

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

Annual Report

01 April 2017 - 31 March 2018



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
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:	Miss Natasha Bridgeman
REC Assistant:	Miss Elizabeth Hearn (01/04/2017 – 30/10/2017) Stacey Bamford (01/11/2017- present)
Committee Address:	Bristol Research Ethics Committee Centre Whitefriars Level 3 Block B Lewins Mead Bristol BS1 2NT
Telephone:	0117 342 1329
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Chair's overview of the past year:

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 Evelyn Chan	Clinical Trials Pharmacist	Expert	21/07/2017	
Ms Jane Cheeseman	Research Nurse	Expert	20/05/2013	
Dr Hugh Davies	Consultant Paediatrician / HRA Training Adviser	Expert	01/04/2015	
Dr Stephanie Jones	Postdoctoral Research Scientist	Expert	01/11/2014	
Mrs Alison Kealy	Legal Assistant – Wills and Probate	Lay Plus	28/05/2013	21/05/2017
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	
Dr Fraser Macfarlane	Retired Senior Lecturer - Health Care Management	Lay Plus	16/02/2018	
Ms Morag McCormick-Power	Research Contracts Specialist	Lay Plus	03/07/2017	
Ms Christine Montague-Johnson	Paediatric Nurse	Expert	01/06/2014	
Mr Barry Muir	Retired NHS Management Consultant	Lay	02/06/2017	
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	07/07/2017
Ms Kay Symons	Publishing consultant and trainer	Lay Plus	17/10/2016	
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
Dr Jack Tiong Kit Tan	Post Doctoral Researcher	Lay Plus	01/09/2017, 01/12/2017, 02/02/2018
Mr Joost Van Haasteren	Student - Gene Therapy	Lay	04/08/2017, 01/12/2017, 02/02/2018, 09/03/2018

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

Name	Profession	Status	Meeting date attended
Dr Ronja Bahadori	Pharmacovigilance Business Consultant	Lay Plus	07/04/2017

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

Name	Declaration of Interest	Date
Ms Raj Bains	None	28/02/2018
Ms Evelyn Chan	None	18/08/2017
Ms Jane Cheeseman	None	28/02/2018
Dr Hugh Davies	None	31/03/2018
Dr Stephanie Jones	None	28/02/2018
Mrs Doreen Laity	None	28/02/2018
Mrs Doreen Laity	None	27/02/2018
Dr Pamela Laurie	None	28/02/2018
Miss Jennifer Lawson	None	28/02/2018
Ms Morag McCormick-Power	None	28/03/2018
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.	28/02/2018
Mr Barry Muir	None	28/02/2018
Dr Karen Pulford	None	28/02/2018
Ms Kay Symons	None	28/02/2018
Dr Jack Tiong Kit Tan	None	31/01/2018
Mr Joost Van Haasteren	None	02/08/2017
Mr Nicholas Way	None	28/02/2018

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

Month	Date	Number of Members Present at Meeting
April	07/04/2017	11
May	05/05/2017	10
June	02/06/2017	10
July	07/07/2017	12
August	04/08/2017	10
September	01/09/2017	9
November	03/11/2017	13
December	01/12/2017	13
February	02/02/2018	11
March	09/03/2018	10

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
June	19/06/2017	3
July	16/07/2017	3
August	21/08/2017	3
September	18/09/2017	3
November	20/11/2017	3
December	18/12/2017	3
January	15/01/2018	3
February	19/02/2018	3
March	19/03/2018	3

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

Sub-Committee Meetings held during 01 April 2017 - 31 March 2018:

Month	Date	Number of Members Present at Meeting
April	14/04/2017	2
May	04/05/2017	2
May	25/05/2017	2
June	02/06/2017	2
June	09/06/2017	2
June	23/06/2017	2
July	07/07/2017	2
July	21/07/2017	2
July	31/07/2017	3
August	04/08/2017	2
August	11/08/2017	2
September	01/09/2017	2

September	15/09/2017	2
September	22/09/2017	10
September	29/09/2017	2
October	13/10/2017	2
October	27/10/2017	2
November	10/11/2017	2
November	17/11/2017	8
December	08/12/2017	8
December	08/12/2017	2
December	20/12/2017	2
January	05/01/2018	2
January	19/01/2018	2
January	27/01/2018	2
February	05/02/2018	5
February	09/02/2018	2
February	23/02/2018	3
March	02/03/2018	2
March	09/03/2018	2
March	23/03/2018	2

32 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
Ms Raj Bains	3
Ms Evelyn Chan	4
Ms Jane Cheeseman	10
Dr Hugh Davies	9
Dr Stephanie Jones	8
Mrs Alison Kealy	1
Mrs Doreen Laity	6
Dr Pamela Laurie	8
Miss Jennifer Lawson	6
Dr Fraser Macfarlane	1
Ms Morag McCormick-Power	4
Ms Christine Montague-Johnson	8
Mr Barry Muir	6
Dr Karen Pulford	8
Dr Mohit Sharma	3
Ms Kay Symons	9
Dr Jack Tiong Kit Tan	3
Mr Joost Van Haasteren	4
Mr Nicholas Way	7

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

Name	Number of Meetings Attended
Ms Raj Bains	3
Ms Jane Cheeseman	3
Dr Hugh Davies	5
Dr Stephanie Jones	1
Dr Pamela Laurie	1
Miss Jennifer Lawson	3
Ms Christine Montague-Johnson	3
Mr Barry Muir	1
Dr Karen Pulford	2
Ms Kay Symons	2
Mr Nicholas Way	3

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

Name	Number of Meetings Attended
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Ms Evelyn Chan	1
Ms Jane Cheeseman	6
Dr Hugh Davies	17
Dr Stephanie Jones	5
Mrs Doreen Laity	4
Dr Pamela Laurie	5
Miss Jennifer Lawson	11
Ms Morag McCormick-Power	2
Ms Christine Montague-Johnson	12
Mr Barry Muir	6
Dr Karen Pulford	6
Ms Kay Symons	6
Mr Joost Van Haasteren	3
Mr Nicholas Way	3

Training 01 April 2017 - 31 March 2018

Name of Member	Date	Event(s) attended
Ms Evelyn Chan	11/01/2018	Members Induction
Ms Jane Cheeseman	02/06/2017	Local training day
Dr Hugh Davies	02/06/2017	Local training day
Dr Stephanie Jones	02/06/2017	Local training day
Dr Pamela Laurie	16/03/2018	Research Involving Participants Lacking Mental Capacity
Miss Jennifer Lawson	02/06/2017	Local training day
Dr Fraser Macfarlane	01/10/2017	E&D
Ms Morag McCormick-Power	27/09/2017	members training day
Ms Morag McCormick-Power	29/09/2017	Regional Training Day
Ms Christine Montague-Johnson	02/06/2017	Local training day
Ms Christine Montague-Johnson	24/11/2017	HRA - National Chairs' Day and Policy Event
Dr Karen Pulford	08/03/2018	Research Involving Participants lacking mental capacity
Ms Kay Symons	02/06/2017	Local training day
Ms Kay Symons	25/07/2017	Members Induction
Dr Jack Tiong Kit Tan	11/01/2018	Members Induction
Mr Joost Van Haasteren	01/08/2017	Induction for new Research Ethics Service Committee members
Mr Joost Van Haasteren	11/01/2018	Members Induction
Mr Nicholas Way	02/06/2017	Local training day
Mr Nicholas Way	25/07/2017	Members Induction

PART 2: REC WORKLOAD AND ACTIVITY DURING THE REPORTING PERIOD

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

Applications for full ethical review – Study Type	Number	%
Clinical Trial of Investigational Medicinal Product	21	41.18
Phase 1	7	13.73
Gene Therapy	7	13.73
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	0	0.00
Others	16	31.37
Total Applications Reviewed	51	100

Table 2: Breakdown of full applications and other activity during reporting period

Number of applications made invalid by the REC Manager	0
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	5
Number of paediatric applications reviewed	8
Number of device applications reviewed	2
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	0
Number of applications reviewed that are funded by the US DHHS	0
Number of qualitative applications reviewed	0

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

Decisions taken at meetings following review of applications	Number	%
Favourable Opinion with Standard Conditions	5	9.80
Favourable Opinion with Additional Conditions	11	21.57
Unfavourable Opinion	0	0.00
Provisional Opinion	33	64.71
Provisional Opinion Pending Consultation with Referee	2	3.92
Total	51	100
Number of studies sent back to full committee meeting for final opinion	3	

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	29	56.86
Further Information Favourable Opinion with Additional Conditions	4	7.84
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	5	9.80
Favourable Opinion with Additional Conditions	12	23.53
Unfavourable Opinion	0	0.00
Provisional Opinion	1	1.96
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	51	100

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

Total Applications Reviewed	20
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Table 6: Breakdown of PRS applications and other activity during reporting period:

Number of applications made invalid by the REC Manager	1
Number of studies withdrawn prior to the meeting	1
Number of student applications reviewed	8
Number of paediatric applications reviewed	5
Number of device applications reviewed	1
Number of qualitative applications reviewed	5

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	4	20.00
Favourable Opinion with Additional Conditions	5	25.00
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	11	55.00
Unfavourable Opinion	0	0.00
Total	20	100

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

Average number of applications reviewed per full meeting	5.10
Number of completed applications for full ethical review	51
Number of completed applications for full ethical review over 60 days	3
Number of completed applications over 60 days as a % of total	5.88%
Number of completed applications for full ethical review over 40 days	26
Number of completed applications over 40 days as a % of total	50.98%
Number of days taken to final decision – average (mean)	41
Number of completed proportionate review applications for ethical review	20
Number of completed proportionate review applications for ethical review over 21 days	2
Number of completed proportionate review applications over 21 days as a % of total	10.00%
Number of SSAs (non-Phase 1) reviewed	4
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	25.00%
Number of SSAs (Phase 1) reviewed	5
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	156
Number of completed substantial amendments over 35 days	8
Number of completed substantial amendments over 35 days as a % of total substantial amendments	5.13%
Number of completed substantial amendments over 28 days	49
Number of completed substantial amendments over 28 days as a % of total substantial amendments	31.41%
Number of modified amendments reviewed	3
Number of completed modified amendments over 14 days	1
Number of completed modified amendments over 14 days as a % of total modified amendments	33.33%
Number of non substantial amendments received	123
Number of substantial amendments received for information	5
Number of substantial amendments received for new sites/Pis	45
Number of annual progress reports received	81
Number of safety reports received	51
Number of Serious Adverse Events received	0

Number of final reports received	12
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Table 9.1: Breakdown of current status of all full applications reviewed within the reporting period

Further Information Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
17/SC/0121	PemBla	53
17/SC/0167	Bariatric Surgery and the Cardiovascular System	44
17/SC/0201	Tazemetostat Rollover Study (TRuST)	57
17/SC/0237	Investigation of BI 1467335 versus placebo in patients with NASH.	57
17/SC/0244	ASTEROID 5 (version 1.0)	61
17/SC/0245	SHP633-304 Extension prospective study in Paediatric Patients with SBS	45
17/SC/0314	Phase 1/2 Study of RP1 +/- other therapies in solid tumours	30
17/SC/0317	RiVa	55
17/SC/0319	A phase II study of Cobimetnib + Atezolizumab in patients with tumours	41
17/SC/0347	Nephstrom (V1.1 07/03/2017)	49
17/SC/0387	MiNivAN trial	46
17/SC/0393	Phase 1 Open-Label Study of DCC-2618 in Patients with Adv Malignancies	59
17/SC/0395	Open Label Study of Relugolix in Men with Advanced Prostate Cancer	47
17/SC/0403	Phase1/2 with AT132 in patients with X-linked Myotubular Myopathy	47
17/SC/0443	APPA	45
17/SC/0470	Investigating a new Vaccine Against Meningitis B in Oxford (VAMBOX)	40
17/SC/0551	Cross-sectional AOSLO in IRD	33
17/SC/0554	CR-AIR-009	54
17/SC/0577	Adults with a ASD symptoms parenting a child with ASD	43
17/SC/0627	Absolute Bioavailability of BMS-986205 Tablet (QCL118212)	44
17/SC/0639	BMN 270-302 Gene therapy study in severe Haemophilia A patients	42
17/SC/0641	BMN270-203 Gene Therapy Study in Patients with Antibodies Against AAV5	42
17/SC/0644	RESCUE and REVERSE Long-term Follow-up	28
18/SC/0016	Focus: A study to test a new treatment for dry AMD	28
18/SC/0019	GPPAD-POInT	55
18/SC/0041	TITAN	73
18/SC/0097	Resuscitation optimisation study	43
18/SC/0108	CAROSELL Colon and Rectal cancer Opdivo Safety and Efficacy with 101	51
18/SC/0117	KD025 Drug-Drug Interaction Study (QSC200311)	41

Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
17/SC/0174	Home-based Combined Exercise in Type 2 Diabetes	14
17/SC/0325	Ph1,dose-escalation & cohort expansion REGN3767 in adv. malignancies	44
17/SC/0411	REVEAL 1 Trial	34
17/SC/0438	CTMT212X2102 Study of Trametinib in female patients with solid tumours	28

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
17/SC/0169	Persistence of the immune response after Ebola vaccine immunisation	32
17/SC/0172	An investigation into new measures of lung function	32
17/SC/0432	Multi-omic Analysis of T-reg cells and their Role in Pregnancy	28
17/SC/0584	CR-AIR-008	34
17/SC/0585	CR-AIR-007	34

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
17/SC/0165	GS-US-419-4015 Filgotinib in treatment of Small Bowel Crohn's Disease	32
17/SC/0236	PALISADE follow-on study	32
17/SC/0242	Phase 2A Study of IV FDY-5301 in Acute Myocardial Infarction	76
17/SC/0304	Imaging glioblastoma pH using CEST-MRI	25
17/SC/0389	VAC068. Study of controlled human Plasmodium vivax infection	32
17/SC/0392	Home-Based Stool Testing in IBD (HOST-IBD)	32
17/SC/0416	Alternating DBS for stepping control in Parkinson's disease v1	28
17/SC/0436	Remission and Flare in Psoriatic Arthritis (ReFlaP) Study	28
17/SC/0552	Safety and Immunogenicity of a candidate MERS-CoV vaccine (MERS001)	32
17/SC/0631	Wearable technology for the diagnosis & monitoring of RBD	32
18/SC/0004	Safety and Immunogenicity of a candidate CHIKV vaccine (CHIK001)	22
18/SC/0120	Abreast of Health: Phase 3 – v1.0	34

Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock

Provisional Opinion		
REC Reference	Title	Number of Days on Clock
18/SC/0083	The HIFUB study (HIFU in Breast cancer)	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/0308	Patients' and physicians' experiences of decision-making in MS	16
17/SC/0357	POWER: Participation of women in HIV research	19
17/SC/0444	Pain in children with Spinal Muscular Atrophy Type II	11
17/SC/0495	A cadaveric study of the supraclavicular nerve	3
17/SC/0499	Optimal Intervals for Abdominal Aortic Aneurysm (AAA) Surveillance. V1	17
17/SC/0671	A mobile phone app for monitoring Raynaud's phenomenon attacks	28
18/SC/0029	The impact of parent-led CBT on intervention for children who stammer	21
18/SC/0077	HD-SAGA	20
18/SC/0099	Multimodal MRI brain scanning of patients from NHS clinics	19
18/SC/0150	The support needs of first time fathers	26

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
17/SC/0668	Identifying needs of patients with interstitial lung disease	19

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/0360	Validation of the Surface Voltage Test in Nucleus implant users	17
17/SC/0666	Advanced analytics in primary care: actionable information (ACTION)	21
18/SC/0147	Review of the results of rectocoele repair	15
18/SC/0165	Investigation of non-invasive transdermal sensors in neonates V1.1	21

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
17/SC/0309	VIRTU-3	17
17/SC/0311	Patient journey following lumbar spinal fusion surgery	6
17/SC/0312	Optive Brand for Day and Night Dry Eye Management	15
17/SC/0623	Heart Two	20
18/SC/0100	Hospital acquisition of resistant enteric organisms	13

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
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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/AM10	Expression pattern of C-type Lectins	11	12/05/2017	32
09/H0604/20/AM06	OxBRC Prospective Cohort Study in Hepatitis C virus infection	Amendment 6	01/12/2016	35
09/H0604/58/AM15	Biomarkers for endometriosis	SA10	06/09/2017	18
09/H0604/79/AM62	Myeloma XI	9	02/11/2017	37
10/H0604/51/AM08	Natural history and pathogenesis of systemic IgG4 disease	4	16/10/2017	27
11/SC/0163/AM03	Genetics of papillary kidney cancers	AM03	06/09/2017	23
11/SC/0218/AM04	Measuring motor symptoms in clinical conditions	2	31/08/2017	16
11/SC/0409/AM18	VanSel-1: A Phase I trial of Vandetanib and Selumetinib.	CTA Amendment No17	26/01/2018	21
12/SC/0198/AM15	Cell Bandage (Mesenchymal Stem Cell Therapy) to Treat Meniscal Tears	AZ/CTA-01-005	10/09/2017	15
12/SC/0557/AM08	Prism and tDCS Treatment of Complex Regional Pain Syndrome (CRPS)	Amendment 7	15/01/2018	17
12/SC/0559/AM12	Anti-PD-1/Everolimus in Advanced or Metastatic ClearCell Renal Cancer	SA9	04/10/2016	16
12/SC/0559/AM13	Anti-PD-1/Everolimus in Advanced or Metastatic ClearCell Renal Cancer	SA10	12/06/2017	34
12/SC/0559/AM14	Anti-PD-1/Everolimus in Advanced or Metastatic ClearCell Renal Cancer	5.6	25/10/2017	27
12/SC/0655/AM01	Identifying genetic predictors of transplanted pancreas function	AM01 SA1	10/08/2017	22
13/SC/0173/AM16	Phase III Study in Metastatic Castration Resistant Prostate Cancer	SA11	02/05/2017	14
13/SC/0322/AM12	Immunotherapy with CD25/71 Allodepleted T-cells (ICAT)	12	01/08/2017	29
13/SC/0374/AM18	Phase I, AZD8186 in Patients with CRPC, sqNSCLC, TNBc, PTEN malignancy	AM18	07/09/2017	21
13/SC/0376/AM04	Cardiac MRI at higher magnetic field strength to assess heart function	2.0	14/04/2014	8
13/SC/0421/AM12	A Phase 1, randomized, blinded, dose-escalation study of rAAV1-PG9DP recombinant AAV vector coding for PG9 antibody in healthy male adults	SA8	27/04/2017	14
14/SC/0077/AM04	Investigating the immune response to 4CMenB in infants(EUCLIDS)2+1	SA3	01/02/2018	17

14/SC/0170/AM10	Phase 3 study to test the effects of SA237 in patients with NMO&NMOSD	SA10-Protocol Amenment 7.1	01/06/2017	34
14/SC/0170/AM12	Phase 3 study to test the effects of SA237 in patients with NMO&NMOSD	IMPD July 2017, Prefilled Syri	02/11/2017	14
14/SC/0281/AM03	ExPresSO	#1, 2 Feb 2017	22/02/2017	20
14/SC/1275/AM04	Growth Assessment of Preterm infants (GAP study)	4	06/06/2017	20
14/SC/1333/AM11	PATH-2: Platelet Rich Plasma in Achilles Tendon Healing	SA03	21/04/2017	11
14/SC/1333/AM12	PATH-2: Platelet Rich Plasma in Achilles Tendon Healing	4	24/07/2017	18
14/SC/1362/AM02	IAVI LONG TERM FOLLOW-UP STUDY		19/05/2017	11
14/SC/1416/AM18	IgNiTE: Immunoglobulin in the treatment of encephalitis	10	06/07/2017	27
14/SC/1416/AM20	IgNiTE: Immunoglobulin in the treatment of encephalitis	SA12	28/09/2017	21
14/SC/1427/AM07	Vaccines Against Salmonella Typhi (VAST)	SA08	24/11/2017	18
15/SC/0054/AM11	CheckMate 238: CHECKpoint pathway and nivolumAb clinical Trial Evaluation 238	7	08/08/2017	21
15/SC/0103/AM04	SCALOP-2 V5.0 31Jul2015	3	16/10/2017	35
15/SC/0103/AM06	SCALOP-2 V5.0 31Jul2015	SCALOP_2_SubA mend004	14/02/2018	18
15/SC/0109/AM10	OxLith	OxLith SA10	28/04/2017	28
15/SC/0115/AM11	HARMONY Outcomes Trial	5	23/05/2017	30
15/SC/0115/AM13	HARMONY Outcomes Trial	07	14/07/2017	16
15/SC/0115/AM14	HARMONY Outcomes Trial	8	09/08/2017	29
15/SC/0206/AM10	Genetic Research into Childhood Onset Psychosis	2	03/07/2017	13
15/SC/0211/AM10	Evaluating Optimal Vaccine schedules against Ebola (EVOLVE)	substantial amendment 7	24/05/2017	32
15/SC/0211/AM12	Evaluating Optimal Vaccine schedules against Ebola (EVOLVE)	9	21/09/2017	33
15/SC/0211/AM14	Evaluating Optimal Vaccine schedules against Ebola (EVOLVE)	10	23/11/2017	19
15/SC/0240/AM14	Randomised Ambulatory Management of Primary Pneumothorax (RAMPP)	7.0	03/11/2017	28
15/SC/0242/AM13	BMN 270-201: Gene Therapy Study in Severe Haemophilia A Patients	AM13	24/05/2017	34
15/SC/0242/AM14	BMN 270-201: Gene Therapy Study in Severe Haemophilia A Patients	AM14	27/06/2017	21
15/SC/0242/AM15	BMN 270-201: Gene Therapy Study in Severe Haemophilia A	SA12	11/08/2017	34

	Patients			
15/SC/0242/AM18	BMN 270-201: Gene Therapy Study in Severe Haemophilia A Patients	Substantial Amendment 15 - Pro	23/01/2018	38
15/SC/0317/AM03	Feasibility of sentinel lymph node biopsy in rectal cancer	SA1 - 2 April 2017	02/04/2017	33
15/SC/0370/AM10	TB040: MVA85A aerosol vs IM in adults with latent M.tb infection	SA06	21/04/2017	20
15/SC/0370/AM12	TB040: MVA85A aerosol vs IM in adults with latent M.tb infection	8	04/08/2017	21
15/SC/0370/AM13	TB040: MVA85A aerosol vs IM in adults with latent M.tb infection	09	19/12/2017	9
15/SC/0373/AM03	Energy metabolism and MRS	3: 17.03.17	17/03/2017	17
15/SC/0373/AM04	Energy metabolism and MRS	4	10/07/2017	59
15/SC/0432/AM17	Trial of Intranasal Esketamine for Treatment of Depression TRANSFORM-3	10	27/04/2017	21
15/SC/0432/AM18	Trial of Intranasal Esketamine for Treatment of Depression TRANSFORM-3	SA11	06/07/2017	21
15/SC/0434/AM29	Long-term Safety & Efficacy Study of IN Esketamine in TRD (SUSTAIN-2)	14	23/05/2017	27
15/SC/0434/AM30	Long-term Safety & Efficacy Study of IN Esketamine in TRD (SUSTAIN-2)	15	12/06/2017	15
15/SC/0434/AM31	Long-term Safety & Efficacy Study of IN Esketamine in TRD (SUSTAIN-2)	SA16	11/07/2017	22
15/SC/0444/AM02	AZ D5680C00001 - Ph1 MEDI7352 in Painful Osteoarthritis of the Knee		19/07/2017	27
15/SC/0638/AM02	NiCaS device in Herceptin patients – PHASE I, version 2.0_22/11/2015	SA1	09/09/2017	16
15/SC/0648/AM03	Cognitive-behaviour therapy and losartan	3	15/06/2017	29
15/SC/0648/AM04	Cognitive-behaviour therapy and losartan	3	30/08/2017	31
15/SC/0716/AM05	TB041: Aerosol BCG challenge trial in healthy UK adults	SA4	12/10/2017	35
15/SC/0716/AM07	TB041: Aerosol BCG challenge trial in healthy UK adults	5	12/10/2017	28
16/SC/0045/AM04	CP Hip Outcomes Project (CHOP)	SA1	11/09/2017	32
16/SC/0048/AM03	CA209-274 Adjuvant Nivolumab versus Placebo in Urothelial Cancer	SA3	27/04/2017	34
16/SC/0048/AM04	CA209-274 Adjuvant Nivolumab versus Placebo in Urothelial Cancer	4	29/08/2017	23

16/SC/0048/AM07	CA209-274 Adjuvant Nivolumab versus Placebo in Urothelial Cancer	5	23/11/2017	27
16/SC/0048/AM08	CA209-274 Adjuvant Nivolumab versus Placebo in Urothelial Cancer	SA6	07/03/2018	32
16/SC/0049/AM03	EZH-102 - Paediatric		12/05/2017	39
16/SC/0108/AM08	Targeting pathways to Parkinson's	5	27/11/2017	35
16/SC/0110/AM03	MAPLE study	2	31/07/2017	30
16/SC/0110/AM04	MAPLE study	3	05/09/2017	20
16/SC/0140/AM02	PQR309 and Eribulin in patients with advanced breast cancer:PQR309-007	IB V6.0 dated 04 January 2018	06/02/2018	24
16/SC/0147/AM08	TriMaster v1	SA4 REC V1	20/03/2017	19
16/SC/0147/AM10	TriMaster v1	05	08/05/2017	29
16/SC/0147/AM11	TriMaster v1	6	01/08/2017	23
16/SC/0147/AM15	TriMaster v1	SA8	30/01/2018	30
16/SC/0200/AM03	SAVE UK Trial M-2016-313	2	30/05/2017	25
16/SC/0201/AM03	A Study of OXB-102, a Gene Therapy, for Parkinsons Disease	Protocol Amendment 2	06/11/2017	11
16/SC/0227/AM03	Ebola Vaccine Registry	Substantial Amendment 2-Proto	17/05/2017	16
16/SC/0227/AM04	Ebola Vaccine Registry	Substantial Amendment 3	22/02/2018	31
16/SC/0231/AM04	AG-120/AG-221 plus azacitidine in treatment of IDH1/IDH2 AML	AG-120 IB v5.0	17/05/2017	16
16/SC/0231/AM05	AG-120/AG-221 plus azacitidine in treatment of IDH1/IDH2 AML	2	24/07/2017	22
16/SC/0231/AM06	AG-120/AG-221 plus azacitidine in treatment of IDH1/IDH2 AML	6	05/10/2017	35
16/SC/0298/AM02	Exploring young people's conversations about parental mental health	Substantial amendment 1 22.03.	22/03/2017	28
16/SC/0331/AM02	A Pilot Study of NY-ESO-1c259T in Synovial Sarcoma	SA2	05/04/2017	19
16/SC/0345/AM03	Safety, immunogenicity and efficacy of RH5.1/AS01 (VAC063)	2	12/06/2017	15
16/SC/0345/AM04	Safety, immunogenicity and efficacy of RH5.1/AS01 (VAC063)	003	11/09/2017	14
16/SC/0345/AM06	Safety, immunogenicity and efficacy of RH5.1/AS01 (VAC063)	1	23/11/2017	22
16/SC/0345/AM07	Safety, immunogenicity and efficacy of RH5.1/AS01 (VAC063)	SA005	23/01/2018	6

16/SC/0345/AM08	Safety, immunogenicity and efficacy of RH5.1/AS01 (VAC063)	SA6	07/02/2018	1
16/SC/0351/AM09	Randomised Phase III Colorectal Cancer Study with 3 Treatment Arms	SA08	02/08/2017	27
16/SC/0358/AM03	Investigating Typhoid Fever Pathogenesis (TYGER)	3	17/07/2017	34
16/SC/0358/AM04	Investigating Typhoid Fever Pathogenesis (TYGER)	Substantial Amendment 4	19/01/2018	6
16/SC/0358/AM05	Investigating Typhoid Fever Pathogenesis (TYGER)	Substantial Amendment 5	16/02/2018	29
16/SC/0376/AM01	TRoMbone	1	24/07/2017	24
16/SC/0376/AM05	TRoMbone	2.0	30/10/2017	17
16/SC/0404/AM01	fMRI study of ABX-1431	2	28/02/2017	26
16/SC/0526/AM02	EYS606-CT1 - version 2 2016-09-27	SA2	27/09/2017	25
16/SC/0526/AM03	EYS606-CT1 - version 2 2016-09-27	2	27/11/2017	34
16/SC/0537/AM02	Gene therapy for Haemophilia A; version 1	SA1	16/10/2017	8
16/SC/0537/AM03	Gene therapy for Haemophilia A; version 1	5	24/11/2017	14
16/SC/0545/AM02	Safety and immunogenicity of MAP vaccine ChAdOx2 HAV (HAV001)	2	07/12/2017	40
16/SC/0545/AM03	Safety and immunogenicity of MAP vaccine ChAdOx2 HAV (HAV001)	SA003	05/12/2017	17
16/SC/0551/AM02	XIRIUS	3	26/05/2017	17
16/SC/0551/AM04	XIRIUS	Substantial Amendment #03	16/01/2018	25
16/SC/0628/AM03	OPTiMISE	SA2	15/11/2017	27
16/SC/0628/AM04	OPTiMISE	SA3	21/02/2018	31
16/SC/0640/AM01	A phase 1b combination study of PDR001	CPDR001X2102 2	13/03/2017	35
16/SC/0645/AM01	FRONTIER: Fluciclovine (18F) imaging of breast cancer	SA1 - 30 May 2017	30/05/2017	28
16/SC/0645/AM02	FRONTIER: Fluciclovine (18F) imaging of breast cancer	SA2	13/12/2017	7
16/SC/0653/AM05	PRIMA UK	3 - Updated radiology risk ass	08/06/2017	19
16/SC/0653/AM06	PRIMA UK	4	25/07/2017	23
16/SC/0653/AM08	PRIMA UK	6	22/12/2017	26
17/SC/0006/AM01	Bordetella Pertussis Colonisation Challenge Study	1	19/05/2017	30
17/SC/0006/AM02	Bordetella Pertussis Colonisation Challenge Study	2	21/07/2017	9
17/SC/0006/AM03	Bordetella Pertussis Colonisation Challenge Study	3	17/10/2017	35
17/SC/0022/AM01	Intravitreal Aflibercept in patients with diabetic eye disease	1.0	28/06/2017	25

17/SC/0032/AM01	Selected Mesenchymal Stromal Cells to reduce liver inflammation	SA01	16/10/2017	17
17/SC/0035/AM03	PLX-CLI-03_PACE_Ph3 IM PLX-PAD in Patients with Critical Limb Ischemia	9.0	23/05/2017	19
17/SC/0035/AM04	PLX-CLI-03_PACE_Ph3 IM PLX-PAD in Patients with Critical Limb Ischemia	4	02/11/2017	34
17/SC/0057/AM01	Chronological evaluation of Functional changes in Neonatal Skin (CFNS)	1	14/08/2017	23
17/SC/0079/AM02	CORGI 2	1	25/07/2017	15
17/SC/0091/AM01	Women's experiences of breast cancer follow-up care	1	10/10/2017	5
17/SC/0093/AM01	GBGC: Comparing efficacy of Dulaglutide vs Placebo in Pediatric DM	Addition of eConsent, Recruitm	26/10/2017	29
17/SC/0121/AM01	PemBla	1.0	28/07/2017	33
17/SC/0165/AM01	GS-US-419-4015 Filgotinib in treatment of Small Bowel Crohn's Disease	1	19/07/2017	28
17/SC/0169/AM01	Persistence of the immune response after Ebola vaccine immunisation	SA1	12/09/2017	28
17/SC/0169/AM02	Persistence of the immune response after Ebola vaccine immunisation	Substantial Amendment 2	02/03/2018	39
17/SC/0172/AM01	An investigation into new measures of lung function	5.6	20/10/2017	24
17/SC/0201/AM03	Tazemetostat Rollover Study (TRuST)	IB V7	10/08/2017	10
17/SC/0236/AM01	PALISADE follow-on study	1	03/07/2017	14
17/SC/0236/AM03	PALISADE follow-on study	2	17/11/2017	22
17/SC/0237/AM03	Investigation of BI 1467335 versus placebo in patients with NASH.	Substantial Amendment 3	09/03/2018	27
17/SC/0242/AM02	Phase 2A Study of IV FDY-5301 in Acute Myocardial Infarction	2	03/08/2017	30
17/SC/0242/AM05	Phase 2A Study of IV FDY-5301 in Acute Myocardial Infarction	SA3	19/10/2017	8
17/SC/0242/AM10	Phase 2A Study of IV FDY-5301 in Acute Myocardial Infarction	SA6	15/02/2018	25
17/SC/0244/AM01	ASTEROID 5 (version 1.0)	SA2	31/07/2017	29
17/SC/0244/AM05	ASTEROID 5 (version 1.0)	1	24/11/2017	11
17/SC/0244/AM06	ASTEROID 5 (version 1.0)	Substantial Amendment 4	09/02/2018	18
17/SC/0244/AM07	ASTEROID 5 (version 1.0)	Substantial Amendment 5	15/02/2016	26
17/SC/0245/AM01	SHP633-304 Extension prospective study in Paediatric	1	11/08/2017	33

	Patients with SBS			
17/SC/0304/AM01	Imaging glioblastoma pH using CEST-MRI	1	18/12/2017	26
17/SC/0309/AM01	VIRTU-3	Substantial Amendment 1	05/03/2018	28
17/SC/0311/AM01	Patient journey following lumbar spinal fusion surgery	1	04/12/2017	23
17/SC/0317/AM02	RiVa	Amendment 1	09/01/2018	35
17/SC/0319/AM01	A phase II study of Cobimetnib + Atezolizumab in patients with tumours	sa1	26/09/2017	28
17/SC/0319/AM02	A phase II study of Cobimetnib + Atezolizumab in patients with tumours	Substantial amendment 2 - Prot	31/01/2018	17
17/SC/0347/AM03	Nephstrom (V1.1 07/03/2017)	Amendment 01 Version 1.1	30/01/2018	34
17/SC/0387/AM01	MiNivAN trial	1	07/12/2017	20
17/SC/0393/AM02	Phase 1 Open-Label Study of DCC-2618 in Patients with Adv Malignancies	5	03/11/2017	27
17/SC/0395/AM02	Open Label Study of Relugolix in Men with Advanced Prostate Cancer	Substantial Amendment 1 Protoc	18/01/2018	17
17/SC/0554/AM02	CR-AIR-009	Am-001 (Global)	26/09/2017	28

Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
13/SC/0200/AM06	(May) Stem Cell Research in Early-Onset Psychosis	v4	26/07/2017	34
16/SC/0049/AM05	EZH-102 - Paediatric	5.3	26/07/2017	36
16/SC/0351/AM10	Randomised Phase III Colorectal Cancer Study with 3 Treatment Arms	9	12/12/2017	36

Table 10.2: Breakdown of current status of all modified amendments reviewed within the reporting period

Favourable opinion timeline

Amendment REC	Title	Version	Date	Number of Days on
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Reference				Clock
16/SC/0048/AM02/1	CA209-274 Adjuvant Nivolumab versus Placebo in Urothelial Cancer	1 (Revised Protocol 2; dd:18-0	27/04/2017	46
16/SC/0049/AM05/2	EZH-102 - Paediatric	Mod Am - SA5	02/10/2017	9
16/SC/0351/AM10/1	Randomised Phase III Colorectal Cancer Study with 3 Treatment Arms	Amendment 9 - Modified 1 (subs	30/01/2018	14

Unfavourable opinion timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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Table 11: Items exceeding timelines**Full applications for ethical review over 60 day timeline**

REC Reference	Title	Number of Days on Clock
17/SC/0242	Phase 2A Study of IV FDY-5301 in Acute Myocardial Infarction	76
17/SC/0244	ASTEROID 5 (version 1.0)	61
18/SC/0041	TITAN	73

Proportionate review applications for ethical review over 21 day timeline

REC Reference	Title	Number of Days on Clock
17/SC/0671	A mobile phone app for monitoring Raynaud's phenomenon attacks	28
18/SC/0150	The support needs of first time fathers	26

SSAs (non Phase 1) over 25 day timeline

REC Reference	Title	Number of Days on Clock
17/SC/0553	A Phase 2A, Randomized, Double	28

SSAs (Phase 1) over 14 day timeline

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

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
09/H0604/79/AM62	Myeloma XI	9	02/11/2017	37
15/SC/0242/AM18	BMN 270-201: Gene Therapy Study in Severe Haemophilia A Patients	Substantial Amendment 15 - Pro	23/01/2018	38
15/SC/0373/AM04	Energy metabolism and MRS	4	10/07/2017	59
16/SC/0049/AM03	EZH-102 - Paediatric		12/05/2017	39
16/SC/0049/AM05	EZH-102 - Paediatric	5.3	26/07/2017	36
16/SC/0351/AM10	Randomised Phase III Colorectal Cancer Study with 3 Treatment Arms	9	12/12/2017	36

16/SC/0545/AM02	Safety and immunogenicity of MAP vaccine ChAdOx2 HAV (HAV001)	2	07/12/2017	40
17/SC/0169/AM02	Persistence of the immune response after Ebola vaccine immunisation	Substantial Amendment 2	02/03/2018	39

Modified Amendments over 14 day timeline				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
16/SC/0048/AM02/1	CA209-274 Adjuvant Nivolumab versus Placebo in Urothelial Cancer	1 (Revised Protocol 2; dd:18-0	27/04/2017	46