

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

Annual Report

01 April 2016 - 31 March 2017



Part 1 – Committee Membership and Training

Name of REC:	South Central - Oxford A Research Ethics Committee
Type of REC:	RECs recognised to review CTIMPS in healthy volunteers - type I RECs recognised to review CTIMPS in patients - type III
Type of Flag:	Gene Therapy or Stem Cell Clinical Trials IRB Registered Phase 1 Studies in Healthy Volunteers Phase 1 Studies in Patients Research Involving Children.
Chair:	Dr Hugh Davies
Vice-Chair:	Ms Christine Montague-Johnson
Alternate Vice-Chair:	Miss Jennifer Lawson
REC Manager:	Ms Natasha Bridgeman
REC Assistant:	Ms Lidia Gonzalez
Committee Address:	Bristol Research Ethics Committee Centre Whitefriars Level 3 Block B Lewins Mead Bristol BS1 2NT
Telephone:	02071048045
Email:	nrescommittee.southcentral-oxforda@nhs.net

Chair's overview of the past year:

We're still afloat! I'd like to think we have continued our rigorous debate and fair assessment of research put before us over the last year.

We appointed Chris Montague Johnson as VC and Jenny Lawson as AVC and thanks must go to them for helping run the REC. We sadly said goodbye (and thanks) to Dr Elizabeth Coates, Mr Robert Nicholls, Mr Martin Usherwood, Mr Stuart Cole, Ms Ana de Veciana and REC Assistant Lidia Gonzalez.

And we welcomed Dr Pamela Laurie, Miss Jennifer Lawson, Ms Kay Symons and Mr Nicholas Way.

Of the topics that challenged us the year before last:-

- **Placebo surgery** – we have tried to think through “question and considerations “ around this issue
- **Grappling with Participant Information Sheets and their increasing length** – we have tried to draw up a “key facts information sheet”

This year, we've tried to think around

- How best to be a lead reviewer
- Listing side effects on the PIS in a meaningful way
- Confidentiality
- Early cancer research

We also held a very successful training day exploring gene therapy and modern data handling. The chair is trying to sum these initiatives up and would be happy to provide more information.

So again thanks to all the members who give up their time, thanks to those who have left for the time they gave, thank to our new members but I can't finish without mentioning our great REC officers, Tash and Lidia. All would be of nothing without your industry. Lidia has now moved on and we all wish her well in future endeavours.

Dr Hugh Davies
Chair

South Central - Oxford A Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Ms Raj Bains	Pharmacovigilance Business Consultant	Lay Plus	29/05/2008	
Ms Jane Cheeseman	Research Nurse	Expert	20/05/2013	
Dr Elizabeth Coates	Research Governance Coordinator	Lay	22/01/2016	30/08/2016
Mr Stuart Cole	Head of Communications	Lay Plus	01/06/2011	01/06/2016
Dr Hugh Davies	Consultant Paediatrician	Expert	01/04/2015	
Ms Ana de Veciana	Clinical Trials Pharmacist	Expert	06/02/2015	31/08/2016
Dr Stephanie Jones	Postdoctoral Research Scientist	Expert	01/11/2014	
Mrs Alison Kealy	Legal Assistant – Wills and Probate	Lay Plus	28/05/2013	
Mrs Doreen Laity	Retired Pharmacist	Lay	05/08/2013	
Dr Pamela Laurie	(Retired) Consultant Anaesthetist	Expert	17/06/2016	
Miss Jennifer Lawson	Trials Manager	Lay	19/08/2016	
Ms Christine Montague-Johnson	Paediatric Nurse	Expert	01/06/2014	
Mr Robert Nicholls	Retired Health Service Manager	Lay	13/05/2015	06/03/2017
Dr Karen Pulford	Freelance medical/scientific writer and the honorary title of Emeritus Reader of Immunodiagnosics, NDCLS	Lay Plus	01/01/2016	
Dr Mohit Sharma	Consultant in Public Health	Expert	29/05/2013	
Ms Kay Symons	Publishing consultant and trainer	Lay	17/10/2016	
Mr Martin Usherwood	Retired Gynaecologist	Expert	05/09/2011	05/05/2016
Mr Nicholas Way	Former Director General - Historic Houses Association	Lay Plus	06/05/2016	

South Central - Oxford A Research Ethics Committee: Deputy Members

Name	Profession	Status	Meeting date attended

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

Name	Profession	Status	Meeting date attended
Miss Wendy Bertram	Orthopaedic Research Fellow	Lay	04/11/2016

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

Name	Declaration of Interest	Date
Ms Raj Bains	None	31/03/2017
Ms Jane Cheeseman	None	31/03/2017
Dr Hugh Davies	None	31/03/2017
Dr Stephanie Jones	None	05/12/2016
Mrs Doreen Laity	None	31/03/2017
Dr Pamela Laurie	Volunteer at Heritage Museum, Association of Anaesthetists	04/11/2016
Miss Jennifer Lawson	None	31/03/2017
Ms Christine Montague-Johnson	Attends the Oxford University Hospitals Trust Trial Safety Group Committee meetings monitoring and reporting adverse events to trials running within the Trust and University.	31/03/2017
Mr Barry Muir	None	31/03/2017
Dr Karen Pulford	None	09/08/2016
Dr Mohit Sharma	Employed by Public Health England as a consultant in healthcare Public Health for the South East Centre Member of NICE Technology Appraisal Committee D	25/01/2017
Ms Kay Symons	None	31/03/2017
Mr Nicholas Way	None	06/05/2016

Meetings for Full Ethical Review 01 April 2016 - 31 March 2017:

Month	Date	Number of Members Present at Meeting
April	01/04/2016	10
May	06/05/2016	11
June	03/06/2016	9
July	01/07/2016	9
August	05/08/2016	8
November	04/11/2016	14
December	02/12/2016	12
February	03/02/2017	11
March	03/03/2017	11

9 full committee meetings were held during the reporting period.

Proportionate Review Sub-Committee Meetings held during 01 April 2016 - 31 March 2017:

Month	Date	Number of Members Present at Meeting
February	27/02/2017	3
March	27/03/2017	3

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

Sub-Committee Meetings held during 01 April 2016 - 31 March 2017:

Month	Date	Number of Members Present at Meeting
April	01/04/2016	2
April	08/04/2016	2
April	15/04/2016	2
April	29/04/2016	2
May	13/05/2016	2
May	20/05/2016	3
May	27/05/2016	2
May	31/05/2016	3
June	10/06/2016	2
June	24/06/2016	2
July	08/07/2016	2
July	22/07/2016	2
August	05/08/2016	2
August	19/08/2016	2
September	02/09/2016	2
September	16/09/2016	2
September	30/09/2016	3
October	07/10/2016	3
October	21/10/2016	2
November	04/11/2016	2

November	18/11/2016	2
November	24/11/2016	3
December	02/12/2016	2
December	16/12/2016	2
December	18/12/2016	3
January	06/01/2017	2
January	20/01/2017	2
February	03/02/2017	2
February	14/02/2017	2
February	15/02/2017	2
February	17/02/2017	2
March	03/03/2017	2
March	17/03/2017	2
March	22/03/2017	2
March	31/03/2017	2

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

Details of inquorate meeting held:01 April 2016 - 31 March 2017

None

Attendance of Members at full committee meetings:01 April 2016 - 31 March 2017

Name	Number of Meetings Attended
Ms Raj Bains	5
Ms Jane Cheeseman	8
Dr Elizabeth Coates	5
Mr Stuart Cole	1
Dr Hugh Davies	8
Ms Ana de Veciana	2
Dr Stephanie Jones	3
Mrs Alison Kealy	7
Mrs Doreen Laity	6
Dr Pamela Laurie	5
Miss Jennifer Lawson	4
Ms Christine Montague-Johnson	7
Mr Robert Nicholls	7
Dr Karen Pulford	8
Dr Mohit Sharma	6
Ms Kay Symons	4
Mr Martin Usherwood	2
Mr Nicholas Way	6

Attendance of Members at proportionate review sub-committee meetings: 01 April 2016 - 31 March 2017

Name	Number of Meetings Attended
Ms Jane Cheeseman	1
Dr Hugh Davies	1
Mrs Alison Kealy	1
Dr Pamela Laurie	1
Ms Christine Montague-Johnson	1
Dr Karen Pulford	1

Attendance of Members at sub-committee meetings: 01 April 2016 - 31 March 2017

Name	Number of Meetings Attended
Ms Raj Bains	1
Miss Wendy Bertram	1
Ms Jane Cheeseman	6
Dr Elizabeth Coates	1
Mr Stuart Cole	1
Dr Hugh Davies	21

Dr Stephanie Jones	1
Mrs Alison Kealy	1
Mrs Doreen Laity	3
Dr Pamela Laurie	4
Miss Jennifer Lawson	8
Ms Christine Montague-Johnson	13
Dr James Morgan	1
Mr Robert Nicholls	6
Dr Karen Pulford	6
Mr Nicholas Way	2

Training 01 April 2016 - 31 March 2017

Name of Member	Date	Event(s) attended
Ms Raj Bains	02/09/2016	Joint Oxford Training Day 02.09.16
Dr Elizabeth Coates	11/05/2016	Assessing the Consequences (benefits and harms) of Research: a Health Research Authority workshop
Dr Elizabeth Coates	24/05/2016	Training - Introduction to Phase 1 Research -
Dr Hugh Davies	01/05/2016	Equality & Diversity
Ms Ana de Veciana	24/09/2016	Committee Members Induction
Mrs Alison Kealy	02/09/2016	Joint Oxford Training Day 02.09.16
Mrs Doreen Laity	02/09/2016	Joint Oxford Training Day 02.09.16
Dr Pamela Laurie	30/09/2016	E&D
Dr Pamela Laurie	16/02/2017	National Members Training Day
Miss Jennifer Lawson	20/09/2016	Equality Diversity and Human rights
Ms Christine Montague- Johnson	02/09/2016	Joint Oxford Training Day 02.09.16
Ms Christine Montague- Johnson	01/12/2016	Chairs Training
Mr Robert Nicholls	02/09/2016	Joint Oxford Training Day 02.09.16
Dr Karen Pulford	21/09/2016	Equality Diversity & Human rights
Dr Karen Pulford	16/02/2017	National Members Training Day

PART 2: REC WORKLOAD AND ACTIVITY DURING THE REPORTING PERIOD

Table 1: Applications assigned to a full committee meeting held within the reporting period:

Applications for full ethical review – Study Type	Number	%
Clinical Trial of Investigational Medicinal Product	15	34.09
Phase 1	3	6.82
Gene Therapy	9	20.45
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	0	0.00
Others	17	38.64
Total Applications Reviewed	44	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	1
Number of student applications reviewed	11
Number of paediatric applications reviewed	8
Number of device applications reviewed	0
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	0
Number of applications reviewed that are funded by the US DHHS	0
Number of qualitative applications reviewed	2

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

Decisions taken at meetings following review of applications	Number	%
Favourable Opinion with Standard Conditions	1	2.27
Favourable Opinion with Additional Conditions	12	27.27
Unfavourable Opinion	0	0.00
Provisional Opinion	27	61.36
Provisional Opinion Pending Consultation with Referee	4	9.09
Total	44	100
Number of studies sent back to full committee meeting for final opinion	1	

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	30	68.18
Further Information Favourable Opinion with Additional Conditions	0	0.00
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	1	2.27
Favourable Opinion with Additional Conditions	12	27.27
Unfavourable Opinion	0	0.00
Provisional Opinion	1	2.27
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	44	100

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

Total Applications Reviewed	3
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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	0
Number of studies withdrawn prior to the meeting	0
Number of student applications reviewed	1
Number of paediatric applications reviewed	0
Number of device applications reviewed	0
Number of qualitative applications reviewed	0

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	66.67
Favourable Opinion with Additional Conditions	0	0.00
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	1	33.33
Unfavourable Opinion	0	0.00
Total	3	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	4.89
Number of completed applications for full ethical review	44
Number of completed applications for full ethical review over 60 days	2
Number of completed applications over 60 days as a % of total	4.55%
Number of completed applications for full ethical review over 40 days	14
Number of completed applications over 40 days as a % of total	31.82%
Number of days taken to final decision – average (mean)	37
Number of completed proportionate review applications for ethical review	3
Number of completed proportionate review applications for ethical review over 14 days (Please note, the timeline for the review of PR applications was extended from 14 to 21 calendar days in December 2016)	2
Number of completed proportionate review applications for ethical review over 21 days	2
Number of completed proportionate review applications over 14 days as a % of total	66.67%
Number of SSAs (non-Phase 1) reviewed	11
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	9.09%
Number of SSAs (Phase 1) reviewed	3
Number of completed applications for SSA review over 14 days	1
Number of completed applications for SSA review over 14 days as % of all Phase 1 SSAs	33.33%
Number of substantial amendments reviewed	160
Number of completed substantial amendments over 35 days	13
Number of completed substantial amendments over 35 days as a % of total substantial amendments	8.13%
Number of completed substantial amendments over 28 days	35
Number of completed substantial amendments over 28 days as a % of total substantial amendments	21.88%
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	124

Number of substantial amendments received for information	10
Number of substantial amendments received for new sites/PIs	49
Number of annual progress reports received	83
Number of safety reports received	113
Number of Serious Adverse Events received	0
Number of final reports received	12

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
16/SC/0140	PQR309 and Eribulin in patients with advanced breast cancer:PQR309-007	40
16/SC/0159	TWILIGHT Study	38
16/SC/0168	Emotional Facial Expression Decoding in Personality Disorders	54
16/SC/0178	Modifying negative self-beliefs in eating disorders - v1	37
16/SC/0200	SAVE UK Trial M-2016-313	46
16/SC/0201	A Study of OXB-102, a Gene Therapy, for Parkinsons Disease	56
16/SC/0227	Ebola Vaccine Registry	29
16/SC/0231	AG-120/AG-221 plus azacitidine in treatment of IDH1/IDH2 AML	69
16/SC/0291	fullPIERS Model study	55
16/SC/0293	Phase III Open-Label Esophageal Cancer - ONO-4538	35
16/SC/0298	Exploring young people's conversations about parental mental health	31
16/SC/0308	Teduglutide in Pediatric Subjects with Short Bowel Syndrome	31
16/SC/0331	A Pilot Study of NY-ESO-1c259T in Synovial Sarcoma	29
16/SC/0345	Safety, immunogenicity and efficacy of RH5.1/AS01 (VAC063)	56
16/SC/0351	Randomised Phase III Colorectal Cancer Study with 3 Treatment Arms	33
16/SC/0376	TRoMbone	38
16/SC/0401	A phase I study of oral ABL001 in patients with CML or Ph+ ALL	33
16/SC/0412	OX-RAMPP	37
16/SC/0526	EYS606-CT1 - version 2 2016-09-27	59
16/SC/0537	Gene therapy for Haemophilia A; version 1	38
16/SC/0551	XIRIUS	58
16/SC/0640	A phase 1b combination study of PDR001	34
16/SC/0653	PRIMA UK	41
17/SC/0006	Bordetella Pertussis Colonisation Challenge Study	27
17/SC/0022	Intravitreal Aflibercept in patients with diabetic eye disease	36
17/SC/0032	Selected Mesenchymal Stromal Cells to reduce liver inflammation	46
17/SC/0035	PLX-CLI-03_PACE_Ph3 IM PLX-PAD in Patients with Critical Limb Ischemia	41
17/SC/0039	MEOF-002 - Methoxyflurane AnalGesia for Paediatric InjuriEs (MAGPIE)	41
17/SC/0093	GBGC: Comparing efficacy of Dulaglutide vs Placebo in Pediatric DM	47
17/SC/0108	Maternal Attitudes to Antibiotic Use: A Community Based Case Study	76

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/0106	Ketamine for Depression and Suicidality: An Interview Study	21

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
16/SC/0110	MAPLE study	26
16/SC/0147	TriMaster v1	26
16/SC/0287	Participant Opinions of Psychosis Subgroups (POPS)	20
16/SC/0358	Investigating Typhoid Fever Pathogenesis (TYGER)	20
16/SC/0395	VX-970 plus standard treatment in oesophageal and other cancer (V1.0)	28
16/SC/0404	fMRI study of ABX-1431	30
16/SC/0545	Safety and immunogenicity of MAP vaccine ChAdOx2 HAV (HAV001)	28
16/SC/0628	OPTiMISE	17
16/SC/0645	FRONTIER: Fluciclovine (18F) imaging of breast cancer	19
17/SC/0057	Chronological evaluation of Functional changes in Neonatal Skin (CFNS)	26
17/SC/0079	CORGI 2	21
17/SC/0091	Women's experiences of breast cancer follow-up care	18

Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock

Provisional Opinion		
REC Reference	Title	Number of Days on Clock
16/SC/0232	Oncomed M18-007	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/0102	Examining the links between eating disorders and IBS. V1	24

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/0099	Investigating the molecular basis of cardiovascular disease	28
17/SC/0153	Predictors of survival in patients with TIPSS for refractory ascites	4

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
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Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
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Provisional Opinion

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

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

REC Reference	Title	Number of Days on Clock
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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/Q1604/21/AM08	Expression pattern of C-type Lectins	13, 06.04.2016	06/04/2016	36
06/Q1604/162/AM08	Rectal Imaging Trial (RIT)	3.6 (27 August 2016)	27/08/2016	18
07/H0604/122/AM41	A comparison of Insulins Detemir and Glargine in Girls with Diabetes	37, Protocol V 17	06/04/2016	16
07/Q1604/33/AM07	GROINSS-V II	4.0	21/03/2016	19
08/H0604/170/AM18	Placebo controlled study of zoledronic acid in osteoporotic children	Protocol version 05 26-Oct-201	27/04/2016	14
08/H0604/170/AM22	Placebo controlled study of zoledronic acid in osteoporotic children		15/03/2017	16
09/H0604/58/AM13	Biomarkers for endometriosis	7.0 3JAN2017	03/01/2017	18
09/H0604/79/AM49	Myeloma XI	8.0	29/09/2016	21
10/H0604/47/AM21	Phase I Study of IMCgp100 in Advanced Malignant Melanoma V1.0	SA021	22/06/2016	21
10/H0604/47/AM22	Phase I Study of IMCgp100 in Advanced Malignant Melanoma V1.0	SA022	03/10/2016	17
10/H0604/51/AM04	Natural history and pathogenesis of systemic IgG4 disease	3 03/11/2015	15/03/2015	22
10/H0604/91/AM11	COASt - Clinical Outcomes in Arthroplasty Study	5.0	08/02/2017	30
11/SC/0149/AM18	V212-011 Study of Safety & Efficacy of V212 in patients with ST or HTM	Substantial Amendment 18	01/10/2015	19
11/SC/0355/AM09	MBSR in the management of psychological distress in prostate cancer	5.0	26/04/2016	9
11/SC/0409/AM17	VanSel-1: A Phase I trial of Vandetanib and Selumetinib.	CTA Amendment No. 16, 10 May 2	10/05/2016	18
11/SC/0433/AM05	IDEB: Irinotecan Drug-Eluting Beads in Glioblastoma	SA3	20/06/2016	16
12/SC/0242/AM13	IPC-PLUS Trial	SA 7	13/09/2016	17
12/SC/0416/AM02	Surveillance of neonatal surgical morbidities	SA2	18/07/2016	28
12/SC/0557/AM07	Prism and tDCS Treatment of Complex Regional Pain Syndrome (CRPS)	6, 15th January 2017	15/01/2017	8
12/SC/0559/AM10	Anti-PD-1/Everolimus in Advanced or Metastatic ClearCell Renal Cancer	EC08	27/06/2016	15

12/SC/0623/AM01	Filaggrin and Food Allergy – FILAFALL 2	3.0	14/03/2016	39
13/SC/0079/AM01	Extension to study of zoledronic acid in osteoporotic children	3	18/05/2016	7
13/SC/0163/AM02	Sensorimotor plasticity and brain stimulation	2	26/01/2017	19
13/SC/0173/AM13	Phase III Study in Metastatic Castration Resistant Prostate Cancer	No. 9 dated 15 November 2016 /	15/11/2016	16
13/SC/0200/AM05	(May) Stem Cell Research in Early-Onset Psychosis	3 20.06.2016	20/06/2016	16
13/SC/0226/AM01	Development of novel treatments based on T cell receptors			32
13/SC/0227/AM01	(duplicate) Development of novel treatments based on T cell receptors	SA1	20/07/2016	32
13/SC/0267/AM06	Pilot Study of Deep Brain Stimulation for Severe Anorexia nervosa	4	11/11/2016	6
13/SC/0317/AM18	IELSG 37	3 29 November 2016	29/11/2016	13
13/SC/0322/AM08	Immunotherapy with CD25/71 Allodepleted T-cells (ICAT)	8: Protocol v5.0, ATIMPD v5.1	04/05/2016	19
13/SC/0322/AM09	Immunotherapy with CD25/71 Allodepleted T-cells (ICAT)	Substantial Amendment 9: PIS v	16/09/2016	18
13/SC/0322/AM10	Immunotherapy with CD25/71 Allodepleted T-cells (ICAT)	SA 10: Protocol v6.0, PIS v5.0	12/12/2016	19
13/SC/0374/AM08	Phase I, AZD8186 in Patients with CRPC, sqNSCLC, TNBc, PTEN malignancy	SA UK Amended ICF (MUGA scan)	23/03/2016	12
13/SC/0374/AM14	Phase I, AZD8186 in Patients with CRPC, sqNSCLC, TNBc, PTEN malignancy	D4620C00001 IB, Clinical Study	12/01/2017	25
13/SC/0387/AM03	Treatment trial of chronic central serous chorioretinopathy	PLACE 13 version 4	28/11/2016	15
13/SC/0421/AM10	A Phase 1, randomized, blinded, dose-escalation study of rAAV1-PG9DP recombinant AAV vector coding for PG9 antibody in healthy male adults	SA007	31/05/2016	28
13/SC/0470/AM15	Platelet-Oriented Inhibition in New TIA and Minor Ischemic stroke	SA-EC-#10	24/05/2016	27
13/SC/0470/AM16	Platelet-Oriented Inhibition in New TIA and Minor Ischemic stroke	SA-EC-#11	24/06/2016	36
13/SC/0492/AM01	B7.1/IL-2 Leukaemia Cell Vaccine for Non-Transplant AML	2, Protocol version 2.0 date	13/09/2016	18
13/SC/0492/AM02	B7.1/IL-2 Leukaemia Cell Vaccine for Non-Transplant AML	RFUSING2-AML2	16/01/2017	15

		trial amendment		
13/SC/0597/AM05	Vital Sign Monitoring of Premature Infants - Pilot Study (v 5.0)	SA2	27/09/2016	18
13/SC/0604/AM10	Treg Liver Trial	#6	16/06/2016	28
14/SC/0065/AM10	28431754DIA4003 (CANVAS-R)	SA#7	07/04/2016	28
14/SC/0065/AM11	28431754DIA4003 (CANVAS-R)	#8	11/05/2016	21
14/SC/0065/AM12	28431754DIA4003 (CANVAS-R)	SA#9	14/06/2016	27
14/SC/0065/AM14	28431754DIA4003 (CANVAS-R)	SA11	14/10/2016	12
14/SC/0170/AM09	Phase 3 study to test the effects of SA237 in patients with NMO&NMOSD	8- Flyer v2.0 30 Mar 2016	30/03/2016	27
14/SC/1204/AM03	Investigating Enteric Fever	2	26/05/2016	29
14/SC/1204/AM04	Investigating Enteric Fever	3	17/11/2016	6
14/SC/1204/AM05	Investigating Enteric Fever	4 (19-DEC-2016)	19/12/2016	14
14/SC/1231/AM06	Vaccination in Prostate Cancer (VANCE), version 1.0	VANCE01 SA 006	16/03/2016	20
14/SC/1231/AM07	Vaccination in Prostate Cancer (VANCE), version 1.0	VANCE01, Substantial Amendment	26/05/2016	25
14/SC/1231/AM08	Vaccination in Prostate Cancer (VANCE), version 1.0	SA8	21/07/2016	25
14/SC/1256/AM11	A Phase I Study to Assess a New Ebola Vaccine, cAd3-EBO Z	SA12	20/04/2016	28
14/SC/1275/AM03	Growth Assessment of Preterm infants (GAP study)			28
14/SC/1309/AM04	The TEMPLATE Study	3, 2016/05/19	19/05/2016	18
14/SC/1309/AM06	The TEMPLATE Study	5	09/02/2017	13
14/SC/1333/AM03	PATH-2: Platelet Rich Plasma in Achilles Tendon Healing	2	08/03/2016	11
14/SC/1361/AM05	Dapagliflozin as an add-on to Insulin Therapy in Type 1 Diabetes	EC05	16/06/2016	27
14/SC/1361/AM06	Dapagliflozin as an add-on to Insulin Therapy in Type 1 Diabetes	EC06	06/09/2016	34
14/SC/1372/AM07	RIVER - Research In Viral Eradication of HIV Reservoirs	2016/05/18	18/05/2016	28
14/SC/1372/AM08	RIVER - Research In Viral Eradication of HIV Reservoirs	Substantial Amendment 2016/10/	12/10/2016	13
14/SC/1372/AM09	RIVER - Research In Viral Eradication of HIV Reservoirs	AM09 SA 24/10/2016	24/10/2016	22
14/SC/1405/AM04	A research study involving imaging patients with rheumatoid arthritis	Substantial amendment dated 24	25/05/2016	24
14/SC/1416/AM08	IgNiTE: Immunoglobulin in the treatment of encephalitis	SA4	10/03/2016	19

		(subamendment 4)		
14/SC/1416/AM09	IgNiTE: Immunoglobulin in the treatment of encephalitis		14/07/2016	32
14/SC/1416/AM14	IgNiTE: Immunoglobulin in the treatment of encephalitis	SA6	10/02/2017	25
14/SC/1427/AM05	Vaccines Against Salmonella Typhi (VAST)	SA6	11/07/2016	22
14/SC/1427/AM06	Vaccines Against Salmonella Typhi (VAST)	Substantial Amendment 7	31/08/2016	22
15/SC/0023/AM07	Catheter Vs Thoracoscopic Surgical Ablation in LSPAF - Multicentre RCT	31/05/2016	31/05/2016	13
15/SC/0023/AM08	Catheter Vs Thoracoscopic Surgical Ablation in LSPAF - Multicentre RCT	Subst_Amend_8, 22/02/2017	22/02/2017	21
15/SC/0054/AM06	CheckMate 238: CHECKpoint pathway and nivoluMAb clinical Trial Evaluation 238	SA03	25/05/2016	26
15/SC/0108/AM08	A Phase I Study to Assess Ebola Vaccines cAd3-EBO Z and MVA-EBO Z	SA005	11/05/2016	35
15/SC/0109/AM02	OxLith	SA02	25/02/2016	19
15/SC/0109/AM03	OxLith	OxLith SA03	06/05/2016	33
15/SC/0109/AM05	OxLith	SA5	08/07/2016	28
15/SC/0109/AM07	OxLith	OxLith SA06	08/09/2016	38
15/SC/0115/AM05	HARMONY Outcomes Trial	SA-03: Updated Trial Documentation	03/06/2016	14
15/SC/0121/AM03	Studying movement control in PD using closed loop DBS.	3, 04.01.2017	04/01/2017	14
15/SC/0143/AM03	AG-CLI-0206: Ph 3 - Efficacy & Safety Study for Critical Limb Ischemia	Amendment #3 – Temporary halt	28/04/2016	13
15/SC/0186/AM01	Proteomics analysis of malignant pleural effusion	1, 17th March 2016	17/03/2016	14
15/SC/0186/AM02	Proteomics analysis of malignant pleural effusion	2	25/02/2017	20
15/SC/0211/AM08	Evaluating Optimal Vaccine schedules against Ebola (EVOLVE)	Evolve Substantial Amendment 5	17/05/2016	37
15/SC/0211/AM09	Evaluating Optimal Vaccine schedules against Ebola (EVOLVE)	SA6 NOSA	11/10/2016	25
15/SC/0239/AM06	ASTEROID 2	Substantial amendment 2	26/05/2016	25
15/SC/0240/AM04	Randomised Ambulatory Management of Primary Pneumothorax (RAMPP)	SA05	11/05/2016	28
15/SC/0240/AM12	Randomised Ambulatory Management of Primary	SA12_06Jan2017	06/01/2017	15

	Pneumothorax (RAMPP)			
15/SC/0242/AM06	BMN 270-201: Gene Therapy Study in Severe Haemophilia A Patients	SA3: Temporary halt to the tri	28/04/2016	13
15/SC/0242/AM08	BMN 270-201: Gene Therapy Study in Severe Haemophilia A Patients	(SA5: Request to restart Enro	12/09/2016	35
15/SC/0242/AM09	BMN 270-201: Gene Therapy Study in Severe Haemophilia A Patients	SA6, IB V2.0	20/10/2016	9
15/SC/0242/AM10	BMN 270-201: Gene Therapy Study in Severe Haemophilia A Patients	SA7: Patient Diary version 2.0	21/11/2016	9
15/SC/0242/AM11	BMN 270-201: Gene Therapy Study in Severe Haemophilia A Patients	SA8	20/12/2016	-15
15/SC/0242/AM12	BMN 270-201: Gene Therapy Study in Severe Haemophilia A Patients	SA9: Protocol Amendment: 270-2	17/02/2017	26
15/SC/0267/AM05	A Phase I Study to Assess New Ebola Vaccines, cAd3-EBO Z & Ad26.ZEBOV	SA005	16/05/2016	30
15/SC/0302/AM04	Phase 3 Efficacy and Safety study of Oral RPC1063 in RMS Patients	SA4 Change in Study Sponsor	04/05/2016	6
15/SC/0370/AM05	TB040: MVA85A aerosol vs IM in adults with latent M.tb infection	SA04	16/06/2016	20
15/SC/0370/AM06	TB040: MVA85A aerosol vs IM in adults with latent M.tb infection	SA05	01/08/2016	22
15/SC/0373/AM02	Energy metabolism and MRS	2 30.09.2016	30/09/2016	23
15/SC/0376/AM01	Children's drops for ear pain in acute otitis media	UoB2305 1.2	22/01/2016	28
15/SC/0376/AM02	Children's drops for ear pain in acute otitis media	UoB2305 1.3	25/04/2016	33
15/SC/0432/AM06	Trial of Intranasal Esketamine for Treatment of Depression TRANSFORM-3	5	04/07/2016	38
15/SC/0432/AM10	Trial of Intranasal Esketamine for Treatment of Depression TRANSFORM-3	SA6	05/08/2016	15
15/SC/0432/AM12	Trial of Intranasal Esketamine for Treatment of Depression TRANSFORM-3	SA7, Part II	14/10/2016	31
15/SC/0432/AM16	Trial of Intranasal Esketamine for Treatment of Depression TRANSFORM-3	9	17/03/2017	23
15/SC/0434/AM06	Long-term Safety & Efficacy Study of IN Esketamine in TRD (SUSTAIN-2)	#5 12/05/2016	12/05/2016	40
15/SC/0434/AM11	Long-term Safety & Efficacy Study of IN Esketamine in TRD (SUSTAIN-2)	7	04/07/2016	36

15/SC/0434/AM13	Long-term Safety & Efficacy Study of IN Esketamine in TRD (SUSTAIN-2)	SA#8	01/08/2016	29
15/SC/0434/AM14	Long-term Safety & Efficacy Study of IN Esketamine in TRD (SUSTAIN-2)	9	12/08/2016	28
15/SC/0434/AM16	Long-term Safety & Efficacy Study of IN Esketamine in TRD (SUSTAIN-2)	SA#10	18/08/2016	21
15/SC/0434/AM27	Long-term Safety & Efficacy Study of IN Esketamine in TRD (SUSTAIN-2)	13	13/03/2017	15
15/SC/0446/AM04	A PET scan study of GSK2256098; ver 1	2015N237824_03	22/04/2016	37
15/SC/0618/AM01	MIBS	1.0	19/04/2016	31
15/SC/0629/AM03	Phase I Tracheal replacement using tracheal scaffold and MSC's	PIS (V5.0) and Protocol (V3.0)	22/05/2016	24
15/SC/0629/AM05	Phase I Tracheal replacement using tracheal scaffold and MSC's	PIS V6	05/09/2016	36
15/SC/0648/AM01	Cognitive-behaviour therapy and losartan	1	14/03/2016	15
15/SC/0648/AM02	Cognitive-behaviour therapy and losartan	2,	10/08/2016	33
15/SC/0716/AM01	TB041: Aerosol BCG challenge trial in healthy UK adults	SA01	18/03/2016	24
15/SC/0716/AM02	TB041: Aerosol BCG challenge trial in healthy UK adults	SA02	16/12/2016	22
15/SC/0716/AM03	TB041: Aerosol BCG challenge trial in healthy UK adults	SA03 2017/01/17	17/01/2017	11
16/SC/0046/AM01	Pipeline Flex with Shield Technology Embolization	SA1	03/08/2016	22
16/SC/0048/AM01	CA209-274 Adjuvant Nivolumab versus Placebo in Urothelial Cancer	SA#01 (EC01)	14/03/2016	20
16/SC/0049/AM01	EZH-102 - Paediatric	Protocol amend 3.2	21/07/2016	43
16/SC/0049/AM02	EZH-102 - Paediatric	Protocol Amendment 4.3	21/10/2016	22
16/SC/0051/AM01	Motion analysis database of healthy and prosthetic UL performance	2.0	13/09/2016	19
16/SC/0108/AM01	Targeting pathways to Parkinson's	1	26/05/2016	25
16/SC/0108/AM04	Targeting pathways to Parkinson's	2	29/07/2016	22
16/SC/0108/AM05	Targeting pathways to Parkinson's	SA3	09/10/2016	20
16/SC/0108/AM06	Targeting pathways to Parkinson's	SA4	27/01/2017	13
16/SC/0110/AM01	MAPLE study	1, 19/09/2016	19/09/2016	5
16/SC/0122/AM04	Psychosis: EIE	1	06/03/2017	13
16/SC/0140/AM01	PQR309 and Eribulin in patients with advanced breast cancer:PQR309-007	Protocol amendment,	20/07/2016	21

		version 4.		
16/SC/0147/AM01	TriMaster v1	SA1	13/07/2016	31
16/SC/0147/AM02	TriMaster v1	SA2 REC	07/08/2016	33
16/SC/0147/AM05	TriMaster v1	SA3 REC	21/10/2016	18
16/SC/0159/AM02	TWILIGHT Study	SA1	26/10/2016	19
16/SC/0168/AM01	Emotional Facial Expression Decoding in Personality Disorders	Substantial Amendment 1	25/08/2016	25
16/SC/0200/AM01	SAVE UK Trial M-2016-313	SA1	16/12/2016	28
16/SC/0201/AM01	A Study of OXB-102, a Gene Therapy, for Parkinsons Disease	Protocol Amendment 1	25/04/2016	23
16/SC/0227/AM02	Ebola Vaccine Registry	1	28/02/2017	11
16/SC/0231/AM01	AG-120/AG-221 plus azacitidine in treatment of IDH1/IDH2 AML	2 2016/10/25	25/10/2016	35
16/SC/0231/AM02	AG-120/AG-221 plus azacitidine in treatment of IDH1/IDH2 AML	AM2	23/02/2017	33
16/SC/0293/AM02	Phase III Open-Label Esophageal Cancer - ONO-4538	CA209473 Protocol Version 5.0,	16/09/2016	37
16/SC/0308/AM04	Teduglutide in Pediatric Subjects with Short Bowel Syndrome	2,	26/10/2016	27
16/SC/0308/AM05	Teduglutide in Pediatric Subjects with Short Bowel Syndrome	SA2: Addendum 1 to Investigator Brochure	21/02/2017	11
16/SC/0345/AM01	Safety, immunogenicity and efficacy of RH5.1/AS01 (VAC063)	SA001	22/09/2016	19
16/SC/0351/AM01	Randomised Phase III Colorectal Cancer Study with 3 Treatment Arms	SA1 New Documents	05/09/2016	22
16/SC/0351/AM07	Randomised Phase III Colorectal Cancer Study with 3 Treatment Arms	SA6	14/02/2017	24
16/SC/0358/AM01	Investigating Typhoid Fever Pathogenesis (TYGER)	SA1	16/12/2016	28
16/SC/0358/AM02	Investigating Typhoid Fever Pathogenesis (TYGER)	Substantial Amendment 2	10/02/2017	29
16/SC/0395/AM01	VX-970 plus standard treatment in oesophageal and other cancer (V1.0)	CHARIOT SubAmend 001	13/12/2016	17
16/SC/0412/AM02	OX-RAMPP	SA02	27/02/2017	13
16/SC/0545/AM01	Safety and immunogenicity of MAP vaccine ChAdOx2 HAV (HAV001)	SA001	12/12/2016	16
16/SC/0551/AM01	XIRIUS	Amendment 1 Feb	22/02/2017	17

		2017		
16/SC/0628/AM02	OPTiMISE	SA1Protocol V2.0	13/01/2017	18
16/SC/0653/AM01	PRIMA UK	Substantial Amendment 1 - IB V	09/02/2017	24
C03.076/AM03	RTKs and germ cell development	8	30/09/2016	11

Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
15/SC/0054/AM07	CheckMate 238: CHECKpoint pathway and nivolumAb clinical Trial Evaluation 238	Substantial Amendment 04, (Rev	04/08/2016	43
15/SC/0432/AM02	Trial of Intranasal Esketamine for Treatment of Depression TRANSFORM-3	#2	21/03/2016	32
15/SC/0434/AM04	Long-term Safety & Efficacy Study of IN Esketamine in TRD (SUSTAIN-2)	4	22/03/2016	30
16/SC/0048/AM02	CA209-274 Adjuvant Nivolumab versus Placebo in Urothelial Cancer	Substantial Amendment 1	31/01/2016	18

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/SC/0054/AM07/1	CheckMate 238: CHECKpoint pathway and nivolumAb clinical Trial Evaluation 238	4.1	26/01/2016	6
15/SC/0432/AM02/1	Trial of Intranasal Esketamine for Treatment of Depression TRANSFORM-3	#3, Modification	09/05/2016	4

Unfavourable opinion timeline

Amendment REC	Title	Version	Date	Number of Days on
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Reference				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
16/SC/0231	AG-120/AG-221 plus azacitidine in treatment of IDH1/IDH2 AML	69
17/SC/0108	Maternal Attitudes to Antibiotic Use: A Community Based Case Study	76

Proportionate review applications for ethical review over 21 day timeline

REC Reference	Title	Number of Days on Clock
17/SC/0099	Investigating the molecular basis of cardiovascular disease	28
17/SC/0102	Examining the links between eating disorders and IBS. V1	24

SSAs (non Phase 1) over 25 day timeline

REC Reference	Title	Number of Days on Clock
16/SC/0446	Investigating the role of typh	27

SSAs (Phase 1) over 14 day timeline

REC Reference	Title	Number of Days on Clock
16/SC/0486	A FTIH study with GSK3008348	30

Substantial Amendments over 35 day timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
04/Q1604/21/AM08	Expression pattern of C-type Lectins	13, 06.04.2016	06/04/2016	36
12/SC/0623/AM01	Filaggrin and Food Allergy – FILAFALL 2	3.0	14/03/2016	39
13/SC/0470/AM16	Platelet-Oriented Inhibition in New TIA and Minor Ischemic stroke	SA-EC-#11	24/06/2016	36
15/SC/0054/AM07	CheckMate 238: CHECKpoint pathway and nivolumAb clinical Trial Evaluation 238	Substantial Amendment 04,	04/08/2016	43
15/SC/0109/AM07	OxLith	OxLith SA06	08/09/2016	38
15/SC/0211/AM08	Evaluating Optimal Vaccine schedules against Ebola (EVOLVE)	Evolve Substantial Amendment 5	17/05/2016	37

15/SC/0432/AM06	Trial of Intranasal Esketamine for Treatment of Depression TRANSFORM-3	5	04/07/2016	38
15/SC/0434/AM06	Long-term Safety & Efficacy Study of IN Esketamine in TRD (SUSTAIN-2)	#5 12/05/2016	12/05/2016	40
15/SC/0434/AM11	Long-term Safety & Efficacy Study of IN Esketamine in TRD (SUSTAIN-2)	7	04/07/2016	36
15/SC/0446/AM04	A PET scan study of GSK2256098; ver 1	2015N237824_03	22/04/2016	37
15/SC/0629/AM05	Phase I Tracheal replacement using tracheal scaffold and MSC's	PIS V6	05/09/2016	36
16/SC/0049/AM01	EZH-102 - Paediatric	Protocol amend 3.2	21/07/2016	43
16/SC/0293/AM02	Phase III Open-Label Esophageal Cancer - ONO-4538	CA209473 Protocol Version 5.0,	16/09/2016	37

Modified Amendments over 14 day timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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