity
Dr Leonard Brookes	30/06/2017	LTD 2017 Medical Devices
Dr Leonard Brookes	08/11/2017	Research involving children - UPCOMING
Dr Leonard Brookes	08/11/2017	The Ethical Issues of Research Involving Children
Dr Linda Cartwright	16/11/2017	Training - Committee Members Induction
Dr Ben Caswell	25/07/2017	REC member induction
Mrs Rebekah Howe	30/06/2017	LTD Medical Devices
Mrs Vivienne Laurie	31/03/2018	Reading Materials
Dr Simon Lord	30/06/2017	LTD Medical Devices
Mrs Susan Lousada	01/06/2017	SDL log
Mrs Susan Lousada	06/06/2017	Online Equality and Diversity module
Mrs Susan Lousada	12/09/2017	Genetic and Genomic Research
Mrs Susan Lousada	12/12/2017	National Members Training Day
Mrs Susan Lousada	20/03/2018	Complex Cases
Dr Lee Potiphar	30/06/2017	LTD Medical Devices- Oxford C
Dr Lee Potiphar	31/03/2018	Reading Data Protection Regulation briefing paper
Dr Lee Potiphar	31/03/2018	Reading research papers
Dr Lee Potiphar	31/03/2018	Reading HRA policy and website information
Ms Anna Rathmell	30/06/2017	LTD Medical Devices
Dr Sabeena Sharma	09/08/2017	CSTF Fire Safety SM-UFS01-01K
Dr Sabeena Sharma	09/08/2017	CSTF Infection Prevention & Control (Clinical) SM-UIPC01-01K
Dr Sabeena Sharma	31/03/2018	Reading ethical issues in BMJ and ELPAT (Ethical , Legal and Psychosocial Aspects of Organ Transplantation).
Dr Surjeet Singh	30/06/2017	LTD Medical Devices
Professor Nigel Wellman	30/06/2017	LTD Medical Devices

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	15	30.00
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	8	16.00
Others	27	54.00
Total Applications Reviewed	50	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	7
Number of paediatric applications reviewed	3
Number of device applications reviewed	3
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	11
Number of applications reviewed that are funded by the US DHHS	0
Number of qualitative applications reviewed	5

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	7	14.00
Favourable Opinion with Additional Conditions	23	46.00
Unfavourable Opinion	0	0.00
Provisional Opinion	20	40.00
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	50	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	15	30.00
Further Information Favourable Opinion with Additional Conditions	2	4.00
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	7	14.00
Favourable Opinion with Additional Conditions	23	46.00
Unfavourable Opinion	0	0.00
Provisional Opinion	3	6.00
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	50	100

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

Total Applications Reviewed	17
------------------------------------	-----------

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

Number of applications made invalid by the REC Manager	2
Number of studies withdrawn prior to the meeting	0
Number of student applications reviewed	8
Number of paediatric applications reviewed	2
Number of device applications reviewed	0
Number of qualitative applications reviewed	3

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

Decisions taken at proportionate review sub-committee meetings	Number	%
Favourable Opinion with Standard Conditions	2	11.76
Favourable Opinion with Additional Conditions	8	47.06
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	5.00
Number of completed applications for full ethical review	50
Number of completed applications for full ethical review over 60 days	2
Number of completed applications over 60 days as a % of total	4.00%
Number of completed applications for full ethical review over 40 days	9
Number of completed applications over 40 days as a % of total	18.00%
Number of days taken to final decision – average (mean)	29
Number of completed proportionate review applications for ethical review	18
Number of completed proportionate review applications for ethical review over 21 days	3
Number of completed proportionate review applications over 21 days as a % of total	16.67%
Number of SSAs (non-Phase 1) reviewed	5
Number of completed applications for SSA review over 25 days	2
Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs	40.00%
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	177
Number of completed substantial amendments over 35 days	8
Number of completed substantial amendments over 35 days as a % of total substantial amendments	4.52%
Number of completed substantial amendments over 28 days	26
Number of completed substantial amendments over 28 days as a % of total substantial amendments	14.69%
Number of modified amendments reviewed	4
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	133
Number of substantial amendments received for information	9
Number of substantial amendments received for new sites/Pis	43
Number of annual progress reports received	91
Number of safety reports received	18
Number of Serious Adverse Events received	1

Number of final reports received	7
-----------------------------------------	---

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/SC/0207	WHITE 7 - WHISH – Wound Healing in Surgery for Hip fractures	44
17/SC/0229	OMO1.01.02	43
17/SC/0262	EMPA-HEART Version 1.0	52
17/SC/0394	A Phase 2 Dose-Finding Study of Pacritinib in Myelofibrosis Patients	50
17/SC/0397	Parent/carer experiences of children's treatment with frames V1	33
17/SC/0488	Steady Together	56
17/SC/0491	PROCLAIM CX-2009 in adults with metastatic/advanced solid tumours	63
17/SC/0512	A grounded theory study of PTSD following ICU	32
17/SC/0514	Primary Care for children and young people with eating disorders	33
17/SC/0537	INPUT questionnaire database	40
17/SC/0543	An explorative interview study for a single case of DID	34
17/SC/0586	Testicular Safety of Filgotinib in Males with Ulcerative Colitis	56
17/SC/0605	Phase 1/2 dose-escalation study of CTX-SPL9111 in cancer patients	62
18/SC/0044	COMPASS	37
18/SC/0095	BREEZE-AD4 - Baricitinib in moderate to severe atopic dermatitis	33

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
17/SC/0628	LoRETA	27
18/SC/0086	eLIXIR, Early Lifecourse data Cross-Linkage in Research	20

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/SC/0430	Namaste Care Implementation	27
17/SC/0581	CRIS Linkage with the DWP Employment and Benefits Data	20
18/SC/0001	SHARP Post-Trial Follow-Up	19

18/SC/0003	CRIS Linkage with the Office for National Statistics (ONS) Census Data	19
18/SC/0006	Using brain signals to control symptoms and assistive devices	16
18/SC/0028	CC-92480 with Dexamethasone in Relapsed & Refractory Multiple Myeloma	19
18/SC/0039	IMPARTS Research Database Renewal	19

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
17/SC/0168	PC SHOP	29
17/SC/0205	Repeatability Study	29
17/SC/0216	Study of Acalabrutinib and Vistusertib in B-cell malignancies	29
17/SC/0231	Pembrolizumab versus standard therapy in mesothelioma (PROMISE-meso)	29
17/SC/0272	Feasibility study of biofeedback in dysphagia therapy post stroke	22
17/SC/0274	Validation of POEM	22
17/SC/0277	C9orf72 Cohort Study	21
17/SC/0414	Experiences and Needs of Patients with Pancreatic Cancer	22
17/SC/0434	Biomarker-guided duration of antibiotic treatment for sepsis	23
17/SC/0494	Neuroimmunology 1.4	21
17/SC/0497	The HOME Study	21
17/SC/0556	MONITOR PsA (Cohort)	19
17/SC/0617	UK IBD Twin Database	23
17/SC/0618	Single&repeat dose of CSJ137 in anaemic chronic haemodialysis patients	16
18/SC/0011	Physical activity in patients with malignant pleural effusion	19
18/SC/0074	PF-04995274 and emotional processing in treatment-resistant depression	47
18/SC/0078	Utility of Digital Dermoscopy in the Skin Cancer Screening Clinic	18
18/SC/0103	Prostate MOlecular Targeting to Enhance surgery using IR800 IAB2M	18
18/SC/0104	RCT of COPe-support online resource for carers	18
18/SC/0111	Evaluation of the Valsalva Assist Device to treat SVT [EVADE]	20
18/SC/0139	DCC-2618 in the Treatment of Advanced Gastrointestinal Stromal Tumors	20
18/SC/0154	Forearm Blood Flow in Chronic Kidney Disease patients	20
18/SC/0155	The EMPA-KIDNEY Study	20

Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock

Provisional Opinion		
REC Reference	Title	Number of Days on Clock
17/SC/0464	Escalation in Acute psychiatry: Immersive Observation	n/a
18/SC/0146	PENTAGONS	n/a
18/SC/0158	KePPOD	n/a

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

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

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

Table 9.2: Breakdown of current status of all PRS applications reviewed within the reporting period

Further Information Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
17/SC/0149	A study comparing orthodontic brackets	38
17/SC/0194	SHERG: Electroretinography: investigation of a protocol change	23
17/SC/0220	Factors influencing skin wound healing v1.0	11
17/SC/0453	Observational real world study of effectiveness of pazopanib in RCC	8
17/SC/0461	Ida telecare version 1.0	8
17/SC/0503	The carbon footprint, for an elective DCC, comparing warfarin & NOACs	12
18/SC/0173	Deriving design implications for serious videogame for psychosis	19
18/SC/0176	Measuring maternal miRNA to predict pregnancy outcome	10

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/SC/0361	TEXAS Trial	16
18/SC/0113	Pilot of DNA extraction from saliva samples	6

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
17/SC/0270	BAFTA- AT (Version 1)	7
17/SC/0331	Outcome prediction following CPET and oesophagogastric surgery	12
17/SC/0386	Clients' Experience of Structured Self-therapy After CBT Discharge	18
17/SC/0459	MRCP Repeatability	8
17/SC/0479	Public Health England Physical Activity Infographic Study	33
17/SC/0630	MALIMAR - MACHine Learning In MyelomA Response	7
18/SC/0171	UGLA/ENSAT-HT_v1	6
18/SC/0179	Time variation of PRO scores in patients with chronic conditions	8

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
06/Q1606/139/AM08	Immune function in Inflammatory Arthritis version 1	V8 6 FEB 2018	21/02/2018	15
07/H0606/148/AM16	The Maternal Inflammatory Response and Pre-eclampsia	No:4 dated 20th February 2018	20/02/2018	6
07/Q1606/15/AM50	AVAST-M	41	21/08/2017	12
07/Q1606/15/AM56	AVAST-M	(Amendment no. 47, 28th Februa	28/02/2018	8
08/H0606/107+5/AM09	Oxford BioBank	5.0 30/05/2017	30/05/2017	8
08/H0606/107+5/AM10	Oxford BioBank	6.0 22/09/2017	22/09/2017	21
08/H0606/133/AM06	Understanding the neural basis of amnesia version 1.0	Amendment 4 ¹ / ₄ 23rd March 2017	12/05/2017	32
08/H0606/139/AM24	Intergrowth - 21st	15 - dated 18/01/2018	18/01/2018	6
08/H0606/29/AM21	W020698, Pertuzumab Study in HER2 + MBC Patients	#17 (substantial) - updated Pe	27/03/2017	22
08/H0606/71+5/AM05	South London and Maudsley Biomedical Research Centre Case Register	5 ¹ / ₄ 10th April 2017	10/04/2017	35
08/H0606/71+5/AM07	South London and Maudsley Biomedical Research Centre Case Register	8.0	23/11/2017	17
08/H0606/92/AM24	Bioavailability of 2 oral formulations of AZD2281 in cancer patients	Investigators Brochure, versio	27/03/2017	22
09/H0606/102/AM04	Phase I Trial of CXD101 in Patients with Advanced Cancer	SA07	04/10/2017	11
09/H0606/102/AM05	Phase I Trial of CXD101 in Patients with Advanced Cancer	OUH/PID/5933-SA08 1.0	22/02/2018	9
09/H0606/11/AM07	Oxford Musculoskeletal Tissue Bank - A resource for research into the	1 22/01/2018	27/02/2018	12

09/H0606/115/AM22	Phase 3 study - Lenalidomide in Patients with Myelodysplastic Syndrome	IB Edition 21 dated 24 Apr 201	09/06/2017	11
09/H0606/115/AM23	Phase 3 study - Lenalidomide in Patients with Myelodysplastic Syndrome	02a. Notice of Amendment.pdf	09/01/2018	21
09/H0606/78/AM04	The role of signalling pathways in human cancer	Amendment 5, 30th January 2018	01/03/2018	8
10/H0606/36/AM09	Mechanisms of dilatation in human arteries	21/11/17	29/11/2017	12
11/H0606/1/AM07	WBRT post local treatment in melanoma study	Amendment 007_28Mar2017	31/03/2017	8
11/SC/0064/AM06	PROCON (version 3.0)	Amendment 4.0	30/06/2017	20
11/SC/0140/AM07	AdipoRedox Study	AM07, AUG 2017	22/09/2017	14
11/SC/0329/AM15	IMUNITI	UK 2.0	16/06/2017	7
11/SC/0397/AM07	OXAMI	Number 5, 20 February 2017	20/04/2017	13
12/SC/0124/AM05	Magnetic Resonance Spectroscopy in Autoimmune Encephalitis	4, 6/11/2017	22/11/2017	18
12/SC/0241/AM14	Avastin EXTENSION	Amendment 11 (substantial) - a	25/04/2017	20
12/SC/0366/AM06	Nitric oxide in subarachnoid haemorrhage	Amendment 7 20th of July 2017	20/07/2017	13
12/SC/0474/AM01	Mechanisms of lung disease	2.0	14/06/2017	4
13/SC/0007/AM21	C28001 - MLN2480 patients with melanoma or solid tumour	SA#14 Updated ICFs for PA9	28/07/2017	17
13/SC/0096/AM16	MK-3475 compared to Ipilimumab in Patients with Advanced Melanoma	SA10 - IB13 & PIS update	29/03/2017	26
13/SC/0096/AM22	MK-3475 compared to Ipilimumab in Patients with Advanced Melanoma	SA19- IB 15 update	24/10/2017	14
13/SC/0096/AM24	MK-3475 compared to Ipilimumab in Patients with Advanced Melanoma	SA21 - Protocol Amendment 06 +	23/02/2018	8
13/SC/0111/AM16	FOCUS4: Molecular selection of therapy in colorectal cancer	11	04/04/2017	37
13/SC/0111/AM20	FOCUS4: Molecular selection of therapy in colorectal cancer	14 5.0 2018/01/09	22/01/2018	16
13/SC/0157/AM06	ROMAZA: Phase I study of Romidespin and Azacitidine in AML patients	Amendment 07	19/02/2018	16
13/SC/0184/AM13	212082PCR3011	SA-7	18/04/2017	16
13/SC/0184/AM14	212082PCR3011	212082PCR3011 SA-8	30/10/2017	19

13/SC/0184/AM15	212082PCR3011	9	14/02/2018	13
13/SC/0243/AM05	NICOLA V1.0	amendment 4	11/05/2017	6
13/SC/0273/AM18	Phase I of Pembrolizumab (MK-3475) in Pts with non small cell lung cancer	15 (REC)	04/08/2017	20
13/SC/0273/AM19	Phase I of Pembrolizumab (MK-3475) in Pts with non small cell lung cancer	SA16 (REC)	05/10/2017	32
13/SC/0273/AM20	Phase I of Pembrolizumab (MK-3475) in Pts with non small cell lung cancer	SA17	09/03/2018	12
13/SC/0354/AM19	PankoMab-GEXâ,ç in recurrent ovarian cancer GEXMab 25201 v1.0 12Mar13	Investigator Brochure dated 28	06/07/2017	14
13/SC/0361/AM03	Out of Hospital Cardiac Arrest Outcomes Project	3.0 25 January 2018	29/01/2018	10
13/SC/0457/AM07	Pain in spinal cord injuries: investigating associated factors (1)	Amendment 7 24th April 2017	26/04/2017	9
13/SC/0541/AM20	Nivolumab Monotherapy vs Nivolumab combined therapy in Solid Tumors	EC18 dated 22 Aug 2017	22/08/2017	21
13/SC/0541/AM21	Nivolumab Monotherapy vs Nivolumab combined therapy in Solid Tumors	EC19 dated 18 Jan 2018	18/01/2018	11
14/SC/0157/AM21	PARAMEDIC 2: The Adrenaline Trial	18 2018/02/28	28/02/2018	0
14/SC/0157/AM22	PARAMEDIC 2: The Adrenaline Trial	19	26/03/2018	5
14/SC/0189/AM15	TIGER-2	Investigator's Brochure (Editi	25/10/2017	13
14/SC/0231/AM01	Dyspnoea perception in stroke and glioma patients (version 7)	Amendment 1 (05/10/2017)	01/11/2017	17
14/SC/0258/AM01	OPTIMAM Image Database: Version 1	1	21/06/2017	42
14/SC/1010/AM11	MERCuRIC1: MEK and MET Inhibition in Colorectal Cancer	MERCuRIC_SubA mend_011 dated 1	20/03/2017	29
14/SC/1010/AM12	MERCuRIC1: MEK and MET Inhibition in Colorectal Cancer	MERCuRIC_SubA mend_012	11/05/2017	8
14/SC/1010/AM14	MERCuRIC1: MEK and MET Inhibition in Colorectal Cancer	013	22/09/2017	21
14/SC/1101/AM08	Efficacy of Consuming LcS In Spinal cord injury Patients (ECLISP)	Amendment no. 4 27April2017	15/04/2017	21
14/SC/1128/AM12	Phase1/2 study, First in Human, of SRP-4053 in DMD patients (4053-101)	Protocol version Amendment 7 d	28/04/2017	13

14/SC/1128/AM16	Phase1/2 study, First in Human, of SRP-4053 in DMD patients (4053-101)	8	08/11/2017	2
14/SC/1219/AM09	Airway Management in cardiac arrest patients (AIRWAYS-2)	6.0	20/12/2017	29
14/SC/1219/AM10	Airway Management in cardiac arrest patients (AIRWAYS-2)	Amendment 7, 21/02/2018	21/02/2018	14
14/SC/1290/AM09	Antifibrinolytics for haematology patients. Version 1.0	6. Substantial Amendment 6 - R	05/05/2017	38
14/SC/1346/AM16	National Lung Matrix: Multi-drug Phase II trial in NSC Lung Cancer	Substantial Amendment 10 07/06	07/06/2017	11
14/SC/1346/AM20	National Lung Matrix: Multi-drug Phase II trial in NSC Lung Cancer	SA12	27/10/2017	12
14/SC/1370/AM05	CENTER-TBI UK	Amendment 6	04/07/2017	15
15/SC/0037/AM06	MRI study in FKRP	Substantial amendment 1	06/03/2017	23
15/SC/0046/AM12	C28002- Adult Patients With Advanced Nonhematologic Malignancies	SA13 - Patient ID card v2	04/05/2017	10
15/SC/0117/AM01	Developing a Magnetic Resonance Imaging Biomarker for Parkinson's	1.0	28/11/2017	28
15/SC/0215/AM10	CAMELLIA: Anti-CD47 antibody therapy in relapsed/refractory AML	CAMELLIA_Amend ment010	08/05/2017	19
15/SC/0215/AM12	CAMELLIA: Anti-CD47 antibody therapy in relapsed/refractory AML	Substantial Amendment 012	06/07/2017	22
15/SC/0215/AM13	CAMELLIA: Anti-CD47 antibody therapy in relapsed/refractory AML	CAMELLIA_Amend ment013	25/08/2017	18
15/SC/0215/AM14	CAMELLIA: Anti-CD47 antibody therapy in relapsed/refractory AML	CAMELLIA_Amend ment014	29/08/2017	12
15/SC/0215/AM16	CAMELLIA: Anti-CD47 antibody therapy in relapsed/refractory AML	CAMELLIA_Amend ment016	05/01/2018	24
15/SC/0310/AM10	THE BOX FAMILY STUDY: (BOX 3) Version 1	AM08	31/10/2017	21
15/SC/0388/AM02	NIHR BRC BioResource for Mental and Neurological Health 2.0	2 - 14/07/2017	25/09/2017	18
15/SC/0480/AM04	Inhaled furosemide for dyspnoea relief in advanced heart	SA03 15Feb2018	01/03/2018	12

	failure			
15/SC/0545/AM02	The Oxford Risk Factors And Non-invasive imaging Study	AM02 January 2018	18/01/2018	18
15/SC/0600/AM04	SIMPLE	SA04 03May2017	03/05/2017	24
15/SC/0644/AM04	NUC-3373 in Advanced Solid Tumours (NuTide: 301)	Substantial Amendment 006	23/06/2017	24
15/SC/0644/AM07	NUC-3373 in Advanced Solid Tumours (NuTide: 301)	008	05/02/2018	10
15/SC/0644/AM08	NUC-3373 in Advanced Solid Tumours (NuTide: 301)	SubsAmend009 V1.0 2018/03/16	16/03/2018	6
16/SC/0035/AM07	A Phase III Study of Pembrolizumab vs. Chemotherapy in MSI-H or dMMR S	SA05 IB13 & ICF Update	13/04/2017	29
16/SC/0035/AM10	A Phase III Study of Pembrolizumab vs. Chemotherapy in MSI-H or dMMR S	SA08 - Addition of Two New UK	07/09/2017	37
16/SC/0035/AM12	A Phase III Study of Pembrolizumab vs. Chemotherapy in MSI-H or dMMR S	SA11	12/12/2017	30
16/SC/0039/AM05	AMAC,PrtAmendment(18-Sep-2015), Prt UK Addendum 1.1(08-Dec-2015)	Substantial Amendment 4 - UK	22/01/2018	9
16/SC/0068/AM05	MEDI4736-MDS-001_Phase II_Durvalumab_MDS/AML	Protocol Amendment 1 dated 27	05/05/2017	13
16/SC/0068/AM06	MEDI4736-MDS-001_Phase II_Durvalumab_MDS/AML	Durvalumab Investigator's Broc	31/07/2017	14
16/SC/0068/AM08	MEDI4736-MDS-001_Phase II_Durvalumab_MDS/AML	Protocol Amendment 2.0, IBs an	26/01/2018	12
16/SC/0074/AM01	EPAD Longitudinal Cohort Study	Substantial Amendment 1 - 06 M	12/04/2017	9
16/SC/0114/AM04	STING (Study of Immunotherapy in Newly Diagnosed Glioblastoma)	Substantial Amendment 1	31/03/2017	19
16/SC/0143/AM05	Pembrolizumab (MK3457) in high risk NMIBC patients unresponsive to BCG	SA04 - (IB edition 13 + PIS up	04/04/2017	17
16/SC/0143/AM08	Pembrolizumab (MK3457) in high risk NMIBC patients unresponsive to BCG	SA09 - Protocol 05 + IB 15 + P	05/03/2018	10
16/SC/0161/AM07	PhaseIII Study-Atezolizumab with chemotherapy in Stage IV Non-Squamous	Re-submission - Patient and Si	22/03/2017	28
16/SC/0161/AM09	PhaseIII Study-Atezolizumab with chemotherapy in Stage IV	ICF v7.0	28/06/2017	7

	Non-Squamous			
16/SC/0161/AM11	Phase III Study-Atezolizumab with chemotherapy in Stage IV Non-Squamous	5.0	09/01/2018	15
16/SC/0187/AM04	Bone density and body composition in sporting athletes	3.0	16/08/2017	16
16/SC/0189/AM05	Segmentation of head and neck radiotherapy scans with machine learning	5	15/08/2017	10
16/SC/0207/AM03	CA209-436 Nivolumab with Brentuximab Vedotin in Non-Hodgkin Lymphoma	Substantial Amendment 03 dated	26/04/2017	23
16/SC/0207/AM04	CA209-436 Nivolumab with Brentuximab Vedotin in Non-Hodgkin Lymphoma	Substantial Amendment Number 0	17/09/2017	26
16/SC/0260/AM02	Predicting treatment response to radiotherapy for bone cancer pain	2.0	14/06/2017	10
16/SC/0264/AM08	HAVEN	Substantial Amendment 1	17/10/2017	22
16/SC/0264/AM09	HAVEN	Substantial Amendment 2 1/4 20th	01/02/2018	7
16/SC/0266/AM08	Biology of Juvenile Myoclonic Epilepsy	Substantial Amendment 2 - Stud	01/11/2017	16
16/SC/0271/AM05	plasmaMATCH	4	07/11/2017	20
16/SC/0277/AM03	Point Of Care Testing For Sepsis: A Diagnostic Accuracy Study	5 - 29/08/2017 (Substantial Am	29/08/2017	34
16/SC/0317/AM01	The experience of TYAC offered ovarian tissue cryopreservation	1 14/09/2017	14/09/2017	11
16/SC/0323/AM03	Adenosine Triphosphate Delivery Rates in Myocardial Hypertrophy	3. 2017-11-01.	17/11/2017	24
16/SC/0338/AM03	PITCH PILOT	Amendment: Version 3.0: Date 0	05/03/2018	5
16/SC/0344/AM02	Oxford Genetic Frontotemporal Dementia Initiative (Oxford GENFI)	001 1/4 16th February 2017	30/03/2017	14
16/SC/0435/AM07	Trial of Intranasal Esketamine for Treatment of Depression SUSTAIN-3	4	23/03/2017	27
16/SC/0435/AM08	Trial of Intranasal Esketamine for Treatment of Depression SUSTAIN-3	Substantial Amendment 5	26/06/2017	21

16/SC/0435/AM09	Trial of Intranasal Esketamine for Treatment of Depression SUSTAIN-3	Substantila Amendment 6	11/07/2017	12
16/SC/0435/AM12	Trial of Intranasal Esketamine for Treatment of Depression SUSTAIN-3	Substantial Amendment 7	03/10/2017	21
16/SC/0502/AM01	The ACL SNNAP Trial: ACL Surgery Necessity in Non Acute Patients.	Amendment number 1 Date 07 Mar	03/05/2017	6
16/SC/0502/AM02	The ACL SNNAP Trial: ACL Surgery Necessity in Non Acute Patients.	2	11/10/2017	13
16/SC/0503/AM01	SCOTCHIS trial	SubAm 3	25/05/2017	11
16/SC/0503/AM06	SCOTCHIS trial	Sub am6	10/10/2017	24
16/SC/0524/AM01	DRIVE - Desmopressin for procedures or Radiological InterVEntions	1	27/10/2017	13
16/SC/0547/AM02	A Phase I/II trial of intralesional administration of RGT100	SA #2	27/03/2017	22
16/SC/0547/AM03	A Phase I/II trial of intralesional administration of RGT100	SA#3	11/08/2017	35
16/SC/0553/AM03	Ebselen as an add-on treatment in hypo/mania V1.0	1	06/06/2017	8
16/SC/0554/AM01	Environmental Engineering to Increase Hand-Hygiene Compliance	Version 4_17- March 2017	17/03/2017	27
16/SC/0554/AM02	Environmental Engineering to Increase Hand-Hygiene Compliance	SAO1 16/02/2018	22/02/2018	7
16/SC/0566/AM03	3743/0001_Pulse_MEDIS-INT16-002	03 (04 September 2017)	04/09/2017	42
16/SC/0567/AM04	R2810-ONC-1606, Treatment-naïve Unresectable Stag III/IV Melanoma	R2810-ONC-1606 Protocol Amendm	30/06/2017	21
16/SC/0567/AM05	R2810-ONC-1606, Treatment-naïve Unresectable Stag III/IV Melanoma	R2810-ONC-1606 Protocol Amendm	24/09/2017	19
16/SC/0678/AM01	MAPS-PD version 1	1.0	04/12/2017	27
16/SC/0683/AM01	RACE FIT (Phase I)	Substantial Amendment 1 29.06.	03/07/2017	17
17/SC/0029/AM01	OxCAMS: The Oxford Calcium Channel Antagonism Study	1. 11/8/2017	11/08/2017	17
17/SC/0029/AM02	OxCAMS: The Oxford Calcium Channel Antagonism Study	2 22/12/2017	25/01/2018	7
17/SC/0033/AM03	Combination therapy with isatuximab in patients with multiple myeloma	Amendment 3: Substantial amend	21/07/2017	12
17/SC/0033/AM04	Combination therapy with isatuximab in patients with multiple myeloma	4	10/05/2017	8

17/SC/0034/AM02	ARK-hospital	SA02_12Apr2017	20/04/2017	29
17/SC/0034/AM10	ARK-hospital	9.0	01/12/2017	30
17/SC/0065/AM01	7T MRS in first episode psychosis	1	21/04/2017	38
17/SC/0071/AM01	Speech processing in children born with cleft palate (1)	Amendment 1	18/07/2017	19
17/SC/0089/AM01	Effect of FlowOxâ„¢ treatment on healing of lower limb ischaemic ulcers	1 27_06_2017	29/06/2017	14
17/SC/0089/AM07	Effect of FlowOxâ„¢ treatment on healing of lower limb ischaemic ulcers	Amendment number: 2 18/12/17	18/12/2017	25
17/SC/0090/AM01	c-TRAK TN	REC1	19/04/2017	37
17/SC/0090/AM02	c-TRAK TN	REC2	22/06/2017	30
17/SC/0090/AM03	c-TRAK TN	MHRA1REC3	01/08/2017	8
17/SC/0090/AM05	c-TRAK TN	REC4 2018/01/31	31/01/2018	8
17/SC/0092/AM01	Hidden Hearing Loss	Amendment no. 1	15/05/2017	30
17/SC/0128/AM01	Timed Interval Measurement of Eotaxin in Stroke Study (TIMES Study) v1	1 15/05/2017	26/05/2017	27
17/SC/0128/AM03	Timed Interval Measurement of Eotaxin in Stroke Study (TIMES Study) v1	2 16/02/2018	21/02/2018	14
17/SC/0142/AM03	The 65 Trial (v1.0)	1	05/12/2017	36
17/SC/0146/AM01	Expanding Community Ultrasound Services in Rural Scotland	Substantial Amendment 1 12/07/	04/07/2017	20
17/SC/0168/AM01	PC SHOP	2.0	01/10/2017	7
17/SC/0194/AM01	SHERG: Electroretinography: investigation of a protocol change	Amendment 1	02/08/2017	20
17/SC/0205/AM01	Repeatability Study	AM 1.0 19/07/2017	19/07/2017	18
17/SC/0205/AM02	Repeatability Study	AM 2.0 - 13/09/2017	06/10/2017	31
17/SC/0207/AM02	WHITE 7 - WHISH – Wound Healing in Surgery for Hip fractures	001 Date 21/06/2017	21/06/2017	21
17/SC/0207/AM05	WHITE 7 - WHISH – Wound Healing in Surgery for Hip fractures	005 6th September 2017	06/09/2017	23
17/SC/0207/AM06	WHITE 7 - WHISH – Wound Healing in Surgery for Hip fractures	006 08/11/2017	21/11/2017	7
17/SC/0207/AM07	WHITE 7 - WHISH – Wound Healing in Surgery for Hip fractures	007 12/02/2018	21/02/2018	14
17/SC/0216/AM01	Study of Acalabrutinib and Vistusertib in B-cell malignancies	IRAS Form	09/06/2017	10

17/SC/0216/AM02	Study of Acalabrutinib and Vistusertib in B-cell malignancies	IRAS form, IB v6.1 dated 1 Sep	26/10/2017	17
17/SC/0229/AM01	OMO1.01.02	1.0	09/08/2017	20
17/SC/0229/AM03	OMO1.01.02	Protocol amendment v3.0	22/01/2018	16
17/SC/0231/AM01	Pembrolizumab versus standard therapy in mesothelioma (PROMISE-meso)	SA-01	12/07/2017	20
17/SC/0231/AM04	Pembrolizumab versus standard therapy in mesothelioma (PROMISE-meso)	SA-02	01/09/2017	10
17/SC/0262/AM01	EMPA-HEART Version 1.0	03	06/02/2018	8
17/SC/0274/AM01	Validation of POEM	V1.1 dated 07 September 2017	07/09/2017	31
17/SC/0394/AM01	A Phase 2 Dose-Finding Study of Pacritinib in Myelofibrosis Patients	SA1	30/10/2017	24
17/SC/0394/AM02	A Phase 2 Dose-Finding Study of Pacritinib in Myelofibrosis Patients	SA2	19/01/2018	14
17/SC/0414/AM01	Experiences and Needs of Patients with Pancreatic Cancer	Amendment 1 140318	14/03/2018	5
17/SC/0434/AM01	Biomarker-guided duration of antibiotic treatment for sepsis	1.0	21/11/2017	11
17/SC/0461/AM01	Ida telecare version 1.0	SA1_13.11.17	20/11/2017	7
17/SC/0488/AM02	Steady Together	Substantial amendment 1 05.03.	06/03/2018	6
17/SC/0491/AM01	PROCLAIM CX-2009 in adults with metastatic/advanced solid tumours	Protocol Amendment 02	07/03/2018	12
17/SC/0514/AM01	Primary Care for children and young people with eating disorders	Amendment 1, 23/01/18	31/01/2018	6
18/SC/0028/AM01	CC-92480 with Dexamethasone in Relapsed & Refractory Multiple Myeloma	PA 02 Final	16/02/2018	14

Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
13/SC/0096/AM21	MK-3475 compared to Ipilimumab in Patients with Advanced Melanoma	17	09/08/2017	29
13/SC/0273/AM16	Phase I of Pembrolizumab (MK-3475) in Pts with non small cell	SA13	21/03/2017	29

	lung cancer			
14/SC/1270/AM05	A Register for New Anti-Epileptic Drugs In ID/PDD populations	2	05/07/2017	35
16/SC/0143/AM07	Pembrolizumab (MK3457) in high risk NMIBC patients unresponsive to BCG	SA07	25/09/2017	18
17/SC/0414/AM02	Experiences and Needs of Patients with Pancreatic Cancer	Amendment 2 140318	14/03/2018	5

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
13/SC/0096/AM21/1	MK-3475 compared to Ipilimumab in Patients with Advanced Melanoma	SA17	29/09/2017	14
13/SC/0273/AM16/1	Phase I of Pembrolizumab (MK-3475) in Pts with non small cell lung cancer	SA13 (modified REC submission)	03/05/2017	1
14/SC/1270/AM05/1	A Register for New Anti-Epileptic Drugs In ID/PDD populations	2.0	23/08/2017	12
16/SC/0143/AM07/1	Pembrolizumab (MK3457) in high risk NMIBC patients unresponsive to BCG	SA07- PIS update - MODIFIED	16/11/2017	7

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
17/SC/0491	PROCLAIM CX-2009 in adults with metastatic/advanced solid tumours	63
17/SC/0605	Phase 1/2 dose-escalation study of CTX-SPL9111 in cancer patients	62

Proportionate review applications for ethical review over 21 day timeline

REC Reference	Title	Number of Days on Clock
17/SC/0149	A study comparing orthodontic brackets	38
17/SC/0194	SHERG: Electroretinography: investigation of a protocol change	23
17/SC/0479	Public Health England Physical Activity Infographic Study	33

SSAs (non Phase 1) over 25 day timeline

REC Reference	Title	Number of Days on Clock
17/SC/0086	A Multi-Centre Randomised Cont	43
17/SC/0105	A Multi-Centre Randomised Cont	40

SSAs (Phase 1) over 14 day timeline

REC Reference	Title	Number of Days on Clock
---------------	-------	-------------------------

Substantial Amendments over 35 day timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
13/SC/0111/AM16	FOCUS4: Molecular selection of therapy in colorectal cancer	11	04/04/2017	37
14/SC/0258/AM01	OPTIMAM Image Database: Version 1	1	21/06/2017	42
14/SC/1290/AM09	Antifibrinolytics for haematology patients. Version 1.0	6. Substantial Amendment 6 - R	05/05/2017	38
16/SC/0035/AM10	A Phase III Study of Pembrolizumab vs. Chemotherapy in MSI-H or dMMR S	SA08 - Addition of Two New UK	07/09/2017	37
16/SC/0566/AM03	3743/0001_Pulse_MEDIS-INT16-002	03 (04 September 2017)	04/09/2017	42

17/SC/0065/AM01	7T MRS in first episode psychosis	1	21/04/2017	38
17/SC/0090/AM01	c-TRAK TN	REC1	19/04/2017	37
17/SC/0142/AM03	The 65 Trial (v1.0)	1	05/12/2017	36

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