NHS
Health Research Authority

Research Ethics Service

South Central - Oxford B Research Ethics Committee

Annual Report

01 April 2017 - 31 March 2018

Part 1 – Committee Membership and Training

Name of REC:	South Central - Oxford B Research Ethics Committee
Type of REC:	Type III (CTIMP)
Type of Flag:	IRB, Phase 1 in Patients
Chair:	Mr Chris Foy
Vice-Chair:	Dr Kim Cheetham
Alternate Vice-Chair:	Dr Liesl Osman
REC Manager:	Mrs Vicky Canfield-Duthie Mrs Claudia Bywater
REC Assistant:	None
Committee Address:	Whitefriars Level 3, Block B Lewin's Mead Bristol BS1 2NT
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Email:	nrescommittee.southcentral-oxfordb@nhs.net

Chair's overview of the past year:

We held nine full meetings during the year (May 2017 was cancelled for lack of business). Two meetings needed co-optees, and we are most grateful to them.

From July, all our meetings were held in our new spacious and elegant venue, the Deanery at Christ Church, by kind invitation of our member Rev Canon Dr Emma Percy. We are grateful to her and the staff of the Deanery for looking after us so well. The previous room at the John Radcliffe Hospital was a little cramped, lacking a proper waiting area for applicants, and there were recurring traffic and parking problems.

During the year we said goodbye to Emma Plested and Fozia Mushtaq, owing to work pressure and a move away respectively. Their stays with us had been brief but welcome. We also said our farewells to a member of longer standing, Iveta Simera, who found that a new job prevented her spending the time needed. We shall miss her wisdom, insight and cheerfulness.

In November we welcomed a member new to REC work, clinical trials pharmacist Vanshika Sharma.

HRA staff Vicky Canfield-Duthie and Claudia Bywater (Deputy Regional Manager), between them, have looked after us most ably.

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	
Professor Ron King	Mathematician (Retired)	Lay Plus	30/08/2016	
Dr Wilhelm Kuker	Consultant Neuroradiologist	Expert	01/12/2010	
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	30/06/2017
Dr Liesl Osman	Retired Research Advisor	Lay	10/10/2009	
Rev Canon Dr Emma Percy	College Chaplain, Trinity College	Lay Plus	01/09/2011	
Mrs Emma Plested	Clinical Trials Coordinator	Lay	28/06/2016	02/06/2017
Miss Vanshika Sharma	Clinical Trial Manager	Expert	13/11/2017	
Dr Iveta Simera	Head of Programme Development, EQUATOR Network, Centre for Statistics in Medicine	Lay	21/09/2011	14/03/2018
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
Ms Yasumati Damodar	Pharmacist	Expert	12/09/2017
Ms Fanny Mitchell	Retired NHS Manager	Lay Plus	12/09/2017
Mr John Richardson	Retired Director of COREC: former Ecumenical Officer for Churches Together in South London	Lay Plus	11/07/2017

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

Name	Declaration of Interest	Date
Mr Peter Brown	None	08/03/2018
Dr Kim Cheetham	None	13/03/2018
Dr Richard Philip Craven	None	08/03/2018
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.	08/03/2018
Professor Ron King	None	08/03/2018
Mr Ian MacKenzie	None	08/03/2018
Dr Liesl Osman	Â£5000 in Glaxo Smith Kline shares	08/03/2018
Rev Canon Dr Emma Percy	None	19/05/2017
Miss Vanshika Sharma	None	14/11/2017
Dr Iveta Simera	Deputy Director of the UK EQUATOR Centre and Programme Manager of the EQUATOR Network.	18/05/2017
Mrs Kate Thompson	None	08/03/2018
Dr Wilhelm Kuker	None	31/03/2018

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

Month	Date	Number of Members Present at Meeting
June	13/06/2017	9
July	11/07/2017	8
September	12/09/2017	8
October	10/10/2017	9
November	14/11/2017	9
December	12/12/2017	8
January	09/01/2018	10
February	13/02/2018	8
March	13/03/2018	9

9 full committee meetings were held during the reporting period.

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

Month	Date	Number of Members Present at Meeting
April	24/04/2017	3
May	22/05/2017	3
June	26/06/2017	4
July	24/07/2017	3
August	21/08/2017	3
September	25/09/2017	3
November	27/11/2017	3
December	18/12/2017	3
January	22/01/2018	3
March	26/03/2018	3

10 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	07/04/2017	2
April	21/04/2017	2
May	05/05/2017	3
May	05/05/2017	2
May	19/05/2017	2
June	02/06/2017	2
June	16/06/2017	2
June	30/06/2017	2
July	14/07/2017	2
July	28/07/2017	2
August	11/08/2017	2
August	25/08/2017	2

September	08/09/2017	2
September	08/09/2017	2
September	22/09/2017	2
September	29/09/2017	2
October	06/10/2017	2
October	20/10/2017	2
November	03/11/2017	2
November	17/11/2017	2
December	01/12/2017	2
December	15/12/2017	3
December	20/12/2017	3
December	29/12/2017	2
January	12/01/2018	2
January	26/01/2018	2
February	09/02/2018	2
February	23/02/2018	2
March	09/03/2018	2
March	20/03/2018	3
March	23/03/2018	2

31 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
Mr Peter Brown	5
Dr Kim Cheetham	5
Dr Richard Philip Craven	7
Mr Chris Foy	9
Professor Ron King	7
Dr Wilhelm Kuker	5
Mr Ian MacKenzie	8
Dr Liesl Osman	7
Rev Canon Dr Emma Percy	7
Miss Vanshika Sharma	4
Dr Iveta Simera	2
Mrs Kate Thompson	8

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

Name	Number of Meetings Attended
Dr Kim Cheetham	2
Dr Richard Philip Craven	3
Mr Chris Foy	5
Professor Ron King	4
Dr Wilhelm Kuker	6
Mr Ian MacKenzie	2
Dr Liesl Osman	5
Rev Canon Dr Emma Percy	2
Mrs Kate Thompson	1

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

Name	Number of Meetings Attended
Dr Kim Cheetham	8
Dr Richard Philip Craven	8
Mr Chris Foy	16
Professor Ron King	6
Dr Wilhelm Kuker	4
Mr Ian MacKenzie	6
Dr Liesl Osman	11
Rev Canon Dr Emma Percy	3
Mrs Emma Plested	1
Mrs Kate Thompson	3

Training 01 April 2017 - 31 March 2018

Name of Member	Date	Event(s) attended
Mr Peter Brown	01/03/2018	SDL - Read Bad Science; Ben Goldacre
Dr Kim Cheetham	02/06/2017	Oxford Joint Training Day
Dr Kim Cheetham	31/10/2017	arranged a review (through the Royal Society of Medicine) of anaphylaxis after monoclonal antibodies
Dr Richard Philip Craven	02/06/2017	Oxford Joint Training Day
Mr Chris Foy	29/09/2017	Regional Training Day - Nottingham
Mr Chris Foy	24/11/2017	Chair's Training Day
Mr Chris Foy	04/09/2017	Complex Ethical Issues
Professor Ron King	02/06/2017	Local Training Day - South Central - Oxford A , Oxford
Professor Ron King	07/02/2018	Introduction to Phase 1 Studies
Mr Ian MacKenzie	02/06/2017	Oxford Joint Training Day
Mr Ian MacKenzie	14/03/2018	Self Directed Learning
Dr Liesl Osman	11/03/2018	Self-Directed Learning; Read various articles relevant to Ethics and completed an Online Course Reviewing Research Design of clinical trials
Rev Canon Dr Emma Percy	27/02/2018	**WAITING LIST** Genetic and Genomic Research
Miss Vanshika Sharma	31/01/2018	Human Tissue Act
Mrs Kate Thompson	21/03/2018	Self Directed Learning; Read several research articles

PART 2: REC WORKLOAD AND ACTIVITY DURING THE REPORTING PERIOD

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

Applications for full ethical review – Study Type	Number	%
Clinical Trial of Investigational Medicinal Product	15	34.09
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	1	2.27
Others	28	63.64
Total Applications Reviewed	**44**	**100**

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

Number of applications made invalid by the REC Manager	1
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	11
Number of paediatric applications reviewed	5
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	1
Number of qualitative applications reviewed	2

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

Decisions taken at meetings following review of applications	Number	%
Favourable Opinion with Standard Conditions	2	4.55
Favourable Opinion with Additional Conditions	10	22.73
Unfavourable Opinion	1	2.27
Provisional Opinion	31	70.45
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	**44**	**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	26	59.09
Further Information Favourable Opinion with Additional Conditions	4	9.09
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	2	4.55
Favourable Opinion with Additional Conditions	10	22.73
Unfavourable Opinion	1	2.27
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	1	2.27
Total	**44**	**100**

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

Total Applications Reviewed	**21**

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

Number of applications made invalid by the REC Manager	0
Number of studies withdrawn prior to the meeting	2
Number of student applications reviewed	12
Number of paediatric applications reviewed	1
Number of device applications reviewed	0
Number of qualitative applications reviewed	8

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	19.05
Favourable Opinion with Additional Conditions	1	4.76
No Opinion transfer to full committee for review	1	4.76
Provisional Opinion	15	71.43
Unfavourable Opinion	0	0.00
Total	**21**	**100**

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

Average number of applications reviewed per full meeting	4.89
Number of completed applications for full ethical review	43
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	5
Number of completed applications over 40 days as a % of total	11.36%
Number of days taken to final decision – average (mean)	30

Number of completed proportionate review applications for ethical review	20
Number of completed proportionate review applications for ethical review over 21 days	3
Number of completed proportionate review applications over 21 days as a % of total	15.00%

Number of SSAs (non-Phase 1) reviewed	10
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	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	120
Number of completed substantial amendments over 35 days	1
Number of completed substantial amendments over 35 days as a % of total substantial amendments	0.83%
Number of completed substantial amendments over 28 days	22
Number of completed substantial amendments over 28 days as a % of total substantial amendments	18.33%

Number of modified amendments reviewed	4
Number of completed modified amendments over 14 days	0
Number of completed modified amendments over 14 days as a % of total modified amendments	0.00%

Number of non substantial amendments received	127
Number of substantial amendments received for information	3
Number of substantial amendments received for new sites/PIs	19
Number of annual progress reports received	91
Number of safety reports received	68
Number of Serious Adverse Events received	0

Number of final reports received	17

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/0286	Skin blisters with systemic LPS or GM-CSF challenge	26
17/SC/0290	PSC FNA Liver Study	29
17/SC/0297	Adaptation to ketosis	29
17/SC/0330	UK Carotid Cohort Study	30
17/SC/0335	Burden of RSV disease	28
17/SC/0338	SVDs@target: TREAT-SVDs	29
17/SC/0450	Ph1b Hu5F9G4Mono or Hu5F9G4&Azacitidine for hematological Malignancies	47
17/SC/0468	The ILiAD Study	37
17/SC/0471	Oral Minocycline for GA	28
17/SC/0506	The HAPI Study	9
17/SC/0531	CC-90009-AML-001_22 March 2017	36
17/SC/0536	COPELIA	33
17/SC/0539	Assessing mistrust in young people	40
17/SC/0580	INFOD-HF V1.0	30
17/SC/0582	Long-term Safety Study of AR101	30
17/SC/0650	SHP647 as induction therapy in moderate to severe Ulcerative Colitis	39
17/SC/0651	SHP647 as maintenance therapy for moderate-severe Ulcerative Colitis	40
17/SC/0652	SHP647 long term extension for moderate to severe Ulcerative Colitis	39
18/SC/0007	Sight threatening chemical injuries BOSU study	33
18/SC/0009	Extension study of Seladelpar in PBC	41
18/SC/0021	Ureter Identification with IRDye 800BK	48
18/SC/0064	Safety of twenty-eight day consumption of Î”GÂ® in healthy adults (V1)	22
18/SC/0068	Airway epithelium study (AES)	28
18/SC/0071	DIAMOND - Dietary Approaches to the Management Of type 2 Diabetes	34
18/SC/0076	PF-04995274 and emotional processing in un-medicated depression	47
18/SC/0107	SPEED	34

Further Information Favourable Opinion with Additional Conditions		
REC Reference	**Title**	**Number of Days on Clock**
17/SC/0315	Deep and Frequent Phenotyping	33
17/SC/0457	REDUCE Programme- WS3	26

17/SC/0578	17303A - Lu AF35700 in patients with schizophrenia	41
18/SC/0118	The Insight Study	34

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**
18/SC/0049	Assessment of new and novel imaging modalities to diagnose cellular pathology	0
18/SC/0092	OSCC Research Database	21

Favourable Opinion with Additional Conditions		
REC Reference	**Title**	**Number of Days on Clock**
17/SC/0299	Validation of ICG to identify the urethra during rectal surgery	20
17/SC/0333	INVEST	22
17/SC/0515	Experiences of feeling exceptional: a qualitative study.	27
17/SC/0574	The incidence of hydroxychloroquine retinopathy in the United Kingdom	22
17/SC/0597	Metacognitive Factors in Spinal Cord Injury	21
17/SC/0607	BASIC	21
17/SC/0661	Cytosponge for post-chemoradiation surveillance of oesophageal cancer	31
17/SC/0664	FENOX	31
18/SC/0020	Simplification of Low Level Internal Dosimetry (SOLLID)	31
18/SC/0121	A brief GP intervention for weight loss: The BWeL-B feasibility trial	21

Unfavourable Opinion		
REC Reference	**Title**	**Number of Days on Clock**
17/SC/0654	Post-mortem dual-energy CT	17

Provisional Opinion		
REC Reference	**Title**	**Number of Days on Clock**

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**
18/SC/0072	Carers' Perspectives of Dysphagia & Tracheostomy	20

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/0203	Cervical Cell Lifts	14
17/SC/0208	D+R Therapy rehabilitation study	22
17/SC/0264	Patients pain perceptions in forefoot surgery	19
17/SC/0265	Pharmalink NEF-203	22
17/SC/0320	Heart Function in patients assessed for Sleep Apnoea	18
17/SC/0437	Patient, carer and clinician experience of routine blood testing	12
17/SC/0513	Fathers caring for a child with a Learning Disability and Autism	14
17/SC/0518	Distinction between AFX and PDS- V1	13
17/SC/0640	Exploring the tensions of the Getting it Right for Every Child policy	14
17/SC/0670	Understanding the experiences of patients living with stage IV CKD	20
18/SC/0051	Core Outcomes for research on Open Lower Limb Fractures (CO-OLLF)	18
18/SC/0182	Father's experiences of antenatal attachment v1	25

Further Information Favourable Opinion with Additional Conditions		
REC Reference	**Title**	**Number of Days on Clock**
17/SC/0441	Novel strategies to enhance xenobiotic penetration into the skin	14

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/0327	Prevalence of Inflammatory Back Pain in Young Adults	9
17/SC/0373	Diagnosis and management of tube infection (version 1)	15
17/SC/0442	Stakeholders views of Medicines Administration by Pharmacy Technicians	15
17/SC/0498	Genetics and The Immune Response to Metal Debris	8

Favourable Opinion with Additional Conditions		
REC Reference	**Title**	**Number of Days on Clock**
17/SC/0667	Biomarkers for ovarian cancer risk assessment	17

Unfavourable Opinion		
REC Reference	**Title**	**Number of Days on Clock**

Provisional Opinion		
REC Reference	**Title**	**Number of Days on Clock**
18/SC/0159	The defining mathematical features of movements disorders	n/a
18/SC/0163	Turkish women experience of psychological therapies for chronic pain	n/a

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/AM10	STUDIES OF THE VASCULAR PROPERTIES OF ARTERIAL BYPASS GRAFTS	Amendment 7, August 2017	21/09/2017	20
09/H0605/62/AM17	Midbrain micturition pathways	version 14	09/08/2017	33
10/H0605/31/AM15	CREW (ColoREctal Wellbeing) cohort	14	13/09/2017	32
10/H0605/59/AM38	WN25203 - Proof of Efficacy of RO4909832 in prodromal alzheimer's	Amendment 22 - Updated Patient	05/09/2017	9
10/H0605/59/AM40	WN25203 - Proof of Efficacy of RO4909832 in prodromal alzheimer's	Amendment 23 - IDMC Updates	23/01/2018	28
11/H0605/12/AM12	Motor consolidation during sleep	Amendment 8	26/04/2017	19
11/SC/0093/AM13	Effect of ocular diseases on sleep and circadian rhythm. version 1.0	6.1	05/05/2017	19
11/SC/0093/AM15	Effect of ocular diseases on sleep and circadian rhythm. version 1.0	7.1	21/07/2017	11
13/SC/0368/AM05	OPTIMISE	NOSA03	15/12/2016	12
13/SC/0467/AM10	Phase I,dose escalation of LTX-315 in transdermally accessible tumours	SA_REC_UK12_Protocol Version 7	12/09/2017	34
13/SC/0503/AM17	B2151002: Phase 1b of PF-05212384 in combination.	B2151002 Substantial Amendment	20/07/2017	12
13/SC/0503/AM18	B2151002: Phase 1b of PF-05212384 in combination.	AM14	29/08/2017	13
13/SC/0517/AM05	FORM -2C v0.1	SA 02 13/07/2017	13/07/2017	25
13/SC/0523/AM09	The impact of AZD4017 on bone turnover in post-menopausal osteopaenia	SA09	07/11/2017	26
13/SC/0617/AM01	Neuroimaging in painful diabetic neuropathy and fibromyalgia v1.0	Amendment 2	28/05/2017	24
13/SC/0635/AM07	AZ D081DC00008 Metastatic Castrate-Resistant Prostate Cancer	SA6	13/04/2017	20
13/SC/0638/AM27	HIPvac Trial	AM25	17/05/2017	7
13/SC/0638/AM28	HIPvac Trial	26	05/07/2017	14
13/SC/0638/AM29	HIPvac Trial	AM27	13/09/2017	15
14/SC/0147/AM03	Red cell membrane cholesterol: a marker of unstable carotid	2	21/01/2018	34

	plaque?			
14/SC/1250/AM04	Identifying dysplasia and cancer using lectins Pilot Study	Amendment 3	11/05/2017	20
14/SC/1369/AM11	ASCOT: Lifestyle study for cancer survivors	Amendment 5, 05/07/2017	05/07/2017	15
15/SC/0004/AM06	The Effect of Obesity and Weight Loss in Heart Failure	Amendment 3	29/03/2017	21
15/SC/0009/AM14	Phase 2 study of PQR309 in Patients with Relapsed/Refractory Lymphoma	Change of the Chief Investigat	15/05/2017	10
15/SC/0009/AM15	Phase 2 study of PQR309 in Patients with Relapsed/Refractory Lymphoma	Protocol Amendment 10.0	16/06/2017	21
15/SC/0009/AM17	Phase 2 study of PQR309 in Patients with Relapsed/Refractory Lymphoma	IB version 6.0 dated 04 Januar	05/02/2018	35
15/SC/0019/AM14	CORKA Community Based Rehabilitation after Knee Arthroplasty	14	24/10/2017	15
15/SC/0072/AM02	DIVA – Diabetes Variants Study	SA2	10/08/2017	14
15/SC/0075/AM07	The LOGIC 2 study in BRAF melanoma	Array Logic 2_Substantial Amen	13/10/2017	11
15/SC/0075/AM08	The LOGIC 2 study in BRAF melanoma	Protocol version 5, dated 19 O	12/02/2018	28
15/SC/0127/AM02	Senescent Hepatocytes and the Innate Immune System	Amendement 1	15/08/2017	18
15/SC/0138/AM06	Antivirals for influenza like illness? Clinical and Cost-effectiveness	ALICE004	22/08/2017	19
15/SC/0259/AM17	Repurposing anti-TNF for treating Dupuytren's disease	Amendment 12	11/12/2017	31
15/SC/0287/AM05	Provision Of Psychological support to People in Intensive care (v1.0)	SA4	05/12/2017	16
15/SC/0381/AM08	FPA008-002_Study of FPA008 in joint disease (PVNS/dt-TGCT)	4.0	16/06/2017	13
15/SC/0406/AM14	Evaluation of avelumab* combined with axitinib in advanced RCC	Investigator’s Brochure Avelum	18/07/2017	13
15/SC/0406/AM15	Evaluation of avelumab* combined with axitinib in advanced RCC	Substantial amendment – Update	25/01/2018	13
15/SC/0414/AM04	PLUMMB: Pembrolizumab in Muscle Invasive/Metastatic Bladder Cancer	Substantial-Amendment 6	12/12/2017	19
15/SC/0491/AM07	ctDNA v6.0	Amendment No3 Protocol Version	02/02/2018	35

15/SC/0493/AM01	Ethnic variations in infant mortality	Amendment 1	22/08/2017	15
15/SC/0508/AM03	Psychological support for fears about other people	3, 13.11.2017	13/11/2017	21
15/SC/0510/AM02	Brown Adipose Tissue Activation Study	3	20/07/2017	24
15/SC/0510/AM04	Brown Adipose Tissue Activation Study	4.0 22/01/2018	22/01/2018	27
15/SC/0658/AM04	Fat and Protein Study	Substantial Amendment 3 (Chang	01/03/2017	23
15/SC/0666/AM04	MOXIe	8	20/07/2017	28
15/SC/0666/AM05	MOXIe	Substantial Amendment for Prot	05/09/2017	13
15/SC/0666/AM06	MOXIe	Substantial Amendment #5	05/09/2017	20
15/SC/0668/AM01	Pregnancy and Childbirth Questionnaire Study	1.1 10/07/2017	10/07/2017	14
15/SC/0699/AM09	M13-549 Phase 3 JAK study csDMARD subjects with Moderate to Severe RA	SA06	02/06/2017	20
15/SC/0699/AM10	M13-549 Phase 3 JAK study csDMARD subjects with Moderate to Severe RA	Protocol amendment 4, IB v7 an	21/06/2017	9
15/SC/0699/AM12	M13-549 Phase 3 JAK study csDMARD subjects with Moderate to Severe RA	SA09 Protocol amendment 5 and	26/10/2017	20
15/SC/0700/AM10	M13-545 Phase 3 JAKstudy MTX Naive subjects with Moderate to Severe RA	IB v7 and ICF v8	11/08/2017	9
15/SC/0701/AM09	M14-465 Phase 3 study in joint structure in Mod/Severe RA with MTX-IR	SA08 - Patient Document Correc	11/05/2017	10
15/SC/0701/AM10	M14-465 Phase 3 study in joint structure in Mod/Severe RA with MTX-IR	SA09 - IB ed7	07/08/2017	19
16/SC/0006/AM04	IMCgp100-201 Phase 1b/2 IMCgp100 in combination or alone	SA03	19/04/2017	35
16/SC/0006/AM05	IMCgp100-201 Phase 1b/2 IMCgp100 in combination or alone	SA4	09/06/2017	17
16/SC/0006/AM07	IMCgp100-201 Phase 1b/2 IMCgp100 in combination or alone	SA5	18/08/2017	18
16/SC/0006/AM08	IMCgp100-201 Phase 1b/2 IMCgp100 in combination or alone	Substantial Amendment 6.0	29/11/2017	5
16/SC/0007/AM04	Phase I Study of Oral PQR309 in Patients with Advanced Solid Tumors	Protocol Amendment 4 UK	16/03/2017	13
16/SC/0007/AM06	Phase I Study of Oral PQR309 in Patients with Advanced Solid Tumors	IB version 6.0 dated 04 Januar	01/02/2018	33

16/SC/0016/AM02	TEPHRA Version 1	Amendment 2	25/04/2017	14
16/SC/0109/AM11	UK STAR	Amendment 009	19/09/2017	32
16/SC/0109/AM12	UK STAR	10	25/10/2017	14
16/SC/0137/AM06	CA209-511 Nivolumab with Ipilimumab in Subjects with Melanoma	SA4	21/08/2017	26
16/SC/0137/AM07	CA209-511 Nivolumab with Ipilimumab in Subjects with Melanoma	Substantial amendment # 5	06/12/2017	9
16/SC/0139/AM09	Phase 1B/2 study of avelumab in patients with advanced malignancies	PA6 2017/05/16	16/05/2017	18
16/SC/0139/AM11	Phase 1B/2 study of avelumab in patients with advanced malignancies	V7.0	01/11/2017	18
16/SC/0246/AM09	A Randomized Ph. 2/3 Study of DACOGENÂ® & JNJ-5602247 vs DACOGENÂ® alone	Substantial Amendment 6	03/05/2017	14
16/SC/0246/AM10	A Randomized Ph. 2/3 Study of DACOGENÂ® & JNJ-5602247 vs DACOGENÂ® alone	Substantial Amendment 7	24/07/2017	28
16/SC/0246/AM11	A Randomized Ph. 2/3 Study of DACOGENÂ® & JNJ-5602247 vs DACOGENÂ® alone	Substantial Amendment 8	23/08/2017	15
16/SC/0246/AM12	A Randomized Ph. 2/3 Study of DACOGENÂ® & JNJ-5602247 vs DACOGENÂ® alone	Substantial Amendment 9	20/11/2017	14
16/SC/0254/AM02	Vedolizumab-4003 (ENTERPRISE), Protocol Amendment 1, 29-Feb-2016	Substantial Amendment 3	20/04/2017	12
16/SC/0326/AM01	Meeting the needs of children following sexual abuse	1	15/01/2018	10
16/SC/0363/AM09	TTP488 Efficacy & Safety Study in Mild Alzheimer's (STEADFAST)	Sub Amd 07 2018/02/28	28/02/2018	35
16/SC/0379/AM02	Vedolizumab IV 300 mg in the Treatment of Chronic Pouchitis (EARNEST)	Substantial Amendment 2	21/04/2017	14
16/SC/0463/AM01	Understanding what maintains social anxiety disorder in children	1	22/11/2017	14
16/SC/0504/AM02	BETA3_LVH V1.0	SA2	02/11/2017	13
16/SC/0511/AM02	IMCgp100-401: Rollover Study for Patients Completing an IMCgp100 study	SA2	03/04/2017	14
16/SC/0511/AM03	IMCgp100-401: Rollover Study for Patients Completing an IMCgp100 study	SA3	01/11/2017	19
16/SC/0570/AM02	A grounded theory of forensic service users' recall to hospital - v1	2	13/06/2017	16
16/SC/0600/AM05	Efficacy and Safety of Filgotinib in Active Ulcerative Colitis	SA#5	10/07/2017	30

16/SC/0601/AM05	Long Term Safety of Filgotinib in Active Ulcerative Colitis	5	10/07/2017	30
16/SC/0604/AM02	PHASE 3 STUDY POF TAFAMIDIS MEGLUMINE IN PATIENTS WITH TTR-CM	IMPD, Patient Card, Protocol A	12/06/2017	16
16/SC/0615/AM02	CONTROL	SA3	17/07/2017	22
16/SC/0615/AM04	CONTROL	SA04 - Updated MTX Dosing Diar	16/08/2017	17
16/SC/0654/AM02	Prebiotic Study in Psychosis	Amendment 2	25/05/2017	20
16/SC/0654/AM03	Prebiotic Study in Psychosis	Amendment 3	01/11/2017	6
17/SC/0007/AM02	To Evaluate ABX-1431 in Central Pain Patients	1	23/05/2017	23
17/SC/0016/AM01	CA209-743: Phase III unresectable Pleural Mesothelioma	Substantial Amendment EC01	12/05/2017	15
17/SC/0016/AM02	CA209-743: Phase III unresectable Pleural Mesothelioma	Amendment No 5 (EC02)	14/08/2017	17
17/SC/0016/AM03	CA209-743: Phase III unresectable Pleural Mesothelioma	3	08/01/2018	17
17/SC/0018/AM02	ARGX-113-1603	1	04/07/2017	31
17/SC/0018/AM03	ARGX-113-1603	Substantial Amendment #2	06/12/2017	31
17/SC/0047/AM01	Photoacoustic imaging of oxygen in blood vessels in SSc	1	13/09/2017	18
17/SC/0109/AM01	CX-072 in patients with advanced/recurrent solid tumours or lymphomas	Substantial Amendment 1:	21/06/2017	35
17/SC/0109/AM04	CX-072 in patients with advanced/recurrent solid tumours or lymphomas	Substantial Amendment 2: Proto	20/09/2017	19
17/SC/0109/AM05	CX-072 in patients with advanced/recurrent solid tumours or lymphomas	Substantial Amendment: Patient	16/10/2017	16
17/SC/0122/AM01	PEANUT ALLERGY STUDY IN CHILDREN	Amendment 1	31/05/2017	18
17/SC/0122/AM04	PEANUT ALLERGY STUDY IN CHILDREN	SA5 - Protocol Am2, IB Ed 4, I	26/09/2017	35
17/SC/0264/AM02	Patients pain perceptions in forefoot surgery	1 16.1.2018	16/01/2018	28
17/SC/0286/AM01	Skin blisters with systemic LPS or GM-CSF challenge	Substantial Amendment 1 07/10/	10/07/2017	19
17/SC/0299/AM01	Validation of ICG to identify the urethra during rectal surgery	2.0	14/09/2017	10
17/SC/0315/AM02	Deep and Frequent Phenotyping	Substantial Amendment 1	13/02/2018	39

17/SC/0320/AM01	Heart Function in patients assessed for Sleep Apnoea	1	31/10/2017	20
17/SC/0333/AM01	INVEST	SA1 16Oct2017	16/10/2017	21
17/SC/0335/AM02	Burden of RSV disease	1	16/09/2017	27
17/SC/0338/AM01	SVDs@target: TREAT-SVDs	SA1	26/10/2017	28
17/SC/0471/AM01	Oral Minocycline for GA	1.0	26/01/2018	29
17/SC/0498/AM01	Genetics and The Immune Response to Metal Debris	Amendment 1	19/01/2018	28
17/SC/0580/AM01	INFOD-HF V1.0	Amendment 1	03/01/2018	29
17/SC/0607/AM01	BASIC	Amendment Number 1	26/01/2018	8
17/SC/0650/AM01	SHP647 as induction therapy in moderate to severe Ulcerative Colitis	Informed Consent Form v2.0, Pr	12/03/2018	27
17/SC/0651/AM01	SHP647 as maintenance therapy for moderate-severe Ulcerative Colitis	Informed Consent Form v2.0, Pr	12/03/2018	27
17/SC/0652/AM01	SHP647 long term extension for moderate to severe Ulcerative Colitis	Informed Consent Form v2.0, Ma	14/03/2018	26
18/SC/0021/AM01	Ureter Identification with IRDye 800BK	1	21/02/2018	21
C02.261/AM01	MRCBHF Heart Protection Study Longterm Followup	Amendment 1	11/02/2016	12

Unfavourable opinion				
Amendment REC Reference	**Title**	**Version**	**Date**	**Number of Days on Clock**
16/SC/0246/AM08	A Randomized Ph. 2/3 Study of DACOGENÂ® & JNJ-5602247 vs DACOGENÂ® alone	Substantial Amendment 5	31/03/2017	22
16/SC/0453/AM02	Novel START (Novel Symbicort Turbuhaler Asthma Reliever Therapy)	SA02	19/04/2017	20
17/SC/0109/AM07	CX-072 in patients with advanced/recurrent solid tumours or lymphomas	Thymoma Specific Safety Amendm	02/02/2018	35
17/SC/0122/AM02	PEANUT ALLERGY STUDY IN CHILDREN	Amendment 2 (protocol v2.4)	21/07/2017	29

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

Favourable opinion timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
15/SC/0075/AM05/1	The LOGIC 2 study in BRAF melanoma	BKM120 IB v.10Í¾ LGX818 IB v.8.	08/05/2017	14
16/SC/0453/AM02/1	Novel START (Novel Symbicort Turbuhaler Asthma Reliever Therapy)	SA02 a	11/07/2017	5
16/SC/0504/AM01/1	BETA3_LVH V1.0	Amendment 01 Re-submission	02/06/2017	13
17/SC/0122/AM02/1	PEANUT ALLERGY STUDY IN CHILDREN	Amendment 2 (protocol 2.4) - M	25/08/2017	3

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**
17/SC/0208	D+R Therapy rehabilitation study	22
17/SC/0265	Pharmalink NEF-203	22
18/SC/0182	Father's experiences of antenatal attachment v1	25

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

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**
17/SC/0315/AM02	Deep and Frequent Phenotyping	Substantial Amendment 1	13/02/2018	39

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