

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

Annual Report

01 April 2015 - 31 March 2016



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:	Dr Cynthia Graham (until 06/06/2015) Mrs Sue Lousada (Acting 22/06/2015 – 22/12/2015) Vacant (22/12/2016 – present)
Alternate Vice-Chair:	Vacant until 01/01/2016 Ms Christine Montague-Johnson (from 01/01/2016 – present)
REC Manager:	Ms Lauren Allen (01/01/2015 - 01/07/2015) Mr Mark Dawson – (01/07/2015 – 01/01/2016) Ms Natasha Bridgeman (01/01/2016 – present)
REC Assistant:	Mr Mark Dawson (01/01/2015 - 01/07/2015) Mr Stephan Ramey – (01/07/2015 – 01/01/2016) Ms Lidia Gonzalez (01/01/2016 – present)
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:

I've enjoyed chairing the meetings and engaging in the discussion for the last year and feel the committee has maintained the rigour of review while also helping researchers. That is the crucial balance we strike in committee.

There's been no shortage of topics that have challenged us over the last 12 months. Amongst others:

Bioengineered grafts

Placebo surgery

Research involving children

Research in those with very limited life expectancy.

Grappling with Participant Information Sheets and their increasing length

From all this we're keen to record our experience and discuss it with others. Throughout the debates we seem to have challenged each other but we've been able to keep a friendly atmosphere at our meetings (and we're still quorate month by month)! For the future, we're looking at areas of expertise that we need to maintain and develop and also seeing how we can work with colleagues at the NHS Trust and University.

So thanks to all the members who give up their time, thanks to our great new members and the officers who have helped us. It's a great team. These are difficult times (are there ever any easy ones?) and it's a credit to all that we're still here! That is a testament to the work all have put in.

Dr Hugh Davies

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	
Mr Stuart Cole	Head of Communications	Lay Plus	01/06/2011	
Dr Hugh Davies	Consultant Paediatrician	Expert	01/04/2015	
Ms Ana de Veciana	Clinical Trials Pharmacist	Expert	06/02/2015	
Mrs Marion Fiddes	Consultant Project Manager	Lay Plus	13/02/2006	31/10/2015
Dr Cynthia Graham	Senior Lecturer in Psychology	Expert	12/12/2005	06/06/2015
Mrs Lyndsay Hills	Retired Registered Nurse	Lay	01/04/2010	16/12/2015
Dr Stephanie Jones	Postdoctoral Research Scientist	Expert	01/11/2014	
Mrs Alison Kealy	Legal Assistant – Wills and Probate	Lay Plus	28/05/2013	
Ms Joanne Keenan	Head of Development	Lay	12/05/2014	
Mrs Doreen Laity	Retired Pharmacist	Lay	05/08/2013	
Mrs Susan Lousada	Company Director (Property) & Non-legal member of first-tier tax tribunal	Lay	22/06/2015	31/12/2015
Ms Christine Montague-Johnson	Paediatric Nurse	Expert	01/06/2014	
Mr Robert Nicholls	Retired Health Service Manager	Lay	13/05/2015	
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	
Mr Martin Usherwood	Retired Gynaecologist	Expert	05/09/2011	

South Central - Oxford A Research Ethics Committee: Deputy Members

Name	Profession	Status	Meeting date attended
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South Central - Oxford A Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended
Professor David Scott	Pharmacist	Expert	10/08/2015

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

Name	Declaration of Interest	Date
Ms Raj Bains	None	31/03/2016
Ms Jane Cheeseman	None	10/02/2016
Dr Elizabeth Coates	None	31/03/2016
Mr Stuart Cole	None	15/01/2016
Dr Hugh Davies	None	07/05/2015
Ms Ana de Veciana	Husband works for VERTEX Pharmaceuticals ltd Europe and has shares in the company.	31/03/2016
Dr Stephanie Jones	None	31/03/2016
Mrs Alison Kealy	Shareholding in GlaxosmithKline	17/02/2016
Ms Joanne Keenan	None	31/03/2016
Mrs Doreen Laity	None	31/03/2016
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.	31/03/2016
Mr Robert Nicholls	Fellow of Institute of Healthcare Management, ISA's in managed funds. May include holdings in Pharmaceutical Companies. Co-Chair of Reference Group for DH Scotland project- Prescribing for Excellence.	15/05/2015
Dr Karen Pulford	None	31/03/2016
Dr Mohit Sharma	None	25/01/2016
Mr Martin Usherwood	None	10/02/2016

Meetings for Full Ethical Review 01 April 2015 - 31 March 2016:

Month	Date	Number of Members Present at Meeting
April	10/04/2015	10
May	01/05/2015	11
June	05/06/2015	12
July	03/07/2015	11
August	07/08/2015	10
November	06/11/2015	12
December	04/12/2015	12
February	05/02/2016	11
March	04/03/2016	14

9 full committee meetings were held during the reporting period.

Proportionate Review Sub-Committee Meetings held during 01 April 2015 - 31 March 2016:

Month	Date	Number of Members Present at Meeting
May	26/05/2015	3

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

Sub-Committee Meetings held during 01 April 2015 - 31 March 2016:

Month	Date	Number of Members Present at Meeting
April	02/04/2015	2
April	10/04/2015	2
April	17/04/2015	2
May	01/05/2015	2
May	15/05/2015	2
May	22/05/2015	3
May	29/05/2015	2
May	29/05/2015	2
June	12/06/2015	2
June	26/06/2015	2
July	10/07/2015	2
July	24/07/2015	2
August	07/08/2015	2
August	14/08/2015	2
August	21/08/2015	2
August	21/08/2015	2
August	28/08/2015	3
September	04/09/2015	2
September	15/09/2015	2
September	18/09/2015	2
October	02/10/2015	2

October	14/10/2015	2
October	28/10/2015	2
November	11/11/2015	2
November	13/11/2015	2
November	27/11/2015	2
December	11/12/2015	2
December	18/12/2015	2
January	04/01/2016	2
January	08/01/2016	2
January	22/01/2016	2
February	05/02/2016	2
February	19/02/2016	2
March	04/03/2016	2
March	14/03/2016	2

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

Details of inquorate meeting held:01 April 2015 - 31 March 2016

None

Attendance of Members at full committee meetings:01 April 2015 - 31 March 2016

Name	Number of Meetings Attended
Ms Raj Bains	7
Ms Jane Cheeseman	8
Dr Elizabeth Coates	2
Mr Stuart Cole	5
Dr Hugh Davies	7
Ms Ana de Veciana	6
Mrs Marion Fiddes	4
Dr Cynthia Graham	3
Mrs Lyndsay Hills	5
Dr Stephanie Jones	7
Mrs Alison Kealy	7
Ms Joanne Keenan	1
Mrs Doreen Laity	9
Mrs Susan Lousada	3
Ms Christine Montague-Johnson	8
Mr Robert Nicholls	6
Dr Karen Pulford	2
Dr Mohit Sharma	5
Mr Martin Usherwood	7

Attendance of Members at proportionate review sub-committee meetings: 01 April 2015 - 31 March 2016

Name	Number of Meetings Attended
Ms Raj Bains	1
Ms Jane Cheeseman	1
Dr Hugh Davies	1

Attendance of Members at sub-committee meetings: 01 April 2015 - 31 March 2016

Name	Number of Meetings Attended
Ms Jane Cheeseman	6
Mr Stuart Cole	1
Dr Hugh Davies	20
Ms Ana de Veciana	1
Mrs Marion Fiddes	6
Dr Cynthia Graham	4
Mrs Lyndsay Hills	7
Dr Stephanie Jones	4

Mrs Alison Kealy	1
Mrs Doreen Laity	1
Mrs Susan Lousada	9
Ms Christine Montague-Johnson	4
Mr Robert Nicholls	3
Dr Mohit Sharma	3
Mr Martin Usherwood	1

Details of inquorate meeting held:01 April 2015 - 31 March 2016

None

Name of Member	Date	Event(s) attended
Ms Raj Bains	16/04/2015	Training - Quantitative Research Methods and Statistics: A Health Research Authority Workshop
Ms Jane Cheeseman	30/06/2015	Training - Human Tissue Act (Use of Human Samples in Research) - An Introductory Level
Ms Jane Cheeseman	04/09/2015	Joint Oxford Training Day
Dr Elizabeth Coates	10/03/2016	Members Induction
Mr Stuart Cole	04/09/2015	Joint Oxford Training Day
Mrs Marion Fiddes	04/09/2015	Joint Oxford Training Day
Dr Stephanie Jones	14/04/2015	What PPI is and why it's important
Dr Stephanie Jones	04/09/2015	Joint Oxford Training Day
Dr Stephanie Jones	03/02/2016	Handling Health-Related Findings in Research
Mrs Alison Kealy	04/09/2015	Joint Oxford Training Day
Mrs Alison Kealy	03/12/2015	Training - HRA Workshop: Pragmatic or Point of Care trials
Mrs Doreen Laity	04/09/2015	Joint Oxford Training Day
Ms Christine Montague-Johnson	04/09/2015	Joint Oxford Training Day
Ms Christine Montague-Johnson	07/10/2015	Introduction to Phase 1 Research - Trials and regulation
Ms Christine Montague-Johnson	19/10/2015	The Ethical Issues of Research Involving Children.
Ms Christine Montague-Johnson	03/12/2015	Training - HRA Workshop: Pragmatic or Point of Care trials
Ms Christine Montague-Johnson	03/02/2016	Handling Health-Related Findings in Research
Mr Robert Nicholls	04/09/2015	Joint Oxford Training Day
Mr Robert Nicholls	24/09/2015	Committee Members Induction
Dr Karen Pulford	10/03/2016	Members Induction
Dr Mohit Sharma	04/09/2015	Joint Oxford Training Day
Mr Martin Usherwood	04/09/2015	Joint Oxford 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	14	31.11
Phase 1	7	15.56
Gene Therapy	3	6.67
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	0	0.00
Others	21	46.67
Total Applications Reviewed	45	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	5
Number of paediatric applications reviewed	7
Number of device applications reviewed	6
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	1	2.22
Favourable Opinion with Additional Conditions	7	15.56
Unfavourable Opinion	0	0.00
Provisional Opinion	36	80.00
Provisional Opinion Pending Consultation with Referee	1	2.22
Total	45	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	36	80.00
Further Information Favourable Opinion with Additional Conditions	1	2.22
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	1	2.22
Favourable Opinion with Additional Conditions	7	15.56
Unfavourable Opinion	0	0.00
Provisional Opinion	0	0.00
Provisional Opinion Pending Consultation with Referee	0	0.00
Further Information response not complete	0	0.00
No decision entered on system	0	0.00
Number of studies withdrawn after the meeting	0	0.00
Total	45	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	3
Number of studies withdrawn prior to the meeting	0
Number of student applications reviewed	2
Number of paediatric applications reviewed	1
Number of device applications reviewed	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	0	0.00
Favourable Opinion with Additional Conditions	1	33.33
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	2	66.67
Unfavourable Opinion	0	0.00
Total	3	100

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

Average number of applications reviewed per full meeting	5.00
Number of completed applications for full ethical review	45
Number of completed applications for full ethical review over 60 days	0
Number of completed applications over 60 days as a % of total	0.00%
Number of completed applications for full ethical review over 40 days	6
Number of completed applications over 40 days as a % of total	13.33%
Number of days taken to final decision – average (mean)	31
Number of completed proportionate review applications for ethical review	3
Number of completed proportionate review applications for ethical review over 14 days	0
Number of completed proportionate review applications over 14 days as a % of total	0.00%
Number of SSAs (non-Phase 1) reviewed	14
Number of completed applications for SSA review over 25 days	0
Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs	0.00%
Number of SSAs (Phase 1) reviewed	7
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	160
Number of completed substantial amendments over 35 days	2
Number of completed substantial amendments over 35 days as a % of total substantial amendments	1.25%
Number of completed substantial amendments over 28 days	7
Number of completed substantial amendments over 28 days as a % of total substantial amendments	4.38%
Number of modified amendments reviewed	4
Number of completed modified amendments over 14 days	1
Number of completed modified amendments over 14 days as a % of total modified amendments	25.00%
Number of minor amendments received	76
Number of substantial amendments received for information	0
Number of substantial amendments received for new sites/PIs	36
Number of annual progress reports received	76

Number of safety reports received	86
Number of Serious Adverse Events received	3
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
15/SC/0121	Studying movement control in PD using closed loop DBS.	21
15/SC/0143	AG-CLI-0206: Ph 3 - Efficacy & Safety Study for Critical Limb Ischemia	24
15/SC/0194	Request Study	18
15/SC/0197	Phase III, Fixed-dose, combination RHB-104, Moderately Active Crohn's	30
15/SC/0205	Young Diabetics' Decision Making Regarding Alcohol	20
15/SC/0206	Genetic Research into Childhood Onset Psychosis	32
15/SC/0211	Evaluating Optimal Vaccine schedules against Ebola (EVOLVE)	20
15/SC/0239	ASTEROID 2	25
15/SC/0242	BMN 270-201: Gene Therapy Study in Severe Haemophilia A Patients	40
15/SC/0267	A Phase I Study to Assess New Ebola Vaccines, cAd3-EBO Z & Ad26.ZEBOV	16
15/SC/0299	Autoantibodies in patients admitted to a general adult ward	25
15/SC/0302	Phase 3 Efficacy and Safety study of Oral RPC1063 in RMS Patients	31
15/SC/0311	VEST III PMS clinical protocol	39
15/SC/0373	Energy metabolism and MRS	28
15/SC/0376	Children's drops for ear pain in acute otitis media	31
15/SC/0378	Treating sleep problems in young people	26
15/SC/0380	4191: Once Daily Semaglutide Dose Finding in Type 2 DM	27
15/SC/0432	Trial of Intranasal Esketamine for Treatment of Depression TRANSFORM-3	46
15/SC/0434	Long-term Safety & Efficacy Study of IN Esketamine in TRD (SUSTAIN-2)	31
15/SC/0444	AZ D5680C00001 - Ph1 MEDI7352 in Painful Osteoarthritis of the Knee	35
15/SC/0446	A PET scan study of GSK2256098; ver 1	39
15/SC/0447	Frequency of SU-hypoglycaemia in older frail patients with diabetes	36
15/SC/0617	Feasibility of Health Coaching in Cancer Patients Version 1.0	32
15/SC/0629	Phase I Tracheal replacement using tracheal scaffold and MSC's	47
15/SC/0638	NICaS device in Herceptin patients – PHASE I, version 2.0_ 22/11/2015	32
15/SC/0665	Absorption & elimination of radiolabelled GSK961081, version 1	37
15/SC/0692	TR2-A: effect on stomach acid in healthy men, v1	37
16/SC/0045	CP Hip Outcomes Project (CHOP)	48
16/SC/0046	Pipeline Flex with Shield Technology Embolization	27
16/SC/0048	CA209-274 Adjuvant Nivolumab versus Placebo in Urothelial Cancer	47
16/SC/0049	EZH-102 - Paediatric	24
16/SC/0051	Motion analysis database of healthy and prosthetic UL performance	33

16/SC/0092	Safer care patient-centred checklist	56
16/SC/0108	Targeting pathways to Parkinson's	58
16/SC/0116	The VIRTUOSO study (Version 1.0)	36
16/SC/0122	Psychosis: EIE	36

Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/SC/0648	Cognitive-behaviour therapy and losartan	35

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
15/SC/0716	TB041: Aerosol BCG challenge trial in healthy UK adults	33

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/SC/0237	A Study to Assess Malaria Vaccines ChAd63/MVA Pfs25-IMX313	21
15/SC/0240	Randomised Ambulatory Management of Primary Pneumothorax (RAMPP)	21
15/SC/0314	PaLS 1	24
15/SC/0317	Feasibility of sentinel lymph node biopsy in rectal cancer	24
15/SC/0370	TB040: MVA85A aerosol vs IM in adults with latent M.tb infection	25
15/SC/0618	MIBS	26
15/SC/0641	200262 - A FTIH study with GSK3008348	27

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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Provisional Opinion Pending Consultation with Referee

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

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

REC Reference	Title	Number of Days on Clock
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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
15/SC/0332	Future of Information Technology and Telecommunication for T1DM	8
15/SC/0339	Communication & sensory profiles of MSI & ASD children	8

Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
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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
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Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
15/SC/0333	Can physiotherapy assessment help predict knee injury in runners?	7

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
05/Q1604/70/AM08	Oxford Vascular Study (OXVASC)	Substantial Amendment 9 dated	18/02/2015	13
06/Q1604/162/AM07	Rectal Imaging Trial (RIT)	Substantial Amendment 3.2	29/12/2014	26
09/H0604/20/AM04	OxBRC Prospective Cohort Study in Hepatitis C virus infection	5	15/05/2015	32
09/H0604/58/AM12	Biomarkers for endometriosis	8	27/10/2015	14
09/H0604/64/AM06	REpeated AutoLogous Infusions of STem cells In Cirrhosis (REALISTIC)	8	15/05/2015	19
09/H0604/79/AM40	Myeloma XI	HM09/8885/P/v7.0/20160126	26/01/2016	15
10/H0604/47/AM16	Phase I Study of IMCgp100 in Advanced Malignant Melanoma V1.0	17	21/05/2015	24
10/H0604/47/AM18	Phase I Study of IMCgp100 in Advanced Malignant Melanoma V1.0	18	05/08/2015	15
10/H0604/47/AM19	Phase I Study of IMCgp100 in Advanced Malignant Melanoma V1.0	SA019, 06 November 2015 (Proto	06/11/2015	23
10/H0604/47/AM20	Phase I Study of IMCgp100 in Advanced Malignant Melanoma V1.0	SA020, 19 January 2016 (Protoc	19/01/2016	18
10/H0604/79/AM10	Phase 3 TookadA® Soluble in low-risk localised prostate cancer patients	7	08/05/2015	25
10/H0604/99/AM07	Markers of Neurodegeneration in Multiple Sclerosis	3, 21/09/2015	29/09/2015	15
11/SC/0218/AM03	Measuring motor symptoms in clinical conditions	1.2	21/05/2015	14
11/SC/0355/AM07	MBSR in the management of psychological distress in prostate cancer	3	06/08/2015	16
11/SC/0355/AM08	MBSR in the management of psychological distress in prostate cancer	4, 17/12/15	17/12/2015	14
11/SC/0409/AM12	VanSel-1: A Phase I trial of Vandetanib and Selumetinib.	14	16/07/2015	6
11/SC/0409/AM16	VanSel-1: A Phase I trial of Vandetanib and Selumetinib.	15, dated 18	18/11/2015	13

		November 2015		
11/SC/0410/AM05	VIT-0910	4.0	01/12/2015	6
11/SC/0433/AM04	IDEB: Irinotecan Drug-Eluting Beads in Glioblastoma	3	25/05/2015	17
11/SC/0452/AM06	Oral MK8669 in Children/Adolescents with Solid Tumours(6 - <18years)	6	17/08/2015	17
12/SC/0328/AM16	CANDID	7	15/07/2015	8
12/SC/0339/AM07	STUDY OF FOLLOW-UP AND OUTCOMES FOLLOWING ADOLESCENT SEXUAL ASSAULT	Substantial Amendment 4	24/03/2015	17
12/SC/0556/AM04	Boosting the therapeutic benefits of prism adaptation using tDCS	Substantial Amendment 3 dated	01/04/2015	21
12/SC/0556/AM07	Boosting the therapeutic benefits of prism adaptation using tDCS	4	03/11/2015	13
12/SC/0559/AM07	Anti-PD-1/Everolimus in Advanced or Metastatic ClearCell Renal Cancer	7	05/02/2015	20
12/SC/0559/AM08	Anti-PD-1/Everolimus in Advanced or Metastatic ClearCell Renal Cancer	EC06 Protocol Amendment 14	12/05/2015	24
12/SC/0559/AM09	Anti-PD-1/Everolimus in Advanced or Metastatic ClearCell Renal Cancer	Substantial Amendment EC07 revised protocol 6	07/09/2015	10
12/SC/0616/AM04	ROCOCO: Radiotherapy & olaparib for oesophageal carcinoma	4	26/08/2015	14
12/SC/0616/AM05	ROCOCO: Radiotherapy & olaparib for oesophageal carcinoma	5, Version 6.0	04/02/2016	10
12/SC/0660/AM05	AdNRGM; VDEPT + GMCSF in locally recurrent prostate cancer	6.0	02/02/2016	25
13/SC/0098/AM06	TB034:ChAdOx1 85A and MVA85A in BCG vaccinated adults	8	08/06/2015	16
13/SC/0156/AM03	Chingford 1000 Women Study	2	03/06/2015	12
13/SC/0163/AM01	Sensorimotor plasticity and brain stimulation	1, 18/12/2015	18/12/2015	10
13/SC/0173/AM10	Phase III Study in Metastatic Castration Resistant Prostate Cancer	7	10/07/2015	13
13/SC/0173/AM11	Phase III Study in Metastatic Castration Resistant Prostate Cancer	8	12/10/2015	24
13/SC/0199/AM04	Protection against Pneumococcal infection in children with T1DM	2	15/06/2015	10
13/SC/0200/AM03	(May) Stem Cell Research in Early-Onset Psychosis	Substantial	20/02/2015	22

		Amendment 2 dated		
13/SC/0291/AM03	GO28053 Ph1 Vemurafenib in BRAF V600 mutation positive cancer patients	Substantial amendment form dat	28/10/2014	21
13/SC/0317/AM12	IELSG 37	2 040216	04/02/2016	14
13/SC/0329/AM04	TB035: MVA85A- Homologous boosting by heterologous route	SA06	10/03/2015	22
13/SC/0329/AM05	TB035: MVA85A- Homologous boosting by heterologous route	8	10/09/2015	7
13/SC/0374/AM03	Phase I, AZD8186 in Patients with CRPC, sqNSCLC, TNBc, PTEN malignancy	3	06/03/2015	23
13/SC/0374/AM06	Phase I, AZD8186 in Patients with CRPC, sqNSCLC, TNBc, PTEN malignancy	6	28/08/2015	17
13/SC/0374/AM07	Phase I, AZD8186 in Patients with CRPC, sqNSCLC, TNBc, PTEN malignancy	Clinical Study Protocol D4620C	15/09/2015	34
13/SC/0383/AM19	MK-8237-009 House Dust Mite Biomarker Study	7	26/05/2015	15
13/SC/0421/AM05	A Phase 1, randomized, blinded, dose-escalation study of rAAV1-PG9DP recombinant AAV vector coding for PG9 antibody in healthy male adults	5	19/05/2015	19
13/SC/0421/AM06	A Phase 1, randomized, blinded, dose-escalation study of rAAV1-PG9DP recombinant AAV vector coding for PG9 antibody in healthy male adults	6	20/08/2015	20
13/SC/0470/AM14	Platelet-Oriented Inhibition in New TIA and Minor Ischemic stroke	SA#09	06/11/2015	10
13/SC/0509/AM01	Investigating brain tumours using next-generation sequencing	1	14/09/2015	20
13/SC/0544/AM05	PREPARE - Preconceptional diet and embryo quality: an RCT.	5	24/08/2015	16
13/SC/0558/AM09	Secukinumab in treatment of chronic palmoplantar pustular psoriasis	8	12/05/2015	17
13/SC/0578/AM03	Understanding Pneumococcal Carriage and Disease	2	14/10/2015	15
13/SC/0597/AM03	Vital Sign Monitoring of Premature Infants - Pilot Study (v 5.0)	1	20/07/2015	22
13/SC/0599/AM08	Parental Responses to Child Experiences of Trauma: PROTECT Study v.1	SA3	26/10/2015	23
13/SC/0604/AM09	Treg Liver Trial	ThRIL, Protocol version 8.0 d	14/10/2015	40
14/SC/0065/AM04	28431754DIA4003 (CANVAS-R)	3	11/03/2015	27
14/SC/0065/AM05	28431754DIA4003 (CANVAS-R)	4	03/07/2015	17
14/SC/0065/AM06	28431754DIA4003 (CANVAS-R)	5	14/10/2015	15

14/SC/0065/AM08	28431754DIA4003 (CANVAS-R)	#6	08/02/2016	10
14/SC/0077/AM02	Investigating the immune response to 4CMenB in infants(EUCLIDS)2+1	Substantial Amendment 2	30/03/2015	7
14/SC/0168/AM02	High-resolution connectivity of the basal ganglia in health & disease	1	24/07/2015	25
14/SC/0170/AM06	Phase 3 study to test the effects of SA237 in patients with NMO&NMOSD	5	07/05/2015	8
14/SC/0170/AM07	Phase 3 study to test the effects of SA237 in patients with NMO&NMOSD	6	17/07/2015	6
14/SC/0170/AM08	Phase 3 study to test the effects of SA237 in patients with NMO&NMOSD	7	10/02/2016	14
14/SC/0190/AM08	HCMR Study	3	18/05/2015	13
14/SC/0195/AM04	Evaluation of the Safety of Simultaneous HCV and HIV-1 Immunisations	Substantial Amendment 5	24/03/2015	15
14/SC/0220/AM09	First Time in Human Study of the TRPV4 blocker GSK2798745	5	03/07/2015	21
14/SC/0220/AM12	First Time in Human Study of the TRPV4 blocker GSK2798745	06, 29th September 2015	29/09/2015	33
14/SC/0232/AM03	MenB vaccine for immunocompromised	2	02/09/2015	15
14/SC/0269/AM05	Revo Phase 3: Coagulation Factor VIIa in Congenital Hemophilia A or B	5	19/05/2015	15
14/SC/0295/AM04	IMPALA trial	Substantial Amendment dated 16	16/04/2015	18
14/SC/1067/AM02	PROMDEP	1.0 27/10/2015	27/10/2015	21
14/SC/1067/AM03	PROMDEP	2.0	25/02/2016	18
14/SC/1124/AM02	RCT of pregnancy outcomes following PGS versus morphological assessment	Substantial Amendment 1	02/04/2015	10
14/SC/1124/AM03	RCT of pregnancy outcomes following PGS versus morphological assessment	2	30/04/2015	18
14/SC/1124/AM04	RCT of pregnancy outcomes following PGS versus morphological assessment	3.0 September 2015	17/09/2015	19
14/SC/1124/AM05	RCT of pregnancy outcomes following PGS versus morphological assessment	SA 4	20/10/2015	15
14/SC/1150/AM02	Red cell transfusion and QoL in myelodysplastic syndromes (REDDS)	1	15/05/2015	13
14/SC/1159/AM01	CO-OP in children with hyperkinetic movement disorders	1	03/07/2015	5

	following DBS			
14/SC/1159/AM02	CO-OP in children with hyperkinetic movement disorders following DBS	2	26/11/2015	12
14/SC/1160/AM01	Molecular Mechanisms of Epidural Related Maternal Fever	2	08/06/2015	14
14/SC/1163/AM03	Understanding meningococcal carriage and disease	1	07/08/2015	8
14/SC/1204/AM01	Investigating Enteric Fever	Substantial amendment 1	17/03/2015	13
14/SC/1231/AM02	Vaccination in Prostate Cancer (VANCE), version 1.0	2	20/05/2015	17
14/SC/1231/AM03	Vaccination in Prostate Cancer (VANCE), version 1.0	3	09/07/2015	14
14/SC/1231/AM04	Vaccination in Prostate Cancer (VANCE), version 1.0	VANCE01, Substantial Amendment	11/09/2015	16
14/SC/1231/AM05	Vaccination in Prostate Cancer (VANCE), version 1.0	SA 5	15/12/2015	4
14/SC/1256/AM09	A Phase I Study to Assess a New Ebola Vaccine, cAd3-EBO Z	8	30/06/2015	8
14/SC/1256/AM10	A Phase I Study to Assess a New Ebola Vaccine, cAd3-EBO Z	SA11	12/11/2015	7
14/SC/1275/AM01	Growth Assessment of Preterm infants (GAP study)	1	21/05/2015	16
14/SC/1275/AM02	Growth Assessment of Preterm infants (GAP study)	2 19/12/15	19/12/2015	10
14/SC/1278/AM01	CHECK AF - Atrial Fibrillation screening study	1	18/08/2015	17
14/SC/1309/AM01	The TEMPLATE Study	Amendment 1	27/04/2015	16
14/SC/1309/AM02	The TEMPLATE Study	2	11/07/2015	9
14/SC/1333/AM02	PATH-2: Platelet Rich Plasma in Achilles Tendon Healing	1	15/06/2015	16
14/SC/1347/AM04	Astellas - 8232-CL-0004 - Chronic Kidney & Diabetes Type 2	Protocol Amendment 2	08/05/2015	18
14/SC/1347/AM07	Astellas - 8232-CL-0004 - Chronic Kidney & Diabetes Type 2	Protocol Amendment 4.0 2015/11	24/11/2015	8
14/SC/1361/AM01	Dapagliflozin as an add-on to Insulin Therapy in Type 1 Diabetes	Substantial Amendment 1	15/04/2015	20
14/SC/1361/AM02	Dapagliflozin as an add-on to Insulin Therapy in Type 1 Diabetes	2	01/06/2015	13
14/SC/1361/AM03	Dapagliflozin as an add-on to Insulin Therapy in Type 1 Diabetes	EC03	06/10/2015	6
14/SC/1361/AM04	Dapagliflozin as an add-on to Insulin Therapy in Type 1 Diabetes	EC04	16/02/2016	21
14/SC/1372/AM01	RIVER - Research In Viral Eradication of HIV Reservoirs	Substantial Amendment	11/06/2015	14

14/SC/1405/AM03	A research study involving imaging patients with rheumatoid arthritis	#1	24/09/2015	13
14/SC/1408/AM07	Evaluating Vaccines against Ebola	Substantial Amendment 5	14/04/2015	20
14/SC/1408/AM10	Evaluating Vaccines against Ebola	EVE Substantial Amendment	09/03/2016	9
14/SC/1416/AM01	IgNiTE: Immunoglobulin in the treatment of encephalitis	1	30/03/2015	13
14/SC/1416/AM04	IgNiTE: Immunoglobulin in the treatment of encephalitis	2	10/08/2015	14
14/SC/1416/AM06	IgNiTE: Immunoglobulin in the treatment of encephalitis	3, 2015/11/05	05/11/2015	11
14/SC/1427/AM01	Vaccines Against Salmonella Typhi (VAST)	SA1	27/02/2015	35
14/SC/1427/AM02	Vaccines Against Salmonella Typhi (VAST)	2	17/06/2015	7
14/SC/1427/AM03	Vaccines Against Salmonella Typhi (VAST)	3	09/10/2015	20
14/SC/1427/AM04	Vaccines Against Salmonella Typhi (VAST)	4	25/01/2016	14
15/SC/0023/AM01	Catheter Vs Thoracoscopic Surgical Ablation in LSPAF - Multicentre RCT	1	01/05/2015	13
15/SC/0023/AM02	Catheter Vs Thoracoscopic Surgical Ablation in LSPAF - Multicentre RCT	2	17/06/2015	8
15/SC/0023/AM03	Catheter Vs Thoracoscopic Surgical Ablation in LSPAF - Multicentre RCT	3, 25/11/2015	25/11/2015	12
15/SC/0023/AM04	Catheter Vs Thoracoscopic Surgical Ablation in LSPAF - Multicentre RCT	Subst_Amend4, 18/01/2015	18/01/2016	7
15/SC/0023/AM05	Catheter Vs Thoracoscopic Surgical Ablation in LSPAF - Multicentre RCT	Subst_Amend5, 20/01/2016	20/01/2016	5
15/SC/0023/AM06	Catheter Vs Thoracoscopic Surgical Ablation in LSPAF - Multicentre RCT	6	28/01/2016	16
15/SC/0054/AM02	CheckMate 238: CHECKpoint pathway and nivolumAb clinical Trial Evaluation 238	01	15/05/2015	21
15/SC/0054/AM05	CheckMate 238: CHECKpoint pathway and nivolumAb clinical Trial Evaluation 238	CA209-238: EC02	17/09/2015	10
15/SC/0055/AM01	Natsal-3: further characterisation of CT and MG specimens	1. 11 November 2015	11/11/2015	23
15/SC/0103/AM01	SCALOP-2 V5.0 31Jul2015	1	28/08/2015	13
15/SC/0103/AM03	SCALOP-2 V5.0 31Jul2015	002	05/11/2015	21
15/SC/0108/AM03	A Phase I Study to Assess Ebola Vaccines cAd3-EBO Z and MVA-EBO Z	Substantial Amendment 2 [SA002	08/04/2015	4

15/SC/0108/AM04	A Phase I Study to Assess Ebola Vaccines cAd3-EBO Z and MVA-EBO Z	SA003	12/05/2015	17
15/SC/0108/AM05	A Phase I Study to Assess Ebola Vaccines cAd3-EBO Z and MVA-EBO Z	004	22/05/2015	7
15/SC/0109/AM01	OxLith	1	22/05/2015	13
15/SC/0115/AM03	HARMONY Outcomes Trial	SA2	14/10/2015	22
15/SC/0121/AM01	Studying movement control in PD using closed loop DBS.	1	27/08/2015	17
15/SC/0121/AM02	Studying movement control in PD using closed loop DBS.	SA2	12/10/2015	24
15/SC/0143/AM02	AG-CLI-0206: Ph 3 - Efficacy & Safety Study for Critical Limb Ischemia	2	26/01/2016	9
15/SC/0211/AM02	Evaluating Optimal Vaccine schedules against Ebola (EVOLVE)	1	19/08/2015	2
15/SC/0211/AM03	Evaluating Optimal Vaccine schedules against Ebola (EVOLVE)	SA2	13/10/2015	9
15/SC/0211/AM05	Evaluating Optimal Vaccine schedules against Ebola (EVOLVE)	sa3	27/01/2016	15
15/SC/0211/AM06	Evaluating Optimal Vaccine schedules against Ebola (EVOLVE)	EVOLVE substantial amendment 4	07/03/2016	4
15/SC/0237/AM01	A Study to Assess Malaria Vaccines ChAd63/MVA Pfs25-IMX313	1	28/05/2015	15
15/SC/0239/AM02	ASTEROID 2	SA1	26/08/2015	21
15/SC/0240/AM02	Randomised Ambulatory Management of Primary Pneumothorax (RAMPP)	2	26/08/2015	16
15/SC/0240/AM03	Randomised Ambulatory Management of Primary Pneumothorax (RAMPP)	SA03_17Nov2015	17/11/2015	14
15/SC/0242/AM02	BMN 270-201: Gene Therapy Study in Severe Haemophilia A Patients	SA2 - REC Only	29/09/2015	21
15/SC/0242/AM03	BMN 270-201: Gene Therapy Study in Severe Haemophilia A Patients	Protocol Amend 3	12/11/2015	20
15/SC/0267/AM02	A Phase I Study to Assess New Ebola Vaccines, cAd3-EBO Z & Ad26.ZEBOV	001	24/06/2015	13
15/SC/0267/AM03	A Phase I Study to Assess New Ebola Vaccines, cAd3-EBO Z & Ad26.ZEBOV	SA002	02/09/2015	14
15/SC/0302/AM03	Phase 3 Efficacy and Safety study of Oral RPC1063 in RMS Patients	2015/09/09	09/09/2015	8

15/SC/0311/AM02	VEST III PMS clinical protocol	2	07/09/2015	10
15/SC/0314/AM01	PaLS 1	1 (26/01/16)	26/01/2016	16
15/SC/0370/AM03	TB040: MVA85A aerosol vs IM in adults with latent M.tb infection	2, 2015/12/08	08/12/2015	9
15/SC/0370/AM04	TB040: MVA85A aerosol vs IM in adults with latent M.tb infection	3.0	02/02/2016	10
15/SC/0373/AM01	Energy metabolism and MRS	1	11/01/2016	14
15/SC/0378/AM01	Treating sleep problems in young people	SA1	31/07/2015	11
15/SC/0378/AM02	Treating sleep problems in young people	2	22/09/2015	9
15/SC/0432/AM01	Trial of Intranasal Esketamine for Treatment of Depression TRANSFORM-3	AM01 Substantial Amendment: 1	15/10/2015	40
15/SC/0434/AM02	Long-term Safety & Efficacy Study of IN Esketamine in TRD (SUSTAIN-2)	2, 27/10/2015	27/10/2015	34
15/SC/0444/AM01	AZ D5680C00001 - Ph1 MEDI7352 in Painful Osteoarthritis of the Knee	AM01 Substantial Amendment: PA	23/10/2015	28
15/SC/0446/AM01	A PET scan study of GSK2256098; ver 1	Information and consent form (30/09/2015	14
15/SC/0447/AM01	Frequency of SU-hypoglycaemia in older frail patients with diabetes	DF07 Version 2 2015/10/03	03/10/2015	14
15/SC/0629/AM01	Phase I Tracheal replacement using tracheal scaffold and MSC's	Addition of Patient Alert Card	20/01/2016	19
15/SC/0692/AM02	TR2-A: effect on stomach acid in healthy men, v1	Protocol incorporating amendme	04/02/2016	12

Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
13/SC/0322/AM06	Immunotherapy with CD25/71 Allodepleted T-cells (ICAT)	Protocol V4	17/12/2015	23
13/SC/0374/AM05	Phase I, AZD8186 in Patients with CRPC, sqNSCLC, TNBc, PTEN malignancy	5	24/07/2015	26

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/0322/AM06/2	Immunotherapy with CD25/71 Allodepleted T-cells (ICAT)	01/03/2016	01/03/2016	9
13/SC/0374/AM05/2	Phase I, AZD8186 in Patients with CRPC, sqNSCLC, TNBc, PTEN malignancy	5	23/12/2015	12

Unfavourable opinion timeline				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
13/SC/0322/AM06/1	Immunotherapy with CD25/71 Allodepleted T-cells (ICAT)	6	01/02/2016	13
13/SC/0374/AM05/1	Phase I, AZD8186 in Patients with CRPC, sqNSCLC, TNBc, PTEN malignancy	5	24/08/2015	16

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

REC Reference	Title	Number of Days on Clock
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Proportionate review applications for ethical review over 14 day timeline

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

REC Reference	Title	Number of Days on Clock
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SSAs (Phase 1) over 14 day timeline

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

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
13/SC/0604/AM09	Treg Liver Trial	ThRIL, Protocol version 8.0 d	14/10/2015	40
15/SC/0432/AM01	Trial of Intranasal Esketamine for Treatment of Depression TRANSFORM-3	AM01 Substantial Amendment: 1	15/10/2015	40

Modified Amendments over 14 day timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
13/SC/0374/AM05/1	Phase I, AZD8186 in Patients with CRPC, sqNSCLC, TNBc, PTEN malignancy	5	24/08/2015	16