NHS
Health Research Authority

Research Ethics Service

South Central - Oxford B Research Ethics Committee

Annual Report

01 April 2016 - 31 March 2017

Part 1 – Committee Membership and Training

Name of REC:	South Central - Oxford B Research Ethics Committee
Type of REC:	REC recognised to review CTIMPs in Patients - Type III
Type of Flag:	IRB Registered , Phase 1 in Patients
Chair:	Mr Chris Foy
Vice-Chair:	Dr Kim Cheetham
Alternate Vice-Chair:	Dr Liesl Osman
REC Manager:	Mrs Claudia Bywater (01/03/2016 – 01/03/2017) Mrs Vicky Canfield-Duthie (01/03/2017 - present)
REC Assistant:	Mr Stephan Ramey (01/09/2015 – 01/03/2017)
Committee Address:	Whitefriars Level 3, Block B Lewin's Mead Bristol BS1 2NT
Telephone:	02071048058
Email:	nrescommittee.southcentral-oxfordb@nhs.net

Chair's overview of the past year:

The Committee had nine full meetings in 2016/17. For one of these, we needed two co-optees from other RECs, and we are most grateful to them.

We experienced a few changes in membership; two of these were because of the "10-year rule". Pamela Laurie reached 10 years on Oxford B and was happy to continue service; she moved to Oxford A REC with our good wishes. And Ron King, previously a REC Chair in Southampton, retired from there and promptly joined us. These are two examples of enduring commitment to ethical review.

We also said goodbye to Nicola Joseph, who needed the time to complete her studies. And we welcomed Fozia Mushtaq as our pharmacist, and Emma Plested, who has a background in clinical trials. Between us, the membership, whether labelled "Expert" or "Lay", has a wide range of expertise.

For most of 2016/17, we were ably managed by Claudia Bywater. She obtained promotion to Deputy Regional Manager in the Bristol office, and we wish her well. Vicky Canfield-Duthie became our manager from March 2017.

South Central - Oxford B Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Mr Peter Brown	Emeritus Professor of Classics, Trinity College	Lay Plus	01/09/2011	
Dr Kim Cheetham	Retired Consultant Paediatrician	Expert	01/09/2010	
Dr Richard Philip Craven	Senior lecturer in physiology	Lay Plus	28/05/2013	
Mr Chris Foy	Medical Statistician	Expert	14/05/2013	
Miss Nicola Joseph	Student, Reading Reproductive and Developmental Biology	Lay Plus	01/01/2015	14/06/2016
Professor Ron King	Mathematician (Retired)	Lay Plus	30/08/2016	
Dr Wilhelm Kuker	Consultant Neuroradiologist	Expert	01/12/2010	
Dr Pamela Laurie	Retired Consultant Anaesthetist	Expert	05/06/2006	05/07/2016
Mr Ian MacKenzie	Retired Consultant / Reader Emeritus in Obstetrics and Gynaecology	Expert	09/11/2010	
Mrs Fozia Mushtaq	Clinical Trials Specialist Pharmacist	Expert	23/05/2016	
Dr Liesl Osman	Retired Research Advisor	Lay	10/10/2009	
Rev Emma Percy	College Chaplain, Trinity College	Lay Plus	01/09/2011	
Mrs Emma Plested	Clinical Trials Coordinator	Lay	28/06/2016	
Dr Iveta Simera	Head of Programme Development, EQUATOR Network, Centre for Statistics in Medicine	Lay	21/09/2011	
Mrs Kate Thompson	Retired In patient and day hospice manager	Lay	01/03/2008	

South Central - Oxford B Research Ethics Committee: Deputy Members

Name	Profession	Status	Meeting date attended

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

Name	Profession	Status	Meeting date attended
Dr Jo Brooke	Associate Professor in Dementia Care	Expert	10/01/2017
Ms Alison Higgs	Lecturer in Social Work	Lay	10/01/2017

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

Name	Declaration of Interest	Date
Mr Peter Brown	None	23/01/2017
Dr Kim Cheetham	None	16/03/2017
Dr Richard Philip Craven	None	09/02/2017
Mr Chris Foy	Employed by NIHR Research Design Service to provide advice to NHS staff and other researchers in South West England on how to make grant applications. For projects sponsored by an NHS body in Gloucestershire contributes to the peer review as part of a Committee.	16/03/2017
Professor Ron King	None	16/03/2017
Dr Wilhelm Kuker	None	10/08/2016
Mr Ian MacKenzie	Director, Elliott Smith Vasectomy Clinic - but company has ceased trading in 2016	16/03/2017
Mrs Fozia Mushtaq	Clinical Trials Pharmacist at Oxford University Hospitals NHS Foundation Trust. Role involves the set up and close down of trials approved within the trust.	01/06/2016
Dr Liesl Osman	£5000 in Glaxo Smith Kline shares	16/03/2017
Rev Emma Percy	None	31/03/2017
Mrs Emma Plested	Project Manager employed by the Oxford Vaccine Group, University of Oxford. I am involved in preparing regulatory applications and amendments for clinical trials	09/02/2017
Dr Iveta Simera	Deputy Director of the UK EQUATOR Centre and Programme Manager of the EQUATOR Network.	31/03/2017
Mrs Kate Thompson	None	16/03/2017

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

Month	Date	Number of Members Present at Meeting
May	10/05/2016	10
June	14/06/2016	12
July	12/07/2016	10
September	13/09/2016	8
October	11/10/2016	12
November	08/11/2016	9
December	13/12/2016	9
January	10/01/2017	9
March	14/03/2017	9

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
April	07/04/2016	3
April	29/04/2016	3
June	24/06/2016	3
July	22/07/2016	3
August	19/08/2016	3
September	23/09/2016	3
October	21/10/2016	3
November	18/11/2016	3
December	23/12/2016	3
January	20/01/2017	3
March	27/03/2017	3

11 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	05/04/2016	2
April	12/04/2016	2
April	15/04/2016	2
April	29/04/2016	2
May	03/05/2016	2
May	06/05/2016	2
May	13/05/2016	2
May	20/05/2016	2
May	27/05/2016	2
June	03/06/2016	2

June	13/06/2016	2
June	17/06/2016	2
June	28/06/2016	2
June	30/06/2016	3
July	01/07/2016	2
July	06/07/2016	3
July	15/07/2016	2
July	29/07/2016	2
August	04/08/2016	2
August	09/08/2016	3
August	12/08/2016	2
August	12/08/2016	2
August	15/08/2016	2
August	16/08/2016	2
August	26/08/2016	2
September	09/09/2016	2
September	19/09/2016	2
September	23/09/2016	2
September	26/09/2016	3
October	07/10/2016	2
October	17/10/2016	3
October	20/10/2016	2
October	21/10/2016	2
November	04/11/2016	2
November	18/11/2016	2
December	02/12/2016	2
December	16/12/2016	2
December	30/12/2016	2
January	13/01/2017	2
January	27/01/2017	2
February	10/02/2017	2
February	17/02/2017	2
February	24/02/2017	2
March	10/03/2017	2
March	24/03/2017	2

46 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
Mr Peter Brown	6
Dr Kim Cheetham	8
Dr Richard Philip Craven	9
Mr Chris Foy	8
Miss Nicola Joseph	1
Professor Ron King	5
Dr Wilhelm Kuker	4
Dr Pamela Laurie	2
Mr Ian MacKenzie	8
Mrs Fozia Mushtaq	4
Dr Liesl Osman	8
Rev Emma Percy	5
Mrs Emma Plested	5
Dr Iveta Simera	5
Mrs Kate Thompson	8

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

Name	Number of Meetings Attended
Dr Kim Cheetham	4
Dr Richard Philip Craven	4
Mr Chris Foy	4
Dr Wilhelm Kuker	4
Dr Pamela Laurie	1
Mr Ian MacKenzie	4
Dr Liesl Osman	3
Rev Emma Percy	3
Dr Iveta Simera	4
Mrs Kate Thompson	1

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

Name	Number of Meetings Attended
Mr Peter Brown	1
Dr Kim Cheetham	13
Dr Richard Philip Craven	7
Mr Chris Foy	28
Professor Ron King	3

Dr Wilhelm Kuker	8
Dr Pamela Laurie	1
Mr Ian MacKenzie	6
Mrs Fozia Mushtaq	1
Dr Liesl Osman	12
Rev Emma Percy	2
Mrs Emma Plested	2
Dr Iveta Simera	7
Mrs Kate Thompson	5

Training 01 April 2016 - 31 March 2017

Name of Member	Date	Event(s) attended
Mr Peter Brown	20/08/2016	Equality and Diversity
Dr Kim Cheetham	18/10/2016	Joint Berkshire Training Day
Dr Kim Cheetham	02/09/2016	Joint Oxford Training Day
Dr Richard Philip Craven	02/09/2016	Joint Oxford Training Day
Mr Chris Foy	02/06/2016	NREAP / REC Chairs' Network Meeting: South Central
Mr Chris Foy	27/03/2017	Chairs Review Programme Workshops
Mr Chris Foy	01/12/2016	National Training Day for Committee Chairs.
Mr Chris Foy	27/03/2017	Chairs Review Programme Workshops
Professor Ron King	02/09/2016	Oxford Joint Training Day
Dr Wilhelm Kuker	11/05/2016	Good Clinical Practice - Online Course
Dr Wilhelm Kuker	11/08/2016	Equality and Diversity
Mr Ian MacKenzie	20/08/2016	Equality and Diversity
Mr Ian MacKenzie	02/09/2016	Oxford Joint Training Day
Dr Liesl Osman	02/09/2016	Oxford Joint Training Day
Dr Liesl Osman	20/09/2016	Equality and Diversity
Dr Liesl Osman	01/12/2016	National Training Day for Committee Chairs
Rev Emma Percy	28/02/2017	Equality and Diversity
Mrs Emma Plested	13/11/2016	E&D
Mrs Emma Plested	13/11/2016	Induction for new RES Members
Mrs Emma Plested	13/03/2017	Members Induction
Dr Iveta Simera	02/09/2016	Oxford Joint Training Day
Mrs Kate Thompson	12/08/2016	Equality and Diversity

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	16	41.03
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	1	2.56
Others	22	56.41
Total Applications Reviewed	**39**	**100**

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

Number of applications made invalid by the REC Manager	1
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	7
Number of paediatric applications reviewed	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	5

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

Decisions taken at meetings following review of applications	Number	%
Favourable Opinion with Standard Conditions	1	2.56
Favourable Opinion with Additional Conditions	6	15.38
Unfavourable Opinion	3	7.69
Provisional Opinion	28	71.79
Provisional Opinion Pending Consultation with Referee	1	2.56
Total	**39**	**100**
Number of studies sent back to full committee meeting for final opinion	0	

Table 4: **Summary of current status of applications reviewed during the reporting period**

Status of applications at date of generation of report	Number	%
Further Information Favourable Opinion with Standard Conditions	17	43.59
Further Information Favourable Opinion with Additional Conditions	10	25.64
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	1	2.56
Favourable Opinion with Additional Conditions	6	15.38
Unfavourable Opinion	3	7.69
Provisional Opinion	2	5.13
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	**39**	**100**

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

Total Applications Reviewed	**27**

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

Number of applications made invalid by the REC Manager	2
Number of studies withdrawn prior to the meeting	2
Number of student applications reviewed	12
Number of paediatric applications reviewed	4
Number of device applications reviewed	1
Number of qualitative applications reviewed	3

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

Decisions taken at proportionate review sub-committee meetings	**Number**	**%**
Favourable Opinion with Standard Conditions	6	22.22
Favourable Opinion with Additional Conditions	11	40.74
No Opinion transfer to full committee for review	1	3.70
Provisional Opinion	9	33.33
Unfavourable Opinion	0	0.00
Total	**27**	**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	4.33
Number of completed applications for full ethical review	39
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	4
Number of completed applications over 40 days as a % of total	10.26%
Number of days taken to final decision – average (mean)	30

Number of completed proportionate review applications for ethical review	27
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)	4
Number of Completed proportionate review applications for ethical review over 21 days	1
Number of completed proportionate review applications over 14 days as a % of total	14.81%

Number of SSAs (non-Phase 1) reviewed	23
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	4.35%

Number of SSAs (Phase 1) reviewed	0
Number of completed applications for SSA review over 14 days	0
Number of completed applications for SSA review over 14 days as % of all Phase 1 SSAs	0.00%

Number of substantial amendments reviewed	144
Number of completed substantial amendments over 35 days	1
Number of completed substantial amendments over 35 days as a % of total substantial amendments	0.69%
Number of completed substantial amendments over 28 days	7
Number of completed substantial amendments over 28 days as a % of total substantial amendments	4.86%

Number of modified amendments reviewed	8
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	135

Number of substantial amendments received for information	3
Number of substantial amendments received for new sites/PIs	46
Number of annual progress reports received	93
Number of safety reports received	25
Number of Serious Adverse Events received	2
Number of final reports received	10

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/0254	Vedolizumab-4003 (ENTERPRISE), Protocol Amendment 1, 29-Feb-2016	33
16/SC/0311	Hip Osteoarthritis treatment using Autologous Stem cell Therapy (HOAST	31
16/SC/0381	Adolescent experiences of sexual orientation disclosure in healthcare	26
16/SC/0383	SphinX trial	32
16/SC/0450	A longitudinal study of patients with unexplained chronic cough(UCCLS)	41
16/SC/0462	DRAFFT 2 - Distal Radius Acute Fracture Fixation Trial 2	35
16/SC/0463	Understanding what maintains social anxiety disorder in children	24
16/SC/0511	IMCgp100-401: Rollover Study for Patients Completing an IMCgp100 study	29
16/SC/0512	The Experience of Receiving Dexamethasone during Adolescence	28
16/SC/0570	A grounded theory of forensic service users' recall to hospital - v1	29
16/SC/0600	Efficacy and Safety of Filgotinib in Active Ulcerative Colitis	32
16/SC/0601	Long Term Safety of Filgotinib in Active Ulcerative Colitis	31
16/SC/0604	PHASE 3 STUDY POF TAFAMIDIS MEGLUMINE IN PATIENTS WITH TTR-CM	32
17/SC/0007	To Evaluate ABX-1431 in Central Pain Patients	35
17/SC/0016	CA209-743: Phase III unresectable Pleural Mesothelioma	23
17/SC/0018	ARGX-113-1603	20
17/SC/0122	PEANUT ALLERGY STUDY IN CHILDREN	36

Further Information Favourable Opinion with Additional Conditions		
REC Reference	**Title**	**Number of Days on Clock**
16/SC/0300	Optimising the implementation of ACP in Heart Failure	32
16/SC/0325	Working with parents with learning difficulties - successful practices	41
16/SC/0326	Meeting the needs of children following sexual abuse	30
16/SC/0363	TTP488 Efficacy & Safety Study in Mild Alzheimer's (STEADFAST)	36
16/SC/0379	Vedolizumab IV 300 mg in the Treatment of Chronic Pouchitis (EARNEST)	31
16/SC/0394	The Oxford Optimisation of PCI Study (OXOPT-PCI study).	23
16/SC/0504	BETA3_LVH V1.0	43
16/SC/0516	Psychological impact of AIP	39
16/SC/0615	CONTROL	25
16/SC/0662	SCAR MPP study	37

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**
16/SC/0654	Prebiotic Study in Psychosis	24

Favourable Opinion with Additional Conditions		
REC Reference	**Title**	**Number of Days on Clock**
16/SC/0246	A Randomized Ph. 2/3 Study of DACOGENÂ® & JNJ-5602247 vs DACOGENÂ® alone	20
16/SC/0315	Treatment of Social Anxiety Disorder in Adolescents	20
16/SC/0453	Novel START (Novel Symbicort Turbuhaler Asthma Reliever Therapy)	20
16/SC/0456	Polyethylene wear of the Oxford Knee replacement	20
16/SC/0457	Mechanisms of wound healing	20
17/SC/0001	NRCT Research Database v 1.0	36

Unfavourable Opinion		
REC Reference	**Title**	**Number of Days on Clock**
16/SC/0237	AFFECT Wales	20
16/SC/0546	Decisional regret after Hypospadias surgery	27
16/SC/0605	Nicotine exposure profile, subjective and behavioral effects of P4M3	27

Provisional Opinion		
REC Reference	**Title**	**Number of Days on Clock**
17/SC/0109	CX-072 in patients with advanced/recurrent solid tumours or lymphomas	n/a
17/SC/0111	Investigating bone marrow Stem Cells in Sickle Cell Disease	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**
16/SC/0133	Impact of Tai Chi on quality of life in palliative care.	15
16/SC/0523	The role of Neurotensin in Colorectal Cancer Diagnosis	14
16/SC/0525	Exploring the Feasibility and Utility of the PSI in Clinical Care	14
16/SC/0579	VOICE	14
16/SC/0641	The RESPECT Study	11
16/SC/0644	Blood immunophenotyping in staging of indolent B-cell lymphomas V1.0	25
16/SC/0695	Electronic Titration study: e-T study	14
17/SC/0047	Photoacoustic imaging of oxygen in blood vessels in SSc	13
17/SC/0048	PANDA: Paediatrics and Dose Accuracy	10

Further Information Favourable Opinion with Additional Conditions		
REC Reference	**Title**	**Number of Days on Clock**
16/SC/0578	The Effect of Tinnitus on Attention and Listening v2	11

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**

16/SC/0250	Bladder function following surgical excision of endometriosis v1.0	9
16/SC/0252	Treatment priority in limb loss with phantom syndrome	16
16/SC/0355	The Mobility and Maternity (MaM) Study 1.1	13
16/SC/0521	GLOBAL AWARE	12
16/SC/0527	Molecular typing of Mycoplasma pneumoniae from clinical samples v 1.0	12
17/SC/0045	PD-L1 Expression in Urothelial Bladder Carcinoma	12

Favourable Opinion with Additional Conditions		
REC Reference	**Title**	**Number of Days on Clock**
16/SC/0257	The MNKs; Novel Markers of Type 2 Diabetes Mellitus Risk v1.0	14
16/SC/0356	Keeping Connected Survey Version 1	7
16/SC/0414	RCT to assess lap cholecystectomy performance using 3D vs 4K systems	11
16/SC/0417	The usefulness of bibliotherapy in a neuropsychology service	13
16/SC/0418	Tooth whitening clinical trial	8
16/SC/0419	Complications and maintenance of Locator retained overdentures V_1	12
16/SC/0458	Platelet-Cancer cell adhesion v02 REC	10
16/SC/0460	Anthropometric estimates of Real-Ear-To-Coupler Difference in children	8
16/SC/0643	EVALUATION OF MCM5 ELISA IN THE DIAGNOSIS OF GYNAECOLOGICAL MALIGNANCY	11
16/SC/0697	PRO development for Giant Cell Arteritis (GCA)	12
17/SC/0151	Lung Clearance Index in Connective Tissue Disease - Pilot Study	15

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**
04/Q1605/95/AM08	STUDIES OF THE VASCULAR PROPERTIES OF ARTERIAL BYPASS GRAFTS	SA6	26/08/2016	10
07/H0605/76/AM43	ICON6 GCIG Trial (International Collaborative Ovarian Neoplasm 6)	ICON6 Substantial Amendment, A	19/04/2016	24
07/Q1605/47/AM46	Efficacy and Safety of 100 mg ASA in CVD risk patients; Version 1	Sponsorship Transfer from Bayer Healthcare AG to Bayer BG	25/07/2016	15
09/H0605/62/AM16	Midbrain micturition pathways	11	07/03/2016	18
10/H0605/31/AM14	CREW (ColoREctal Wellbeing) cohort	SA13	18/05/2016	7
10/H0605/59/AM32	WN25203 - Proof of Efficacy of RO4909832 in prodromal alzheimer's	SA20	23/03/2016	24
10/H0605/59/AM35	WN25203 - Proof of Efficacy of RO4909832 in prodromal alzheimer's	21	04/10/2016	34
10/H0605/83/AM31	REVEAL Version 1.0	29	26/05/2016	14
11/SC/0522/AM02	A study of symptoms and treatment effects in parkinsonian syndromes	2	14/04/2016	25
11/SC/0528/AM23	INTERLACE	17	01/09/2016	26
12/SC/0674/AM08	Palliative thoracic radiotherapy plus BKM120	SA10	24/03/2016	12
12/SC/0674/AM09	Palliative thoracic radiotherapy plus BKM120	SA11	12/01/2017	19
12/SC/0679/AM02	Development of a primary cell HIV latency model (version 1)	Amendment 1	11/01/2017	12
13/SC/0020/AM12	OxRen	10	10/02/2017	8
13/SC/0467/AM06	Phase I,dose escalation of LTX-315 in transdermally accessible tumours	SA8	29/04/2016	27
13/SC/0467/AM07	Phase I,dose escalation of LTX-315 in transdermally accessible tumours	SA9	01/07/2016	18
13/SC/0467/AM09	Phase I,dose escalation of LTX-315 in transdermally accessible tumours	SA REC UK11	21/03/2017	8
13/SC/0502/AM02	Neural Mechanisms underlying tactile perceptual learning	2.0	05/06/2016	4
13/SC/0503/AM11	B2151002: Phase 1b of PF-05212384 in combination.	Substantial Amendment 09	27/04/2016	23

13/SC/0503/AM12	B2151002: Phase 1b of PF-05212384 in combination.	10	11/07/2016	10
13/SC/0503/AM15	B2151002: Phase 1b of PF-05212384 in combination.	SA11	24/01/2017	7
13/SC/0523/AM05	The impact of AZD4017 on bone turnover in post-menopausal osteopaenia	4	26/05/2016	19
13/SC/0553/AM02	Predicting functional outcomes after brain surgery using MRI	1	05/10/2016	27
13/SC/0581/AM04	VIOLA (Version 1.0 15-Oct-2013)	Viola Substantial Amendment 4	18/02/2016	21
13/SC/0638/AM24	HIPvac Trial	24	24/05/2016	15
14/SC/0032/AM38	Pfizer B1481022 - Phase 3 PF-04950615 in Reducing Major CV Events	35	13/04/2016	25
14/SC/0032/AM50	Pfizer B1481022 - Phase 3 PF-04950615 in Reducing Major CV Events	Use of a third party vendor	14/10/2016	27
14/SC/0033/AM38	Pfizer B1481038 - Phase 3 PF-04950615 in Reducing Major CV Events	33	13/04/2016	23
14/SC/0033/AM49	Pfizer B1481038 - Phase 3 PF-04950615 in Reducing Major CV Events	Use of a third party vendor	14/10/2016	27
14/SC/0041/AM02	Methods of ovarian tissue culturing for fertility preservation	SA1	27/01/2016	8
14/SC/0041/AM03	Methods of ovarian tissue culturing for fertility preservation	2	11/08/2016	13
14/SC/0075/AM08	Pfizer B3461028 Study for patients with TTR-CM	B3461028 Substantial Amendment	08/08/2016	28
14/SC/0087/AM02	Pediatric vasculitis initiative (PedVas Study)	SA2	04/03/2016	18
14/SC/0218/AM04	Telemonitoring and/or self monitoring in Hypertension (TASMINH4)	3	12/09/2016	21
14/SC/0222/AM01	WASP: Why Are Shoulders Painful?	SA1	18/11/2015	5
14/SC/0237/AM05	Urodynamic assessment methods before Prostate Surgery	3	30/09/2016	33
14/SC/1008/AM05	Safety and tolerability study of MP0250	SA3	24/03/2016	28
14/SC/1008/AM06	Safety and tolerability study of MP0250	Protocol: Version 2.1	01/06/2016	17
14/SC/1008/AM07	Safety and tolerability study of MP0250	Protocol 2.2 , IB version 2.1	28/11/2016	26
14/SC/1148/AM01	Sodium Valproate and Cytomegalovirus latent viral loads version 1	SA1	21/03/2016	15
14/SC/1148/AM02	Sodium Valproate and Cytomegalovirus latent viral loads version 1	Amendment 2	27/05/2016	15
14/SC/1158/AM01	Tissue collection for biomarkers determining resistance to	SA1	16/03/2016	9

	Ibrutinib.			
14/SC/1158/AM03	Tissue collection for biomarkers determining resistance to Ibrutinib.	2	07/10/2016	28
14/SC/1243/AM02	Gait Analysis of Lower Limb Surgical Patients	SA2	14/07/2016	15
14/SC/1250/AM03	Identifying dysplasia and cancer using lectins Pilot Study	2	12/09/2016	28
14/SC/1312/AM09	IMox study	5	16/09/2016	21
14/SC/1315/AM08	MPD-RC 114	6	03/11/2016	19
14/SC/1369/AM06	ASCOT: Lifestyle study for cancer survivors	SA4	25/04/2016	17
14/SC/1371/AM02	Designing a community based service model for the East of England	SA2	30/03/2016	8
14/SC/1374/AM06	AZD9496 First Time in Patients Ascending Dose Study	SA5	06/04/2016	23
14/SC/1374/AM09	AZD9496 First Time in Patients Ascending Dose Study	7	18/08/2016	19
14/SC/1446/AM01	Utility of the Skin Cancer Quality of Life Impact Tool (SCQOLIT)	SA1	08/11/2016	11
15/SC/0007/AM02	Supplemental oxygen in OSA following CPAP withdrawal	SA03	15/06/2016	21
15/SC/0007/AM03	Supplemental oxygen in OSA following CPAP withdrawal	SA04	07/11/2016	25
15/SC/0009/AM08	Phase 2 study of PQR309 in Patients with Relapsed/Refractory Lymphoma	4	01/06/2016	22
15/SC/0009/AM09	Phase 2 study of PQR309 in Patients with Relapsed/Refractory Lymphoma	9.0	05/07/2016	20
15/SC/0009/AM10	Phase 2 study of PQR309 in Patients with Relapsed/Refractory Lymphoma	Temporary halt of recruitment	04/10/2016	21
15/SC/0009/AM11	Phase 2 study of PQR309 in Patients with Relapsed/Refractory Lymphoma	Restart to recruitment	03/03/2017	6
15/SC/0019/AM11	CORKA Community Based Rehabilitation after Knee Arthroplasty	SA3	01/01/2017	17
15/SC/0059/AM05	SPARC: SBRT pre-operatively for pancreatic cancer	5	06/07/2016	20
15/SC/0072/AM01	DIVA – Diabetes Variants Study	1	17/11/2016	15
15/SC/0075/AM04	The LOGIC 2 study in BRAF melanoma	4.0	01/09/2016	24
15/SC/0138/AM03	Antivirals for influenza like illness? Clinical and Cost-effectiveness	3	02/11/2016	20
15/SC/0259/AM08	Repurposing anti-TNF for treating Dupuytren's disease	5	13/04/2016	27
15/SC/0259/AM12	Repurposing anti-TNF for treating Dupuytren's disease	7	22/09/2016	27
15/SC/0287/AM03	Provision Of Psychological support to People in Intensive care (v1.0)	SA2	18/01/2017	14
15/SC/0287/AM04	Provision Of Psychological support to People in Intensive care	3	06/03/2017	16

	(v1.0)			
15/SC/0324/AM01	Oxford UKR: Second decade outcome study	SA1	02/06/2016	18
15/SC/0337/AM05	Doctor Referral of Overweight People to Low Energy Treatment - DROPLET	3	13/04/2016	26
15/SC/0337/AM06	Doctor Referral of Overweight People to Low Energy Treatment - DROPLET	4	25/10/2016	14
15/SC/0372/AM02	Investigating Pain Mechanisms in Endometriosis - Version 1	SA1	19/05/2016	22
15/SC/0381/AM04	FPA008-002_Study of FPA008 in joint disease (PVNS/dt-TGCT)	4	01/11/2016	21
15/SC/0381/AM05	FPA008-002_Study of FPA008 in joint disease (PVNS/dt-TGCT)	5.0	21/12/2016	23
15/SC/0406/AM09	Evaluation of avelumab* combined with axitinib in advanced RCC	Investigator Brochure V5.0	01/06/2016	8
15/SC/0406/AM10	Evaluation of avelumab* combined with axitinib in advanced RCC	5	09/08/2016	28
15/SC/0406/AM11	Evaluation of avelumab* combined with axitinib in advanced RCC	Participant Information Sheet and Informed Consent Form v4.0	13/10/2016	26
15/SC/0406/AM12	Evaluation of avelumab* combined with axitinib in advanced RCC	IB V6	09/02/2017	20
15/SC/0414/AM03	PLUMMB: Pembrolizumab in Muscle Invasive/Metastatic Bladder Cancer	SA3	08/02/2017	13
15/SC/0491/AM01	ctDNA v6.0	Substantial Amendment 1	09/05/2016	17
15/SC/0491/AM02	ctDNA v6.0	Amendment 2	05/12/2016	25
15/SC/0508/AM02	Psychological support for fears about other people	2	08/09/2016	19
15/SC/0580/AM02	Phase 2/3 study of GS-5745 in patients with Ulcerative Colitis	2	14/04/2016	27
15/SC/0580/AM03	Phase 2/3 study of GS-5745 in patients with Ulcerative Colitis	Protocol Amendment 4	27/07/2016	13
15/SC/0583/AM02	Phase 2 study of GS-5745 in Subjects with Crohn`s Disease	2	07/04/2016	27
15/SC/0587/AM02	Sensory and neural correlates of pain in irritable bowel syndrome	2	01/07/2016	13
15/SC/0587/AM04	Sensory and neural correlates of pain in irritable bowel syndrome	Amendment 3	13/10/2016	22
15/SC/0658/AM01	Fat and Protein Study	SA1	22/06/2016	4

15/SC/0658/AM02	Fat and Protein Study	SA2 - revised version of SA1	05/08/2016	10
15/SC/0666/AM01	MOXIe	6.0	23/05/2016	17
15/SC/0699/AM01	M13-549 Phase 3 JAK study csDMARD subjects with Moderate to Severe RA	1	08/04/2016	35
15/SC/0699/AM02	M13-549 Phase 3 JAK study csDMARD subjects with Moderate to Severe RA	2	17/06/2016	8
15/SC/0699/AM06	M13-549 Phase 3 JAK study csDMARD subjects with Moderate to Severe RA	SA04	19/01/2017	9
15/SC/0699/AM07	M13-549 Phase 3 JAK study csDMARD subjects with Moderate to Severe RA	SA05 Retention materials	01/03/2017	8
15/SC/0700/AM01	M13-545 Phase 3 JAKstudy MTX Naive subjects with Moderate to Severe RA	PA01/02	29/02/2016	53
15/SC/0700/AM02	M13-545 Phase 3 JAKstudy MTX Naive subjects with Moderate to Severe RA	SA03	31/05/2016	8
15/SC/0700/AM03	M13-545 Phase 3 JAKstudy MTX Naive subjects with Moderate to Severe RA	4	12/09/2016	27
15/SC/0700/AM05	M13-545 Phase 3 JAKstudy MTX Naive subjects with Moderate to Severe RA	SA06	30/01/2017	8
15/SC/0700/AM08	M13-545 Phase 3 JAKstudy MTX Naive subjects with Moderate to Severe RA	SA07	08/02/2017	14
15/SC/0701/AM01	M14-465 Phase 3 study in joint structure in Mod/Severe RA with MTX-IR	1	08/04/2016	35
15/SC/0701/AM02	M14-465 Phase 3 study in joint structure in Mod/Severe RA with MTX-IR	2	20/06/2016	8
15/SC/0701/AM03	M14-465 Phase 3 study in joint structure in Mod/Severe RA with MTX-IR	3	01/08/2016	8
15/SC/0701/AM04	M14-465 Phase 3 study in joint structure in Mod/Severe RA with MTX-IR	Substantial Amendment ICF v7 &	05/10/2016	31
15/SC/0701/AM06	M14-465 Phase 3 study in joint structure in Mod/Severe RA with MTX-IR	Amendment 4	11/01/2017	10
15/SC/0731/AM01	ALERT	1	21/10/2016	26
15/SC/0769/AM02	COMBO	SA01 10/08/2016	15/08/2016	21
16/SC/0006/AM01	IMCgp100-201 Phase 1b/2 IMCgp100 in combination or alone	SA1	20/05/2016	14
16/SC/0006/AM03	IMCgp100-201 Phase 1b/2 IMCgp100 in combination or alone	SA2	16/12/2016	24

16/SC/0007/AM01	Phase I Study of Oral PQR309 in Patients with Advanced Solid Tumors	1	01/06/2016	13
16/SC/0007/AM02	Phase I Study of Oral PQR309 in Patients with Advanced Solid Tumors	SA2 (3.0UK)	30/08/2016	22
16/SC/0016/AM01	TEPHRA Version 1	1	18/04/2016	25
16/SC/0109/AM03	UK STAR	002	18/08/2016	24
16/SC/0137/AM01	CA209-511 Nivolumab with Ipilimumab in Subjects with Melanoma	SA1	17/06/2016	4
16/SC/0137/AM03	CA209-511 Nivolumab with Ipilimumab in Subjects with Melanoma	3	13/01/2017	18
16/SC/0139/AM01	Phase 1B/2 study of avelumab in patients with advanced malignancies	1	24/06/2016	21
16/SC/0139/AM06	Phase 1B/2 study of avelumab in patients with advanced malignancies	B9991004 PA5	19/12/2016	25
16/SC/0139/AM07	Phase 1B/2 study of avelumab in patients with advanced malignancies	SA3 - B9991004 avelumab IBv6	11/01/2017	20
16/SC/0246/AM01	A Randomized Ph. 2/3 Study of DACOGENÂ® & JNJ-5602247 vs DACOGENÂ® alone	SA1	28/07/2016	19
16/SC/0246/AM05	A Randomized Ph. 2/3 Study of DACOGENÂ® & JNJ-5602247 vs DACOGENÂ® alone	SA3	05/12/2016	23
16/SC/0246/AM07	A Randomized Ph. 2/3 Study of DACOGENÂ® & JNJ-5602247 vs DACOGENÂ® alone	Substantial Amendment 4	20/03/2017	8
16/SC/0254/AM01	Vedolizumab-4003 (ENTERPRISE), Protocol Amendment 1, 29-Feb-2016	2	09/08/2016	15
16/SC/0257/AM01	The MNKs; Novel Markers of Type 2 Diabetes Mellitus Risk v1.0	SA1	23/05/2016	24
16/SC/0355/AM01	The Mobility and Maternity (MaM) Study 1.1	1	11/08/2016	28
16/SC/0363/AM02	TTP488 Efficacy & Safety Study in Mild Alzheimer's (STEADFAST)	SA2	14/09/2016	14
16/SC/0363/AM03	TTP488 Efficacy & Safety Study in Mild Alzheimer's (STEADFAST)	SA3	28/10/2016	22
16/SC/0379/AM01	Vedolizumab IV 300 mg in the Treatment of Chronic Pouchitis (EARNEST)	1	11/11/2016	19
16/SC/0453/AM01	Novel START (Novel Symbicort Turbuhaler Asthma Reliever Therapy)	1	12/10/2016	27
16/SC/0511/AM01	IMCgp100-401: Rollover Study for Patients Completing an	SA1	04/01/2017	23

	IMCgp100 study			
16/SC/0570/AM01	A grounded theory of forensic service users' recall to hospital - v1	Amendment 1	06/12/2016	20
16/SC/0578/AM02	The Effect of Tinnitus on Attention and Listening v2	1 08/03/2017	10/03/2017	15
16/SC/0600/AM01	Efficacy and Safety of Filgotinib in Active Ulcerative Colitis	SA1	19/12/2016	21
16/SC/0601/AM01	Long Term Safety of Filgotinib in Active Ulcerative Colitis	SA1	19/12/2016	21
16/SC/0654/AM01	Prebiotic Study in Psychosis	Amendment 1	17/02/2017	18

Unfavourable opinion				
Amendment REC Reference	**Title**	**Version**	**Date**	**Number of Days on Clock**
09/H0605/2/AM07	Factors influencing Human Islet structure and function	4	12/10/2016	31
11/SC/0093/AM07	Effect of ocular diseases on sleep and circadian rhythm. version 1.0	5.1	08/08/2016	28
12/SC/0371/AM05	Predicting response to surgery for endometriosis pain	2.0	19/05/2016	27
13/SC/0467/AM08	Phase I,dose escalation of LTX-315 in transdermally accessible tumours		23/11/2016	28
13/SC/0523/AM07	The impact of AZD4017 on bone turnover in post-menopausal osteopaenia	SA08	14/09/2016	21
14/SC/0266/AM02	Biomarker signature and US profile in Rheumatoid Arthritis.v1	3	16/09/2016	28
14/SC/1374/AM08	AZD9496 First Time in Patients Ascending Dose Study	6	21/04/2016	28
15/SC/0075/AM05	The LOGIC 2 study in BRAF melanoma	IMPD updateÍ¾ INC280 IMPD	23/02/2017	23
15/SC/0598/AM06	HEALS Cohort Study	2	08/09/2016	20
15/SC/0701/AM05	M14-465 Phase 3 study in joint structure in Mod/Severe RA with MTX-IR	4	17/10/2016	23
16/SC/0137/AM02	CA209-511 Nivolumab with Ipilimumab in Subjects with Melanoma	2	31/10/2016	28
16/SC/0504/AM01	BETA3_LVH V1.0	1	17/02/2017	22

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
11/SC/0093/AM07/1	Effect of ocular diseases on sleep and circadian rhythm. version 1.0	Modified to SA5.1	28/09/2016	1
12/SC/0371/AM05/1	Predicting response to surgery for endometriosis pain	2	04/08/2016	5
13/SC/0467/AM08/1	Phase I,dose escalation of LTX-315 in transdermally accessible tumours	10	06/01/2017	9
13/SC/0523/AM07/1	The impact of AZD4017 on bone turnover in post-menopausal osteopaenia	Modified to SA08	24/10/2016	11
14/SC/0266/AM02/1	Biomarker signature and US profile in Rheumatoid Arthritis.v1	Modified Amendment to SA3	18/10/2016	8
14/SC/1374/AM08/1	AZD9496 First Time in Patients Ascending Dose Study	6	23/03/2016	5
15/SC/0701/AM05/1	M14-465 Phase 3 study in joint structure in Mod/Severe RA with MTX-IR	Modified Amendment for SA05	27/01/2017	7
16/SC/0137/AM02/1	CA209-511 Nivolumab with Ipilimumab in Subjects with Melanoma	2	30/11/2016	12

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

Table 11: **Items exceeding timelines**

Full applications for ethical review over 60 day timeline		
REC Reference	**Title**	**Number of Days on Clock**

Proportionate review applications for ethical review over 21 day timeline		
REC Reference	**Title**	**Number of Days on Clock**
16/SC/0644	Blood immunophenotyping in staging of indolent B-cell lymphomas V1.0	25

SSAs (non Phase 1) over 25 day timeline		
REC Reference	**Title**	**Number of Days on Clock**
16/SC/0652	Randomized, Double-Blind, Plac	28

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

Substantial Amendments over 35 day timeline				
Amendment REC Reference	**Title**	**Version**	**Date**	**Number of Days on Clock**
15/SC/0700/AM01	M13-545 Phase 3 JAKstudy MTX Naive subjects with Moderate to Severe RA	PA01/02	29/02/2016	53

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