NHS
Health Research Authority

Research Ethics Service

South Central - Berkshire Research Ethics Committee

Annual Report

01 April 2017 - 31 March 2018

Part 1 – Committee Membership and Training

Name of REC:	South Central - Berkshire 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:	IRB Registered Phase 1 Studies in Healthy Volunteers Phase 1 Studies in Patients Qualitative Research Research Involving Adults Lacking Capacity Research Involving Children
Chair:	Mr David Carpenter
Vice-Chair:	Dr Mike Proven
Alternate Vice-Chair:	Ms Ann Quinn
REC Manager:	Mr Alex Martin (01/08/2017 – present) Sadie McKeown-Keegan (01/09/2016 – 31/07/2017)
REC Assistant:	Mr Wai Yeung (01/03/2017 – present) Arun Prathapan (01/03/2017 – 05/02/2018)
Committee Address:	Bristol REC Centre Whitefriars Level 3, Block B Lewins Mead Bristol BS1 2NT
Telephone:	020 7104 8057
Email:	nrescommittee.southcentral-berkshire@nhs.net

Chair’s overview of the past year:

South Central - Berkshire Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Mr David Carpenter	Social Scientist	Lay	01/11/2010	
Dr Mike Emanuel	Pharmaceutical Consultant	Lay	23/11/2009	
Mr Martin Hopkinson	Director of risk management services	Lay Plus	05/09/2017	
Mrs Liz Hunter	Retired Midwife and Clinical Governance Manager	Lay	16/01/2012	
Professor Ron King	Mathematician (Retired) Berkshire contact	Lay Plus	16/12/2016	15/06/2017
Dr Vandana Luthra	R&D Research Co-ordinator	Expert	01/09/2011	
Mr Daniel Charles Mace	Retired Corporate Lawyer	Lay Plus	10/03/2014	
Mr Richard Merewood	Director	Lay Plus	01/10/2011	
Mr Neil Thomas O'Kane	Aviation Safety Consultant	Lay Plus	11/03/2013	
Dr Joanne Philpot	Consultant Paediatrician	Expert	01/10/2011	
Dr Mike Proven	Coordinator for QA in Research	Lay Plus	01/09/2011	
Ms Ann Quinn	Social Worker	Expert	01/12/2011	
Dr Deborah Scholey	Regulatory Affairs Consultant	Lay	01/12/2015	
Mr Donald Scott-Collett	Lead Pharmacist for Elderly Care, Neuro-rehabilitation, Dermatology and Clinical Governance	Expert	05/11/2010	
Dr John Andrew Sutton	Medical Director	Expert	01/03/2014	
Ms Susan Tonks	Senior Research Support Associate	Expert	06/06/2017	
Mrs Helen Turner	Clinical Study Manager	Lay	01/01/2014	

South Central - Berkshire Research Ethics Committee: Deputy Members

Name	Profession	Status	Meeting date attended

South Central - Berkshire Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended

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

Name	Declaration of Interest	Date
Mr David Carpenter	I frequently act as an ethics adviser for DfID funded projects conducted by the University of Portsmouth. This is a form of consultancy. There are no conflicts of interest. I am a member of:The Rowans Hospice Ethics CommitteeThe British Psychological Society Ethics Committee Portsmouth Hospitals Trust Clinical Ethics Committee I am a member of a team undertaking research into the ethical review of social care research – commissioned by the HRA I undertake and support research in the University of Portsmouth as part of my academic role I provide informal support to the R&D team at Portsmouth Hospitals Trust – I also provide informal support to researchers in the Trust. I provide training in research ethics for the Association for Research Managers and Administrators	05/05/2017
Dr Mike Emanuel	Freelance consultant to Oragaenics INC - US pharmaceutical company Freelance consultant to Compass LTD - UK pharmaceutical company Freelance consultant to Pliant - US pharmaceutical company Pensioner and shareholder in Johnson and Johnson (and Jansen) Shareholder in Triumph Research Intelligence - clinical trial risk management organisation	09/05/2017
Mr Martin Hopkinson	Smith and Nephew, GSK, Vectrua Group shares. Married to Professor Jane Hopkinson (Cardiff University and Board member at Venllindre Trust) Daughter, Emily Hopkinson works for National Audit Office, involved in NHS healthcare work.	17/07/2017
Mrs Liz Hunter	None	16/05/2017
Dr Vandana Luthra	None	31/03/2018
Mr Daniel Charles Mace	Volunteer with Evolving Communities (Health Watch Wiltshire)	04/05/2017
Mr Richard Merewood	None	01/06/2017
Dr Joanne Philpot	None	16/05/2017
Dr Mike Proven	I am employed by the University of Reading. I work in the Academic and Governance Services department where my roles include management of the University's Research Ethics Committee. I am also the signatory 'on behalf of the University' where the University acts as the Research Governance Sponsor for HRA REC-reviewed research. As an active research-led university with Schools of Psychology, Food Science and Pharmacy, the University does frequently undertake research in collaboration with others that falls within the scope of HRA and HRA REC review.	01/06/2017

Dr Deborah Scholey	Director/Owner of Best Regulatory Consulting Ltd.See above. Best Regulatory Consulting is a pharmaceutical consultancy providing support for companies in drug development, but not directly involved in clinical research. There have been no changes in my professional status in the last 12 months	02/06/2017
Mr Donald Scott-Collett	Leaving Royal Berkshire NHS Foundation Trust to a new role at Berkshire Healthcare NHS Foundation Trust. Different role but maintaining profession as a pharmacist.	01/06/2017
Dr John Andrew Sutton	Small holding in a company called Tiziana.	25/06/2017
Ms Susan Tonks	None	13/06/2017

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

Month	Date	Number of Members Present at Meeting
April	18/04/2017	12
May	16/05/2017	9
June	20/06/2017	11
August	15/08/2017	11
September	19/09/2017	13
October	17/10/2017	12
November	21/11/2017	14
December	19/12/2017	14
February	20/02/2018	11

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	11/04/2017	3
May	09/05/2017	3
June	13/06/2017	3
August	09/08/2017	3
September	13/09/2017	3
October	11/10/2017	3
November	15/11/2017	3
December	13/12/2017	3
February	14/02/2018	3
March	14/03/2018	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	14/04/2017	2
April	21/04/2017	2
April	28/04/2017	2
May	05/05/2017	2
May	12/05/2017	2
May	19/05/2017	2
May	26/05/2017	2
June	02/06/2017	2
June	09/06/2017	2
June	16/06/2017	2
June	23/06/2017	2

June	30/06/2017	2
July	07/07/2017	2
July	14/07/2017	2
July	21/07/2017	2
July	28/07/2017	2
August	04/08/2017	2
August	11/08/2017	2
August	18/08/2017	2
August	25/08/2017	2
September	01/09/2017	2
September	08/09/2017	2
September	15/09/2017	2
September	22/09/2017	2
September	29/09/2017	2
October	06/10/2017	2
October	13/10/2017	2
October	27/10/2017	2
November	03/11/2017	2
November	10/11/2017	2
November	17/11/2017	2
November	24/11/2017	2
December	08/12/2017	2
December	15/12/2017	2
December	22/12/2017	2
December	29/12/2017	2
January	12/01/2018	2
January	19/01/2018	2
February	09/02/2018	2
February	16/02/2018	2
February	23/02/2018	2
March	02/03/2018	3
March	09/03/2018	2
March	16/03/2018	2
March	30/03/2018	2

46 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 David Carpenter	9
Dr Mike Emanuel	7
Mr Martin Hopkinson	4
Mrs Liz Hunter	8
Professor Ron King	3
Dr Vandana Luthra	6
Mr Daniel Charles Mace	8
Mr Richard Merewood	8
Mr Neil Thomas O'Kane	7
Dr Joanne Philpot	4
Dr Mike Proven	9
Ms Ann Quinn	7
Dr Deborah Scholey	5
Mr Donald Scott-Collett	6
Dr John Andrew Sutton	9
Ms Susan Tonks	5
Mrs Helen Turner	3

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

Name	Number of Meetings Attended
Mr David Carpenter	9
Dr Vandana Luthra	2
Mr Daniel Charles Mace	2
Mr Richard Merewood	6
Mr Neil Thomas O'Kane	1
Ms Ann Quinn	5
Dr John Andrew Sutton	1
Ms Susan Tonks	3
Mrs Helen Turner	1

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

Name	Number of Meetings Attended
Mr David Carpenter	43
Mr Daniel Charles Mace	2
Dr Mike Proven	45
Ms Ann Quinn	3

Training 01 April 2017 - 31 March 2018

Name of Member	Date	Event(s) attended
Mr David Carpenter	10/05/2017	Research & innovation conference 2017
Mr David Carpenter	03/06/2017	ERA-EDTA Congress
Mr David Carpenter	20/03/2018	Berkshire REC member Training Day
Dr Mike Emanuel	20/03/2018	Berkshire REC member Training Day
Mr Martin Hopkinson	20/03/2018	Berkshire REC member Training Day
Mrs Liz Hunter	20/03/2018	Berkshire REC member Training Day
Mr Daniel Charles Mace	20/03/2018	Berkshire REC member Training Day
Mr Richard Merewood	20/03/2018	Berkshire REC member Training Day
Mr Neil Thomas O'Kane	20/03/2018	Berkshire REC member Training Day
Dr Joanne Philpot	20/03/2018	Berkshire REC member Training Day
Dr Mike Proven	20/03/2018	Berkshire REC member Training Day
Ms Ann Quinn	20/03/2018	Berkshire REC member Training Day
Dr Deborah Scholey	20/03/2018	Berkshire REC member Training Day
Mr Donald Scott-Collett	20/03/2018	Berkshire REC member Training Day
Dr John Andrew Sutton	20/03/2018	Berkshire REC member Training Day
Ms Susan Tonks	20/03/2018	Berkshire REC member Training Day
Mrs Helen Turner	20/03/2018	Berkshire REC member 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	10	21.28
Phase 1	10	21.28
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	1	2.13
Others	26	55.32
Total Applications Reviewed	**47**	**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	3
Number of student applications reviewed	16
Number of paediatric applications reviewed	5
Number of device applications reviewed	1
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	9
Number of applications reviewed that are funded by the US DHHS	3
Number of qualitative applications reviewed	6

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	6	12.77
Favourable Opinion with Additional Conditions	32	68.09
Unfavourable Opinion	1	2.13
Provisional Opinion	8	17.02
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	**47**	**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	8	17.02
Further Information Favourable Opinion with Additional Conditions	0	0.00
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	6	12.77
Favourable Opinion with Additional Conditions	32	68.09
Unfavourable Opinion	1	2.13
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	**47**	**100**

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

Total Applications Reviewed	**16**

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

Number of applications made invalid by the REC Manager	1
Number of studies withdrawn prior to the meeting	2
Number of student applications reviewed	7
Number of paediatric applications reviewed	4
Number of device applications reviewed	1
Number of qualitative applications reviewed	4

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	5	31.25
Favourable Opinion with Additional Conditions	5	31.25
No Opinion transfer to full committee for review	2	12.50
Provisional Opinion	4	25.00
Unfavourable Opinion	0	0.00
Total	**16**	**100**

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

Average number of applications reviewed per full meeting	5.22
Number of completed applications for full ethical review	47
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	3
Number of completed applications over 40 days as a % of total	6.38%
Number of days taken to final decision – average (mean)	25

Number of completed proportionate review applications for ethical review	14
Number of completed proportionate review applications for ethical review over 21 days	1
Number of completed proportionate review applications over 21 days as a % of total	7.14%

Number of SSAs (non-Phase 1) reviewed	11
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	11
Number of completed applications for SSA review over 14 days	3
Number of completed applications for SSA review over 14 days as % of all Phase 1 SSAs	27.27%

Number of substantial amendments reviewed	137
Number of completed substantial amendments over 35 days	3
Number of completed substantial amendments over 35 days as a % of total substantial amendments	2.19%
Number of completed substantial amendments over 28 days	35
Number of completed substantial amendments over 28 days as a % of total substantial amendments	25.55%

Number of modified amendments reviewed	7
Number of completed modified amendments over 14 days	1
Number of completed modified amendments over 14 days as a % of total modified amendments	14.29%

Number of non substantial amendments received	146
Number of substantial amendments received for information	1
Number of substantial amendments received for new sites/PIs	12
Number of annual progress reports received	38
Number of safety reports received	41
Number of Serious Adverse Events received	0

Number of final reports received	2

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/0226	Safety and Pharmacokinetics of PL265 in healthy males (QCL117989)	45
17/SC/0243	Physiotherapy for people with dementia who fracture their hip	40
17/SC/0250	LUSTRO: Clinical Assessment Study of Crigler-Najjar Syndrome	35
17/SC/0300	INVICTUS	20
17/SC/0306	LEVI-04 - first doses in humans; version 1	21
17/SC/0417	Ketone drink after cardiac arrest pilot v1	22
17/SC/0626	The EXHALE 1A Study	48
17/SC/0679	The effects of focus of attention on sit to stand	47

Further Information Favourable Opinion with Additional Conditions		
REC Reference	**Title**	**Number of Days on Clock**

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

Favourable Opinion with Standard Conditions		
REC Reference	**Title**	**Number of Days on Clock**
17/SC/0193	Effect of rifabutin on oral cabotegravir in healthy subjects	24
17/SC/0227	Phase 1 Safety, Tolerability, PK and Pharmacological study QCL117938	20
17/SC/0288	Safety of MVA-NP+M1,manufactured on the AGE1.CR.pIX cell line - FLU008	20
17/SC/0429	International congenital cardiac CT practice database v.1	12
17/SC/0616	Dose-Finding Study of Nemiralisib	27
17/SC/0655	Method of drinking and risk of aspiration assessed by videofluoroscopy	28

Favourable Opinion with Additional Conditions		
REC Reference	**Title**	**Number of Days on Clock**
17/SC/0152	NETS2HD-Six year outcomes for children with Hirschsprung's Disease	20
17/SC/0163	A Safety and Efficacy Study of ChAdOx1 LS2 (VAC067)	16

17/SC/0171	The experience of White British fathers providing care to a son/daughter with a diagnosis of psychosis: An exploration of fathers' accounts of coping.	20
17/SC/0192	Perspectives on End of Life Care: Caring for the Muslim patient	18
17/SC/0199	Study to assess brain occupancy of Ïƒ1 receptors following MR309 dosing	10
17/SC/0252	ARO-012 CrenoGIST - Version 2.1	27
17/SC/0254	ELSA - Healthy Cognitive Ageing Project	20
17/SC/0284	The General Breathing Record Study	20
17/SC/0296	Improving diagnosis and support for younger people with dementia	20
17/SC/0367	IDENtiFy: Supporting the identity needs of frail older people	22
17/SC/0369	NEPTUNES	22
17/SC/0391	H4RT	22
17/SC/0462	Developing a vaccine to prevent RSV	23
17/SC/0469	Safety and effects of ICI 118,551 in mild-to-moderate asthmatics; v1	23
17/SC/0472	MobilisAtion in Critical care units Across Wessex (MACAW)	23
17/SC/0476	MERIT Trial	23
17/SC/0496	Phase 1 Dose-Escalation Study of IV Administered HBI-3000 (QCL117964)	23
17/SC/0530	Body image in people with fears about others	22
17/SC/0535	Phase 1 PK and safety study of low-dose Naltrexone (QCL117809)	21
17/SC/0538	Effect of vasospasm on non-invasive intracranial pressure measurement.	22
17/SC/0588	The English Longitudinal Study of Ageing - Wave 9	28
17/SC/0589	ADME study for [14C]-AK0529 in Healthy Male Subjects (QCL117992)	33
17/SC/0615	VIOLETTE	28
17/SC/0619	Living well with Heart Failure	28
17/SC/0620	Measuring the Workload and Impact of Caring: Stroke ESD	28
17/SC/0625	Risk enablement and mobility on an acute medical unit V1.0	28
17/SC/0649	Brain networks underlying body perception-related pain	28
17/SC/0657	A safety study of AL-794	28
18/SC/0034	Exploring personal experiences of EMDR therapy within secure services.	28
18/SC/0037	RO5541007 in lymphoma	28
18/SC/0043	The qualitative development of ICIQ modules	28
18/SC/0089	Comparing CGM with SMBG in gestational diabetes	27

Unfavourable Opinion		
REC Reference	**Title**	**Number of Days on Clock**
18/SC/0033	Physical based leisure activities following childhood ABI	28

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**

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/0291	Define PCI	18
17/SC/0480	Paediatric dietetics videoconsultation study :Version 1.0	11
17/SC/0567	Comparing the Effects of Ketamine and Lidocaine	18

Further Information Favourable Opinion with Additional Conditions		
REC Reference	**Title**	**Number of Days on Clock**

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

Favourable Opinion with Standard Conditions		
REC Reference	**Title**	**Number of Days on Clock**
17/SC/0246	Children's Feedback in Revalidation	22
17/SC/0251	OBSERVER - a new infection diagnostic	13
17/SC/0541	Analysis of facial muscles movements V02	17
18/SC/0144	The PRIMM Study	16
18/SC/0145	Young peoples experiences of peer training within a health setting	19

Favourable Opinion with Additional Conditions		
REC Reference	**Title**	**Number of Days on Clock**
17/SC/0170	PEPSIN	12
17/SC/0421	Sleep & Mood in Stroke Rehab	11
17/SC/0485	REMIX	14
17/SC/0562	(duplicate) Lifestyle changes following head and neck cancer treatment	16
17/SC/0659	Activity & sedentary behaviour in channelopathy and Myotonic Dystrophy	9

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

Provisional Opinion		
REC Reference	**Title**	**Number of Days on Clock**
17/SC/0187	Post-traumatic Stress Disorder in traumatic upper-limb injury	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**
07/H0607/74/AM15	The placenta and pre-eclampsia	AM15	17/10/2017	34
07/Q1607/38/AM03	Role of oxidative stress in the human myocardium	Substantial amendment 21	24/01/2018	25
08/H0505/78/AM07	Genomic Advances in Sepsis (GAinS) Version 1.1	Substantial amendment 4	15/02/2018	18
09/H0505/73/AM15	Dominantly Inherited Alzheimer Network (DIAN)	Amendment 11 (AM15)	03/07/2017	23
09/H0505/94/AM17	BG00012 Monotherapy Safety and Efficacy Extension Study in MS	Substantial Amendment - Protoc	27/03/2017	16
09/H0505/94/AM18	BG00012 Monotherapy Safety and Efficacy Extension Study in MS	Change in PI	25/07/2017	32
09/H0505/94/AM19	BG00012 Monotherapy Safety and Efficacy Extension Study in MS	9	24/10/2017	8
10/H0505/108/AM48	The CAROLINA Trial. Final Protocol, Version 1, 17 Aug 2010	AM48	04/04/2017	26
10/H0505/85/AM29	High risk type 1 diabetes cohort – ADDRESS-2	SA5	15/02/2018	25
11/SC/0014/AM03	GO Target 01. Version 1	Version 4.0, 18 October 2017	18/10/2017	35
11/SC/0488/AM09	Xenon lung imaging in COPD: a COPD Cohort sub-study Version 1.0	7	23/05/2017	19
12/SC/0139/AM32	SafeHer: Safety study with subcutaneous trastuzumab in breast cancer	26 (AM32)	03/05/2017	21
12/SC/0139/AM34	SafeHer: Safety study with subcutaneous trastuzumab in breast cancer	27	02/02/2018	25
12/SC/0653/AM01	Practice Nurse influence on the uptake of the MMR vaccine	1	05/06/2017	31
13/SC/0206/AM09	(May) ACTIB	6	16/06/2017	10
13/SC/0264/AM22	Nivolumab or Nivolumab + Ipilimumab vs Ipilimumab in advanced melanoma	19	30/08/2017	10
13/SC/0264/AM23	Nivolumab or Nivolumab + Ipilimumab vs Ipilimumab in advanced melanoma	20	27/11/2017	36
13/SC/0264/AM24	Nivolumab or Nivolumab + Ipilimumab vs Ipilimumab in advanced melanoma	21	30/01/2018	31

13/SC/0286/AM15	BAN2401-G000-201 BAN2401 in Early Alzheimer's Disease	9	12/07/2017	13
13/SC/0286/AM16	BAN2401-G000-201 BAN2401 in Early Alzheimer's Disease	10	04/10/2017	6
13/SC/0473/AM03	Hyperpolarized xenon gas MR imaging in NSCLC Radiotherapy	AM03	24/04/2017	19
13/SC/0535/AM21	DIAN-TU-001: Ph. II/III Randomized,Double-blind,Placebo in Alzheimer's	14	05/12/2017	29
13/SC/0602/AM02	Ultrastructural and molecular studies in angiogenesis and permeability	2	17/08/2017	27
13/SC/0636/AM05	Nasal Fentanyl and Buccal Midazolam for Dying Patients	AM05	19/09/2017	15
14/SC/0028/AM06	Nivolumab in Relapsed or Refractory Follicular Lymphoma	06	26/04/2017	29
14/SC/0028/AM07	Nivolumab in Relapsed or Refractory Follicular Lymphoma	07	23/08/2017	28
14/SC/0028/AM08	Nivolumab in Relapsed or Refractory Follicular Lymphoma	8	31/01/2018	28
14/SC/0074/AM04	Mechanisms underlying limb apraxia	3	04/09/2017	30
14/SC/0131/AM06	Affecting Problem Solving and Reasoning	6	12/07/2017	14
14/SC/0199/AM11	CheckMate 141: CHECKpoint pathway and nivoluMAb clinical Trial Evaluat	10	06/09/2017	13
14/SC/0199/AM12	CheckMate 141: CHECKpoint pathway and nivoluMAb clinical Trial Evaluat	11	31/01/2018	29
14/SC/0249/AM15	Symbicort in mild asthma	4	05/05/2017	16
14/SC/1206/AM10	ElaTION	4	27/07/2017	30
14/SC/1366/AM19	Therasphere treatment of liver metastases from colorectal cancer	4	02/01/2018	10
14/SC/1437/AM02	Extracellular Vesicles At Rest and Stress – EVAREST Study	AM02	10/04/2017	22
15/SC/0003/AM08	A Study on the Effect of E7438 in Patients with Advanced Tumors	7	03/04/2017	18
15/SC/0003/AM09	A Study on the Effect of E7438 in Patients with Advanced Tumors	7	21/04/2017	27
15/SC/0003/AM10	A Study on the Effect of E7438 in Patients with Advanced Tumors	9	26/09/2017	13
15/SC/0285/AM02	Measuring and comparing breath acetone and blood ketones	2	23/05/2017	20
15/SC/0295/AM10	D0816C00012 (ORZORA), Open Label, Phase IV, Ovarian Cancer (Olaparib)	9	25/04/2017	22
15/SC/0295/AM11	D0816C00012 (ORZORA), Open Label, Phase IV, Ovarian Cancer (Olaparib)	10	25/05/2017	18
15/SC/0295/AM13	D0816C00012 (ORZORA), Open Label, Phase IV, Ovarian Cancer (Olaparib)	SA12	12/02/2018	28

15/SC/0306/AM06	RANGE - Ramucirumab in Advanced Bladder Cancer (JVDC Study)	05(AM06)	08/05/2017	25
15/SC/0355/AM09	Baby Vaccine Study (Sched3)	5	25/04/2017	18
15/SC/0355/AM11	Baby Vaccine Study (Sched3)	6	12/01/2018	17
15/SC/0355/AM12	Baby Vaccine Study (Sched3)	Substantial amendment 7	28/02/2018	23
15/SC/0359/AM08	A Phase 3 Veliparib plus Chemotherapy study in Ovarian Cancer	4 (AM08)	24/04/2017	19
15/SC/0359/AM09	A Phase 3 Veliparib plus Chemotherapy study in Ovarian Cancer	AM09	09/08/2017	17
15/SC/0359/AM10	A Phase 3 Veliparib plus Chemotherapy study in Ovarian Cancer	Veliparib IB Ed 11 Addendum	03/11/2017	25
15/SC/0437/AM04	Fluciclovine (18F) PET/CT in biochemical recurrence of prostate cancer	EC SA-03	28/02/2018	6
15/SC/0456/AM09	MPDL3280A-Early phase study in patients with solid tumours	5	11/05/2017	14
15/SC/0456/AM11	MPDL3280A-Early phase study in patients with solid tumours	6	14/07/2017	15
15/SC/0456/AM12	MPDL3280A-Early phase study in patients with solid tumours	7	20/11/2017	42
15/SC/0456/AM13	MPDL3280A-Early phase study in patients with solid tumours	SA #08	21/02/2018	20
15/SC/0470/AM10	Abatacept-Methotrexate combo vs Methotrexate in adults with early RA	9	02/01/2018	10
15/SC/0475/AM14	CA209-227 - Nivolumab or nivolumab plus ipilimumab vs SOC in NSCLC	11	14/08/2017	31
15/SC/0475/AM15	CA209-227 - Nivolumab or nivolumab plus ipilimumab vs SOC in NSCLC	12	18/12/2017	13
15/SC/0521/AM14	Phase 2 study with nab-Paclitaxel in patients with NSCLC	7	15/06/2017	15
15/SC/0553/AM03	Oxford Telehealth Qualitative Study version 1.2	Substantial Amendment 1	22/03/2017	16
15/SC/0553/AM06	Oxford Telehealth Qualitative Study version 1.2	2	11/12/2017	23
15/SC/0632/AM03	Acoustic emission assessment of knee joint degeneration	1	24/01/2018	30
15/SC/0676/AM04	ANNOUNCE - Olaratumab and Doxorubicin in Soft Tissue Sarcoma (JDGJ)		31/03/2017	32
15/SC/0676/AM05	ANNOUNCE - Olaratumab and Doxorubicin in Soft Tissue Sarcoma (JDGJ)	5	22/08/2017	8
15/SC/0685/AM05	Phase 1 Study in Patients with Advanced Systemic Mastocytosis	4	30/03/2017	32
15/SC/0685/AM06	Phase 1 Study in Patients with Advanced Systemic	05 (AM06)	08/05/2017	31

	Mastocytosis			
15/SC/0685/AM07	Phase 1 Study in Patients with Advanced Systemic Mastocytosis	6	09/06/2017	17
15/SC/0685/AM08	Phase 1 Study in Patients with Advanced Systemic Mastocytosis	SA07 (AM08)	06/07/2017	20
15/SC/0685/AM09	Phase 1 Study in Patients with Advanced Systemic Mastocytosis	8	15/09/2017	6
15/SC/0685/AM10	Phase 1 Study in Patients with Advanced Systemic Mastocytosis	9	13/12/2017	20
15/SC/0694/AM04	KRN23 in Adults with X-linked Hypophosphatemia (XLH) - (Final Version)	3	06/06/2017	31
15/SC/0694/AM05	KRN23 in Adults with X-linked Hypophosphatemia (XLH) - (Final Version)	4	02/11/2017	29
15/SC/0694/AM06	KRN23 in Adults with X-linked Hypophosphatemia (XLH) - (Final Version)	#7 (Protocol Amendment 5, 26 J	01/03/2018	12
15/SC/0724/AM05	PK & Scintigraphic Assessment of Colistimethate Sodium (QCL117619)	5	26/09/2017	12
16/SC/0089/AM03	The REST Study	Amendment 3	16/03/2017	28
16/SC/0149/AM02	Evaluation of PIPEs in Prisons and Approved Premises	1	07/06/2017	22
16/SC/0151/AM04	Endometrial Scratch Trial	4	22/07/2017	33
16/SC/0151/AM05	Endometrial Scratch Trial	AM05	13/11/2017	35
16/SC/0152/AM07	Simvastatin to prevent complications after oesophagectomy v1.0	03	09/04/2017	30
16/SC/0152/AM09	Simvastatin to prevent complications after oesophagectomy v1.0	10	12/09/2017	9
16/SC/0152/AM10	Simvastatin to prevent complications after oesophagectomy v1.0	11	03/01/2018	26
16/SC/0152/AM11	Simvastatin to prevent complications after oesophagectomy v1.0	12	25/01/2018	28
16/SC/0152/AM12	Simvastatin to prevent complications after oesophagectomy v1.0	Amendment 13	16/02/2018	24
16/SC/0256/AM07	Open-Label Extn Study, Safety & Tolerability RVT-101 in AD patients V1	AM07	27/11/2017	30
16/SC/0261/AM06	A Safety and Efficacy Study of R21 + ChAd63/MVA ME-TRAP (VAC065)	5	27/04/2017	27
16/SC/0261/AM07	A Safety and Efficacy Study of R21 + ChAd63/MVA ME-TRAP	6	17/05/2017	9

	(VAC065)			
16/SC/0261/AM08	A Safety and Efficacy Study of R21 + ChAd63/MVA ME-TRAP (VAC065)	7	08/09/2017	15
16/SC/0341/AM12	Phase IIA trial of EZH2 inhibition in mesothelioma	3	15/12/2017	19
16/SC/0432/AM02	WOLVES	SA2	06/02/2018	18
16/SC/0484/AM08	CA209-651: 1st Line Nivo & Ipi vs EXTREME in HNSCC	5	15/09/2017	29
16/SC/0484/AM09	CA209-651: 1st Line Nivo & Ipi vs EXTREME in HNSCC	6	11/01/2018	18
16/SC/0494/AM03	Triple vs dual therapy in inadequately controlled asthma		19/04/2017	12
16/SC/0494/AM04	Triple vs dual therapy in inadequately controlled asthma	4	03/05/2017	20
16/SC/0494/AM05	Triple vs dual therapy in inadequately controlled asthma	SA05 (AM05)	21/06/2017	16
16/SC/0494/AM07	Triple vs dual therapy in inadequately controlled asthma	6	07/07/2017	19
16/SC/0494/AM09	Triple vs dual therapy in inadequately controlled asthma	7	05/09/2017	28
16/SC/0494/AM11	Triple vs dual therapy in inadequately controlled asthma	8	10/01/2018	19
16/SC/0555/AM02	Safety and immunogenicity of novel routes of ChAd63 ME-TRAP (VAC064)	2	02/11/2017	28
16/SC/0555/AM03	Safety and immunogenicity of novel routes of ChAd63 ME-TRAP (VAC064)	3	18/12/2017	13
16/SC/0623/AM01	NURTuRE-CKD	1	11/05/2017	14
16/SC/0657/AM01	ACCEPT	1	12/06/2017	18
16/SC/0657/AM03	ACCEPT	AM3	07/11/2017	33
16/SC/0676/AM02	Phase 2 study GS-9674 in Primary Sclerosing Cholangitis w/o Cirrohsis	2	21/07/2017	27
16/SC/0676/AM04	Phase 2 study GS-9674 in Primary Sclerosing Cholangitis w/o Cirrohsis	3	01/09/2017	20
16/SC/0677/AM02	Phase 2 study GS-9674 in Primary Biliary Cholangitis without cirrhosis	2	21/07/2017	27
16/SC/0677/AM04	Phase 2 study GS-9674 in Primary Biliary Cholangitis without cirrhosis	3	04/09/2017	16
17/SC/0068/AM02	MEasuring TemperatuRe In Children: METRIC	2	02/11/2017	40
17/SC/0070/AM02	Prepare for Kidney Care	1 (AM02)	27/06/2017	7
17/SC/0070/AM03	Prepare for Kidney Care	2	12/09/2017	8
17/SC/0110/AM01	Point-of-care testing for respiratory viruses in critical care v1.0	AM01	10/05/2017	15
17/SC/0119/AM01	Experiences of receiving an adult diagnosis for Cystic Fibrosis (V1)	1	24/08/2017	14
17/SC/0130/AM01	Estrogen Receptor Positive Breast Cancer	1	24/05/2017	27
17/SC/0152/AM06	NETS2HD-Six year outcomes for children with Hirschsprung's	5	29/01/2018	31

	Disease			
17/SC/0163/AM01	A Safety and Efficacy Study of ChAdOx1 LS2 (VAC067)	1	24/05/2017	19
17/SC/0163/AM02	A Safety and Efficacy Study of ChAdOx1 LS2 (VAC067)	SA002 (AM02)	14/06/2017	11
17/SC/0170/AM01	PEPSIN	1	24/07/2017	32
17/SC/0199/AM01	Study to assess brain occupancy of Ïf1 receptors following MR309 dosing	1	05/05/2017	18
17/SC/0227/AM01	Phase 1 Safety, Tolerability, PK and Pharmacological study QCL117938	SA01	01/03/2018	11
17/SC/0250/AM02	LUSTRO: Clinical Assessment Study of Crigler-Najjar Syndrome	3	20/12/2017	12
17/SC/0284/AM01	The General Breathing Record Study	AM01 12 July 2017	12/07/2017	35
17/SC/0291/AM01	Define PCI	1	10/08/2017	17
17/SC/0300/AM01	INVICTUS	1	22/08/2017	23
17/SC/0300/AM02	INVICTUS	2	06/09/2017	12
17/SC/0300/AM05	INVICTUS	3	21/12/2017	12
17/SC/0306/AM02	LEVI-04 - first doses in humans; version 1	SA2	14/03/2018	13
17/SC/0369/AM02	NEPTUNES	Amendment 2	23/02/2018	18
17/SC/0391/AM01	H4RT	1	27/10/2017	6
17/SC/0462/AM01	Developing a vaccine to prevent RSV	1	03/10/2017	6
17/SC/0462/AM04	Developing a vaccine to prevent RSV	2	01/11/2017	34
17/SC/0462/AM07	Developing a vaccine to prevent RSV	3	25/01/2018	34
17/SC/0469/AM01	Safety and effects of ICI 118,551 in mild-to-moderate asthmatics; v1	2	17/10/2017	34
17/SC/0615/AM03	VIOLETTE	3.0	19/02/2018	21
17/SC/0616/AM02	Dose-Finding Study of Nemiralisib	SA02/06Mar2018	06/03/2018	7

Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
13/SC/0535/AM20	DIAN-TU-001: Ph. II/III Randomized,Double-blind,Placebo in Alzheimer's	13	20/09/2017	29
15/SC/0475/AM16	CA209-227 - Nivolumab or nivolumab plus ipilimumab vs SOC in NSCLC	Substantial amendmment dated 2	27/02/2018	28
16/SC/0341/AM08	Phase IIA trial of EZH2 inhibition in mesothelioma	AM08	15/05/2017	28

17/SC/0250/AM01	LUSTRO: Clinical Assessment Study of Crigler-Najjar Syndrome	1	10/08/2017	33
17/SC/0306/AM01	LEVI-04 - first doses in humans; version 1	1	22/01/2018	30

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/0535/AM20/1	DIAN-TU-001: Ph. II/III Randomized,Double-blind,Placebo in Alzheimer's	13	29/11/2017	13
15/SC/0087/AM02/1	TUMS study - version 1.0	1.1	12/07/2017	8
16/SC/0341/AM08/2	Phase IIA trial of EZH2 inhibition in mesothelioma	2	21/07/2017	8
17/SC/0250/AM01/2	LUSTRO: Clinical Assessment Study of Crigler-Najjar Syndrome	2	19/10/2017	6
17/SC/0306/AM01/1	LEVI-04 - first doses in humans; version 1	Substantial Amendment 1 (modif	06/03/2018	7

Unfavourable opinion timeline				
Amendment REC Reference	**Title**	**Version**	**Date**	**Number of Days on Clock**
16/SC/0341/AM08/1	Phase IIA trial of EZH2 inhibition in mesothelioma	8	20/06/2017	17
17/SC/0250/AM01/1	LUSTRO: Clinical Assessment Study of Crigler-Najjar Syndrome	1	28/09/2017	9

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/0246	Children's Feedback in Revalidation	22

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**
17/SC/0247	An exploratory study in health	37
17/SC/0261	A Phase I/II Study to assess t	28
17/SC/0559	A Two Part, Sequential, Open L	74

Substantial Amendments over 35 day timeline				
Amendment REC Reference	**Title**	**Version**	**Date**	**Number of Days on Clock**
13/SC/0264/AM23	Nivolumab or Nivolumab + Ipilimumab vs Ipilimumab in advanced melanoma	20	27/11/2017	36
15/SC/0456/AM12	MPDL3280A-Early phase study in patients with solid tumours	7	20/11/2017	42
17/SC/0068/AM02	MEasuring TemperatuRe In Children: METRIC	2	02/11/2017	40

Modified Amendments over 14 day timeline				
Amendment REC Reference	**Title**	**Version**	**Date**	**Number of Days on Clock**
16/SC/0341/AM08/1	Phase IIA trial of EZH2 inhibition in mesothelioma	8	20/06/2017	17