NHS
Health Research Authority

Research Ethics Service

South Central - Berkshire Research Ethics Committee

Annual Report

01 April 2016 - 31 March 2017

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:	Claudia Bywater (01/04/2016 – 31/12/2016) Sadie McKeown-Keegan (01/01/2017 – present)
REC Assistant:	Stephan Ramey (01/04/2016 – 31/12/2016) Mr Arun Prathapan (01/01/2017 – present)
Committee Address:	Bristol REC Centre Whitefriars Level 3, Block B Lewins Mead Bristol BS1 2NT
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Chair's overview of the past year:

A good year all round. Membership has been relatively stable though it would be helpful if the Committee could have a better skills balance. At the moment we have two thirds lay and one third expert rather than, ideally, the other way round. Fortunately several of the lay members have considerable relevant expertise. There is an ongoing need for at least one more practicing clinician.

It was unfortunate that Claudia had such a short term of office as REC Manager but I am pleased about her promotion. Sadie has been an excellent replacement but, again, it is a pity that she will be seconded from her post shortly. Whilst the staff turnover is not ideal I am pleased that it is due to new opportunities being provided. I have been assured on several occasions that managers enjoy working with Berkshire REC; this is very pleasing. Excellent teamwork has resulted in what I believe to be an excellent service to researchers and the wider research community.

The REC's performance data are good – breaching of timelines is very rare and always due to very unusual circumstances. I am particularly pleased about our sustained position in providing two thirds favourable decisions at full review and an even greater proportion at proportionate review. This position is the result of extremely diligent members who identify and specify ethically necessary changes to protocols.

The success of this year owes much to the strengths of REC members, good central support from the Bristol office and the strong strategic management of the HRA.

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	
Mrs Liz Hunter	Retired Midwife and Clinical Governance Manager	Lay	16/01/2012	
Professor Ron King	Mathematician (Retired)	Lay Plus	16/12/2016	
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	
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	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. The Rowans Hospice Ethics Committee The British Psychological Society Ethics Committee Portsmouth Hospitals Trust Clinical Ethics Member of a team undertaking research into the ethical review of social care research – commissioned by the HRA Undertakes and supports research in the University of Portsmouth as part of my academic role Provides informal support to the R&D team at Portsmouth Hospitals Trust Provides informal support to researchers in the Trust. Provides training in research ethics for the Association for Research Managers and Administrators	31/03/2017
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	31/03/2017
Mrs Liz Hunter	None	31/03/2017
Professor Ron King	None	31/03/2017
Dr Vandana Luthra	None	31/03/2017
Mr Daniel Charles Mace	Volunteer with Evolving Communities (Health Watch Wiltshire)	31/03/2017
Mr Richard Merewood	None	31/03/2017
Mr Neil Thomas O'Kane	Elected governor of Berkshire NHS foundation Trust	24/05/2016
Dr Joanne Philpot	None	31/03/2017
Dr Mike Proven	Employed by the University of Reading in the Academic and Governance Services department where roles include management of the University's Research Ethics Committee. 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	31/03/2017

	of HRA and HRA REC review.	
Ms Ann Quinn	None	20/09/2016
Dr Deborah Scholey	Director/Owner of Best Regulatory Consulting Ltd, Best Regulatory Consulting is a pharmaceutical consultancy providing support for companies in drug development, but not directly involved in clinical research	31/03/2017
Mr Donald Scott-Collett	Working for the NHS in the capacity of a Lead Specialist Pharmacist for Elderly Care, Stroke, Neurology, Neuro-rehab, Dermatology and clinical governance.	31/03/2017
Dr John Andrew Sutton	Previously a medical director for Regen Therapeutics that had a promising compound for Alzheimer's Dementia called Colostriin. Also rights to a new use of zolpidem, the well-known sedative, in reversing brain damage. However, Regen ran out of funds and these essential treatments are in limbo.	31/03/2017
Mrs Helen Turner	Positions, including directorships, non-executive directorships and consultancies, whether paid or unpaid, help in private companies involved in or possibly seeking to be involved in the conduct of research: Clinical Study Manager, Cancer Research UK (current employment)	31/03/2017

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

Month	Date	Number of Members Present at Meeting
April	19/04/2016	11
May	17/05/2016	11
June	21/06/2016	11
August	16/08/2016	10
September	20/09/2016	9
November	15/11/2016	11
December	20/12/2016	11
February	21/02/2017	12
March	21/03/2017	12

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	11/04/2016	3
May	11/05/2016	3
June	13/06/2016	3
July	13/07/2016	3
August	10/08/2016	3
September	12/09/2016	3
October	11/10/2016	3
November	10/11/2016	3
December	13/12/2016	3
January	10/01/2017	3
February	07/02/2017	3
March	07/03/2017	3

12 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	08/04/2016	2
April	15/04/2016	2
April	22/04/2016	2
April	29/04/2016	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	10/06/2016	2
June	17/06/2016	2
June	24/06/2016	2
July	01/07/2016	2
July	08/07/2016	2
July	22/07/2016	2
July	29/07/2016	2
August	05/08/2016	2
August	12/08/2016	2
August	19/08/2016	2
August	26/08/2016	2
September	02/09/2016	2
September	09/09/2016	2
September	16/09/2016	2
September	23/09/2016	2
September	26/09/2016	4
September	30/09/2016	2
October	07/10/2016	2
October	14/10/2016	2
October	21/10/2016	2
October	28/10/2016	2
November	04/11/2016	2
November	11/11/2016	2
November	18/11/2016	2
November	25/11/2016	2
December	09/12/2016	2
December	16/12/2016	2
December	30/12/2016	2
January	13/01/2017	2
January	27/01/2017	2
February	03/02/2017	2
February	10/02/2017	2
February	17/02/2017	2
February	24/02/2017	2
March	03/03/2017	2
March	17/03/2017	2
March	24/03/2017	2
March	31/03/2017	2

48 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 David Carpenter	9
Dr Mike Emanuel	7
Mrs Liz Hunter	7
Professor Ron King	2
Dr Vandana Luthra	7
Mr Daniel Charles Mace	6
Mr Richard Merewood	8
Mr Neil Thomas O'Kane	4
Dr Joanne Philpot	6
Dr Mike Proven	7
Ms Ann Quinn	8
Dr Deborah Scholey	8
Mr Donald Scott-Collett	8
Dr John Andrew Sutton	8
Mrs Helen Turner	3

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

Name	Number of Meetings Attended
Mr David Carpenter	12
Dr Vandana Luthra	5
Mr Daniel Charles Mace	1
Mr Richard Merewood	6
Mr Neil Thomas O'Kane	4
Ms Ann Quinn	6
Dr John Andrew Sutton	1
Dr Andrew Sutton	1

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

Name	Number of Meetings Attended
Mr David Carpenter	48
Dr Mike Emanuel	1
Mr Daniel Charles Mace	1
Dr Mike Proven	47
Ms Ann Quinn	1

Training 01 April 2016 - 31 March 2017

Name of Member	Date	Event(s) attended
Mr David Carpenter	02/06/2016	NREAP / REC Chairs' Network Meeting: South Central
Mr David Carpenter	18/10/2016	Joint Berkshire Training Day
Mr David Carpenter	16/11/2016	Equality and Diversity
Dr Mike Emanuel	16/09/2016	Equality and Diversity
Mrs Liz Hunter	18/10/2016	Joint Berkshire Training Day
Mr Daniel Charles Mace	18/10/2016	Joint Berkshire Training Day
Mr Daniel Charles Mace	24/02/2017	Local Training - Bristol REC
Mr Richard Merewood	18/10/2016	Joint Berkshire Training Day
Mr Neil Thomas O'Kane	18/10/2016	Joint Berkshire Training Day
Dr Joanne Philpot	18/10/2016	Joint Berkshire Training Day
Dr Mike Proven	18/10/2016	Joint Berkshire Training Day
Ms Ann Quinn	18/10/2016	Joint Berkshire Training Day
Ms Ann Quinn	09/11/2016	Training - Training for New REC Chairs
Dr Deborah Scholey	18/10/2016	Joint Berkshire Training Day
Dr Deborah Scholey	16/11/2016	Equality and Diversity
Dr Deborah Scholey	18/11/2016	Online Induction
Mr Donald Scott-Collett	18/10/2016	Joint Berkshire Training Day
Dr John Andrew Sutton	18/10/2016	Joint Berkshire 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	13	27.66
Phase 1	6	12.77
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	1	2.13
Others	27	57.45
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	0
Number of student applications reviewed	9
Number of paediatric applications reviewed	8
Number of device applications reviewed	2
Number of prisoner applications reviewed	1
Number of applications involving adults unable consent reviewed	6
Number of applications reviewed that are funded by the US DHHS	3
Number of qualitative applications reviewed	3

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	4	8.51
Favourable Opinion with Additional Conditions	27	57.45
Unfavourable Opinion	3	6.38
Provisional Opinion	13	27.66
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	11	23.40
Further Information Favourable Opinion with Additional Conditions	0	0.00
Further Information Unfavourable Opinion	1	2.13
Favourable Opinion with Standard Conditions	4	8.51
Favourable Opinion with Additional Conditions	26	55.32
Unfavourable Opinion	3	6.38
Provisional Opinion	0	0.00
Provisional Opinion Pending Consultation with Referee	0	0.00
Further Information response not complete	1	2.13
No decision entered on system	0	0.00
Number of studies withdrawn after the meeting	1	2.13
Total	**47**	**100**

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

Total Applications Reviewed	**28**

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

Number of applications made invalid by the REC Manager	1
Number of studies withdrawn prior to the meeting	1
Number of student applications reviewed	15
Number of paediatric applications reviewed	5
Number of device applications reviewed	1
Number of qualitative applications reviewed	9

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	8	28.57
Favourable Opinion with Additional Conditions	12	42.86
No Opinion transfer to full committee for review	2	7.14
Provisional Opinion	5	17.86
Unfavourable Opinion	1	3.57
Total	**28**	**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	46
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	8.51%
Number of days taken to final decision – average (mean)	29

Number of completed proportionate review applications for ethical review	26
Number of completed proportionate review applications for ethical review over 14 days (Please note, the timeline for th review of PR applications was extended from 14 to 21 calendar days in December 2016)	1
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	3.85%

Number of SSAs (non-Phase 1) reviewed	22
Number of completed applications for SSA review over 25 days	4
Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs	18.18%

Number of SSAs (Phase 1) reviewed	7
Number of completed applications for SSA review over 14 days	0
Number of completed applications for SSA review over 14 days as % of all Phase 1 SSAs	0.00%

Number of substantial amendments reviewed	140
Number of completed substantial amendments over 35 days	0
Number of completed substantial amendments over 35 days as a % of total substantial amendments	0.00%
Number of completed substantial amendments over 28 days	18
Number of completed substantial amendments over 28 days as a % of total substantial amendments	12.86%

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	130

Number of substantial amendments received for information	1
Number of substantial amendments received for new sites/PIs	28
Number of annual progress reports received	33
Number of safety reports received	26
Number of Serious Adverse Events received	2
Number of final reports received	7

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/0198	Biomarkers copeptin and high sensitive troponin versus standard care	28
16/SC/0215	MOCA Version 1.0	29
16/SC/0341	Phase IIA trial of EZH2 inhibition in mesothelioma	35
16/SC/0342	Probing the Neural Basis of Visual Working Memory in Early Development	37
16/SC/0494	Triple vs dual therapy in inadequately controlled asthma	49
16/SC/0588	v0.2 Fitting of artificial eyes in children with retinoblastoma	56
16/SC/0614	A feasibility study for an asthma self-management intervention	37
16/SC/0617	Randomised Pilot Trial of Oxygen Targets in PICU (Oxy-PICU) v1.0	34
16/SC/0646	MISSION ABC	31
17/SC/0070	Prepare for Kidney Care	60
17/SC/0097	An ethnography of emotion regulation within cardiac rehabilitation (1)	36

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**
16/SC/0442	CL04041023 - Clinical Rheumatoid Arthritis Development for Olokizumab	39

Favourable Opinion with Standard Conditions		
REC Reference	**Title**	**Number of Days on Clock**
16/SC/0262	NFPP OnLINE Proof of Concept	22
16/SC/0555	Safety and immunogenicity of novel routes of ChAd63 ME-TRAP (VAC064)	20
17/SC/0110	Point-of-care testing for respiratory viruses in critical care v1.0	17
17/SC/0126	ADME study of [14C]-BTD-001 in healthy male subjects (QCL117854)	16

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

16/SC/0195	Safety, tolerability, pharmacokinetics and efficacy of ZPL-5212372	28
16/SC/0256	Open-Label Extn Study, Safety & Tolerability RVT-101 in AD patients V1	22
16/SC/0261	A Safety and Efficacy Study of R21 + ChAd63/MVA ME-TRAP (VAC065)	22
16/SC/0265	Virus and host immune system interaction during HIV-1 infection	21
16/SC/0299	Offender Personality Disorder Pathway – National Evaluation	27
16/SC/0327	Effect of taping on patellar mal-alignment 001	27
16/SC/0336	UNCOVER-AF CL-AF-002	27
16/SC/0415	Mindfulness in Ovarian Cancer	28
16/SC/0432	WOLVES	28
16/SC/0433	Assessment of elemental impurities level after taking Diosmectite	28
16/SC/0441	Safety and immunogenicity of a novel intranasal RSV vaccine	29
16/SC/0448	Outcomes for patients seen by medical student therapists. Version 1	29
16/SC/0484	CA209-651: 1st Line Nivo & Ipi vs EXTREME in HNSCC	29
16/SC/0485	AMICE Pilot Study	29
16/SC/0571	Study to compare the PK of Benralizumab when injected with APFS vs AI	21
16/SC/0651	High Energy High Protein Peptide Feed Study HEHP16	30
16/SC/0657	ACCEPT	16
16/SC/0676	Phase 2 study GS-9674 in Primary Sclerosing Cholangitis w/o Cirrohsis	34
16/SC/0677	Phase 2 study GS-9674 in Primary Biliary Cholangitis without cirrhosis	34
17/SC/0066	Exploring Service User experiences of Mental Health Act assessments	25
17/SC/0068	MEasuring TemperatuRe In Children: METRIC	25
17/SC/0075	International A-T Registry	24
17/SC/0082	Exploring memory and thinking difficulties in opiate users.	26
17/SC/0120	ADDRESS C-Peptide	20
17/SC/0130	Estrogen Receptor Positive Breast Cancer	20
17/SC/0135	PK Evaluation of Intravenous F901318 in healthy volunteers (QCL117986)	16

Unfavourable Opinion		
REC Reference	**Title**	**Number of Days on Clock**
16/SC/0335	Does compassion for self or others predict violent behaviour?	28
16/SC/0493	The Contribution of Physical Therapy to Difference in Walking Outcome	44
16/SC/0682	Outcomes in Social Care Assessments - Pilot	34

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**
17/SC/0083	CV185362 Pediatric Anticoagulation for Prevention of Thromboembolism	n/a

Withdrawn after the meeting		
REC Reference	**Title**	**Number of Days on Clock**
16/SC/0214	Study to Evaluate Evolocumab in Type 2 Diabetes & High Cholesterol	17

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/0193	Post-therapy experiences of parents of children who stutter	12
16/SC/0295	Update of EORTC BR23 study: Phases I-III	8
16/SC/0398	To assess parental perception of weight status in 4-7 year children	11
16/SC/0500	NPWT Observational Study - Project Paisley	14

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**
16/SC/0270	Evaluation of a panel of autoantibody biomarkers for lung cancer	6
16/SC/0337	Contact lens visual performance with incorporation of black annulus	11
16/SC/0340	Pre-Operative 3D Computer Simulation for Arthroscopic FAI surgery	11
16/SC/0396	The Impact of Pharmacist Interventions via tele-consultations on COPD.	10
16/SC/0557	The role of Health Anxiety in Mild Cognitive Impairment	13
16/SC/0559	Lifestyle change in people with type 2 diabetes	13
17/SC/0012	TUMMY-CD	22
17/SC/0118	Exploring the Family Nurse Partnership Model across systems	6

Favourable Opinion with Additional Conditions		
REC Reference	**Title**	**Number of Days on Clock**
16/SC/0172	Expectations of a Pain Management Programme	6
16/SC/0272	The evaluation of MyPreOp, an online preoperative assessment tool	11
16/SC/0424	Language deficits in patients with a diagnosis of schizophrenia.	13
16/SC/0495	Faecal immunotesting and faecal calprotectin for IBD	10
16/SC/0623	NURTuRE-CKD	12
16/SC/0685	Perceptions and attitudes towards robotic surgery	9
16/SC/0686	Assessing the quality of upper gastrointestinal endoscopy	13
17/SC/0010	3D Bio-printing of Human Bone and Cartilage Constructs	13
17/SC/0060	Promoting good outcomes in LGBT cancer care.	10
17/SC/0062	Developing public engagement in the QA of teaching program	11
17/SC/0063	RDIAP	11
17/SC/0119	Experiences of receiving an adult diagnosis for Cystic Fibrosis (V1)	13

Unfavourable Opinion		
REC Reference	**Title**	**Number of Days on Clock**
16/SC/0499	Does Improving Medication Adherence Improve Clinical- outcomes?	3

Provisional Opinion		
REC Reference	**Title**	**Number of Days on Clock**
16/SC/0444	Influencing Factors In CBTp for Early Intervention Service Users	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**
06/MRE12/10/AM09	Study of haematology in newborns with Down syndrome (version 2)	4 (AM09)	10/03/2017	7
07/H0607/73/AM08	Pathophysiological mechanisms of pulmonary fibrosis	Amendment 3	10/08/2016	12
09/H0505/121/AM07	Free 4 Flow (2)	1	15/07/2016	19
09/H0505/94/AM13	BG00012 Monotherapy Safety and Efficacy Extension Study in MS	AM13	19/10/2016	27
09/H0505/94/AM14	BG00012 Monotherapy Safety and Efficacy Extension Study in MS	Substantial Amendment - Change	04/01/2017	15
10/H0505/108/AM41	The CAROLINA Trial. Final Protocol, Version 1, 17 Aug 2010	26	20/10/2016	26
10/H0505/108/AM46	The CAROLINA Trial. Final Protocol, Version 1, 17 Aug 2010	AM46 Substantial Amendment 28	12/01/2017	28
10/H0505/108/AM47	The CAROLINA Trial. Final Protocol, Version 1, 17 Aug 2010	AM47	14/03/2017	22
10/H0505/95/AM03	Perfusion CT in FOXFIRE to study blood flow to liver metastases v1.0	Version 4.0	20/04/2016	20
11/SC/0454/AM10	Treatment of HBeAg positive chronic hepatitis B (CHB) in children.	7	01/09/2016	27
11/SC/0454/AM12	Treatment of HBeAg positive chronic hepatitis B (CHB) in children.	8	08/11/2016	30
11/SC/0487/AM04	Regional lung imaging using hyperpolarized xenon gas MR	SA6	20/07/2016	30
12/SC/0139/AM30	SafeHer: Safety study with subcutaneous trastuzumab in breast cancer	SA24 (AM30)	17/01/2017	23
12/SC/0149/AM12	LUX-Lung 8, Afatinib versus Erlotinib in Squamous NSCLC	AM12	29/09/2016	23
12/SC/0309/AM16	B1931022 Inotuzumab in Acute Lymphoblastic Leukaemia	B1931022 Investigator Brochure	16/08/2016	18
12/SC/0539/AM09	Intravenous iron in COPD	SA09	26/11/2016	28
13/SC/0183/AM17	Everolimus in patients who have TSC related seizures	Protocol Amendment 3	25/03/2016	9
13/SC/0264/AM17	Nivolumab or Nivolumab + Ipilimumab vs Ipilimumab in advanced melanoma	SA14	27/04/2016	22

13/SC/0264/AM18	Nivolumab or Nivolumab + Ipilimumab vs Ipilimumab in advanced melanoma	SA15	27/06/2016	16
13/SC/0264/AM19	Nivolumab or Nivolumab + Ipilimumab vs Ipilimumab in advanced melanoma	SA16	03/10/2016	29
13/SC/0264/AM20	Nivolumab or Nivolumab + Ipilimumab vs Ipilimumab in advanced melanoma	17 (AM20)	17/01/2017	23
13/SC/0535/AM17	DIAN-TU-001: Ph. II/III Randomized,Double-blind,Placebo in Alzheimer's	Protocol Amendment 5	18/07/2016	17
13/SC/0636/AM03	Nasal Fentanyl and Buccal Midazolam for Dying Patients	2	12/04/2016	11
14/SC/0028/AM05	Nivolumab in Relapsed or Refractory Follicular Lymphoma	5	16/08/2016	27
14/SC/0083/AM05	Advancing biomarkers in neurodegeneration	3 (AMO5 21/02/2017)	21/02/2017	7
14/SC/0092/AM17	Laminar Airflow in Severe Asthma for Exacerbation Reduction - LASER	SA8	24/03/2016	14
14/SC/0092/AM18	Laminar Airflow in Severe Asthma for Exacerbation Reduction - LASER	9	17/08/2016	19
14/SC/0131/AM02	Affecting Problem Solving and Reasoning	SA2	09/05/2016	20
14/SC/0131/AM03	Affecting Problem Solving and Reasoning	SA3	19/07/2016	19
14/SC/0131/AM04	Affecting Problem Solving and Reasoning	SA4	13/09/2016	29
14/SC/0131/AM05	Affecting Problem Solving and Reasoning	AM05 Amendment 5	20/01/2017	21
14/SC/0167/AM04	Prescription Of analgesia in Emergency Medicine (POEM)	SA 3.0	31/10/2016	27
14/SC/0193/AM01	SAP-OAD	SAP-OAD 1.4 - 16/10/16 (AM01	13/03/2017	23
14/SC/0199/AM08	CheckMate 141: CHECKpoint pathway and nivoluMAb clinical Trial Evaluat	SA7	30/03/2016	18
14/SC/0199/AM09	CheckMate 141: CHECKpoint pathway and nivoluMAb clinical Trial Evaluat	8	23/08/2016	13
14/SC/0199/AM10	CheckMate 141: CHECKpoint pathway and nivoluMAb clinical Trial Evaluat	AM10 EC09	20/01/2017	21
14/SC/1192/AM06	D5160C00008 - Phase I, Open Label, PK, Advanced Solid Tumour (Hepatic)	SA6	03/06/2016	14
14/SC/1192/AM07	D5160C00008 - Phase I, Open Label, PK, Advanced Solid Tumour (Hepatic)	7	16/09/2016	24
14/SC/1203/AM11	Efficacy and safety of PF06410293 and Adalimumab in RA	8	07/12/2016	22
14/SC/1251/AM06	D5160C00009 - Phase I, Open Label, PK, NSCLC (Food	SA5	06/05/2016	26

	Effect)			
14/SC/1259/AM06	D5160C00013 - Phase I, Open Label, EGFRm positive NSCLC (Inducer)	SA5	06/05/2016	26
14/SC/1260/AM02	PROMOTE: A Prospective Randomised trial cOMparing embryO developmenT.	2	14/04/2016	11
14/SC/1366/AM08	Therasphere treatment of liver metastases from colorectal cancer	Amendment 2	28/04/2016	22
14/SC/1366/AM11	Therasphere treatment of liver metastases from colorectal cancer	3	24/06/2016	21
15/SC/0003/AM04	A Study on the Effect of E7438 in Patients with Advanced Tumors	SA4	28/04/2016	16
15/SC/0003/AM05	A Study on the Effect of E7438 in Patients with Advanced Tumors	SA5	06/10/2016	34
15/SC/0003/AM06	A Study on the Effect of E7438 in Patients with Advanced Tumors	AM10 SA6 Protocol Amendment 10	18/01/2017	18
15/SC/0003/AM07	A Study on the Effect of E7438 in Patients with Advanced Tumors	SA6_Protocol Amendment 10_Main	21/11/2016	14
15/SC/0011/AM15	Phase IIA study of Lanreotide PRF in subjects with Acromegaly	5	06/04/2016	23
15/SC/0011/AM21	Phase IIA study of Lanreotide PRF in subjects with Acromegaly	AM21 Final version (with Amendment)	20/12/2016	29
15/SC/0049/AM01	RETRO-CHOP	Amendment 1, 29/01/2016	13/05/2016	9
15/SC/0080/AM11	Study to Investigate the Use of Biotelemetry in Subjects with ALS	1	25/04/2016	21
15/SC/0280/AM08	1160.204 RE-CIRCUIT: Dabigatran vs warfarin in AF Ablation	SA5	23/03/2016	8
15/SC/0285/AM01	Measuring and comparing breath acetone and blood ketones	3 18 April 2016	18/04/2016	20
15/SC/0295/AM06	D0816C00012 (ORZORA), Open Label, Phase IV, Ovarian Cancer (Olaparib)	SA6	17/08/2016	9
15/SC/0300/AM02	Experiences of people living with rosacea	SA2	26/04/2016	13
15/SC/0359/AM04	A Phase 3 Veliparib plus Chemotherapy study in Ovarian Cancer	1	11/08/2016	25
15/SC/0359/AM05	A Phase 3 Veliparib plus Chemotherapy study in Ovarian Cancer	SA2	26/09/2016	29
15/SC/0359/AM06	A Phase 3 Veliparib plus Chemotherapy study in Ovarian	SA3 - Recruitment	14/10/2016	27

	Cancer	Restart		
15/SC/0359/AM07	A Phase 3 Veliparib plus Chemotherapy study in Ovarian Cancer	PA3	14/12/2016	15
15/SC/0437/AM02	Fluciclovine (18F) PET/CT in biochemical recurrence of prostate cancer	2	25/04/2016	25
15/SC/0456/AM07	MPDL3280A-Early phase study in patients with solid tumours	4	28/11/2016	24
15/SC/0470/AM04	Abatacept-Methotrexate combo vs Methotrexate in adults with early RA	3	05/04/2016	26
15/SC/0470/AM05	Abatacept-Methotrexate combo vs Methotrexate in adults with early RA	EC04 (AM05)	15/02/2017	19
15/SC/0475/AM06	CA209-227 - Nivolumab or nivolumab plus ipilimumab vs SOC in NSCLC	5	16/05/2016	8
15/SC/0475/AM07	CA209-227 - Nivolumab or nivolumab plus ipilimumab vs SOC in NSCLC	SA6	27/06/2016	16
15/SC/0475/AM08	CA209-227 - Nivolumab or nivolumab plus ipilimumab vs SOC in NSCLC	SA7	06/09/2016	27
15/SC/0475/AM09	CA209-227 - Nivolumab or nivolumab plus ipilimumab vs SOC in NSCLC	AM09 v1.0 SA08	16/12/2016	26
15/SC/0475/AM10	CA209-227 - Nivolumab or nivolumab plus ipilimumab vs SOC in NSCLC	SA09 (AM10)	21/02/2017	12
15/SC/0515/AM01	Measuring response to immune stimuli in patients with CTD	Version 2.0	11/05/2016	17
15/SC/0521/AM07	Phase 2 study with nab-Paclitaxel in patients with NSCLC	SA03	21/06/2016	16
15/SC/0521/AM12	Phase 2 study with nab-Paclitaxel in patients with NSCLC	AM12	08/11/2016	30
15/SC/0521/AM13	Phase 2 study with nab-Paclitaxel in patients with NSCLC	Protocol Amendment 5	22/12/2016	27
15/SC/0526/AM01	The English Longitudinal Study of Ageing - Wave 8	1	08/04/2016	14
15/SC/0526/AM02	The English Longitudinal Study of Ageing - Wave 8	2	26/05/2016	7
15/SC/0526/AM03	The English Longitudinal Study of Ageing - Wave 8	SA3	21/12/2016	14
15/SC/0550/AM03	A Single-Dose Open-Label Study of XOMA 358	Amendment 4	31/05/2016	24
15/SC/0550/AM05	A Single-Dose Open-Label Study of XOMA 358	5	26/08/2016	14
15/SC/0676/AM01	ANNOUNCE - Olaratumab and Doxorubicin in Soft Tissue Sarcoma (JDGJ)	SA1	24/03/2016	13
15/SC/0676/AM02	ANNOUNCE - Olaratumab and Doxorubicin in Soft Tissue Sarcoma (JDGJ)	2	13/09/2016	27
15/SC/0676/AM03	ANNOUNCE - Olaratumab and Doxorubicin in Soft Tissue Sarcoma (JDGJ)	3 (AM03)	06/02/2017	7

15/SC/0685/AM02	Phase 1 Study in Patients with Advanced Systemic Mastocytosis	SA1	03/08/2016	19
15/SC/0685/AM04	Phase 1 Study in Patients with Advanced Systemic Mastocytosis	3	22/08/2016	14
15/SC/0694/AM02	KRN23 in Adults with X-linked Hypophosphatemia (XLH) - (Final Version)	SA1	27/04/2016	11
15/SC/0694/AM03	KRN23 in Adults with X-linked Hypophosphatemia (XLH) - (Final Version)	SA2	20/10/2016	28
15/SC/0714/AM01	Phase 3 study of RVT-101 versus placebo in AD patients. V1.0	SA1	25/03/2016	7
15/SC/0714/AM05	Phase 3 study of RVT-101 versus placebo in AD patients. V1.0	3.1 UK	18/07/2016	22
15/SC/0724/AM02	PK & Scintigraphic Assessment of Colistimethate Sodium (QCL117619)	SA01	26/07/2016	20
15/SC/0724/AM04	PK & Scintigraphic Assessment of Colistimethate Sodium (QCL117619)	SA04 (AM04)	14/02/2017	20
16/SC/0023/AM07	GSK COPD	SA1	20/09/2016	30
16/SC/0025/AM01	Reconceptualising PROMs - Feasibility	SA1	24/03/2016	9
16/SC/0047/AM01	A Phase 1b Study of FDL169 in Healthy Volunteers and CF Patients.	1	30/03/2016	19
16/SC/0075/AM01	Evaluation of the Efficacy and Safety of MV140	1	15/08/2016	20
16/SC/0076/AM01	QuicK+fire-P study	1	10/06/2016	26
16/SC/0076/AM02	QuicK+fire-P study	SA2	24/08/2016	16
16/SC/0076/AM04	QuicK+fire-P study	SA3	13/10/2016	28
16/SC/0087/AM01	Feasibility of a calprotectin swab test to detect bacterial throats	v1.2	03/03/2016	6
16/SC/0089/AM01	The REST Study	1	06/10/2016	34
16/SC/0150/AM01	Prostate Cancer UK Module2 - Phase 2: Post-operative continence care	SA1	29/04/2016	25
16/SC/0151/AM02	Endometrial Scratch Trial	Amendment 2, 22/06/2016	22/06/2016	21
16/SC/0151/AM03	Endometrial Scratch Trial	3	20/10/2016	21
16/SC/0152/AM01	Simvastatin to prevent complications after oesophagectomy v1.0	2	23/08/2016	28
16/SC/0195/AM02	Safety, tolerability, pharmacokinetics and efficacy of ZPL-5212372	1	30/06/2016	19
16/SC/0195/AM03	Safety, tolerability, pharmacokinetics and efficacy of ZPL-5212372	2.0	28/07/2016	21
16/SC/0256/AM02	Open-Label Extn Study, Safety & Tolerability RVT-101 in AD	3	12/09/2016	24

	patients V1			
16/SC/0256/AM04	Open-Label Extn Study, Safety & Tolerability RVT-101 in AD patients V1	AM4	16/11/2016	21
16/SC/0261/AM01	A Safety and Efficacy Study of R21 + ChAd63/MVA ME-TRAP (VAC065)	SA001	21/06/2016	24
16/SC/0261/AM02	A Safety and Efficacy Study of R21 + ChAd63/MVA ME-TRAP (VAC065)	2.0	02/08/2016	20
16/SC/0261/AM04	A Safety and Efficacy Study of R21 + ChAd63/MVA ME-TRAP (VAC065)	3	16/09/2016	24
16/SC/0261/AM05	A Safety and Efficacy Study of R21 + ChAd63/MVA ME-TRAP (VAC065)	4	28/10/2016	19
16/SC/0262/AM02	NFPP OnLINE Proof of Concept	Substantial Amendment 1	14/07/2016	14
16/SC/0262/AM03	NFPP OnLINE Proof of Concept	2	17/10/2016	29
16/SC/0295/AM02	Update of EORTC BR23 study: Phases I-III	Substantial Amendment #1	23/01/2017	5
16/SC/0341/AM02	Phase IIA trial of EZH2 inhibition in mesothelioma	SA2 - New Flyer	08/08/2016	14
16/SC/0341/AM03	Phase IIA trial of EZH2 inhibition in mesothelioma	SA3	22/09/2016	33
16/SC/0341/AM06	Phase IIA trial of EZH2 inhibition in mesothelioma	AM06 v1.0	12/01/2017	27
16/SC/0342/AM01	Probing the Neural Basis of Visual Working Memory in Early Development	SA1	27/09/2016	29
16/SC/0342/AM02	Probing the Neural Basis of Visual Working Memory in Early Development	SA2 (AM02)	15/03/2017	20
16/SC/0433/AM01	Assessment of elemental impurities level after taking Diosmectite	1	22/09/2016	18
16/SC/0441/AM01	Safety and immunogenicity of a novel intranasal RSV vaccine	1	31/08/2016	22
16/SC/0484/AM01	CA209-651: 1st Line Nivo & Ipi vs EXTREME in HNSCC	Version 01	21/12/2016	30
16/SC/0484/AM03	CA209-651: 1st Line Nivo & Ipi vs EXTREME in HNSCC	EC SA02 (AM03)	09/03/2017	4
16/SC/0494/AM01	Triple vs dual therapy in inadequately controlled asthma	AM01 Version SA01 1	06/01/2017	31
16/SC/0555/AM01	Safety and immunogenicity of novel routes of ChAd63 ME-TRAP (VAC064)	SA1	15/12/2016	28
16/SC/0676/AM01	Phase 2 study GS-9674 in Primary Sclerosing Cholangitis w/o Cirrohsis	SA#01 (AM01)	13/02/2017	21
16/SC/0677/AM01	Phase 2 study GS-9674 in Primary Biliary Cholangitis without cirrhosis	SA#01 (AM01)	13/02/2017	21

17/SC/0082/AM01	Exploring memory and thinking difficulties in opiate users.	1 (AM01)	12/03/2017	16

Unfavourable opinion				
Amendment REC Reference	**Title**	**Version**	**Date**	**Number of Days on Clock**
08/H0603/34/AM06	Function of fat tissue	4	12/10/2016	28
13/SC/0286/AM12	BAN2401-G000-201 BAN2401 in Early Alzheimer's Disease	8	13/09/2016	31
14/SC/0249/AM12	Symbicort in mild asthma	Protocol Amendment 3	24/03/2016	30
14/SC/1206/AM07	ElaTION	3	09/12/2016	21
15/SC/0087/AM02	TUMS study - version 1.0	1	05/02/2017	8
15/SC/0469/AM02	Genetic Basis of Motor Neurone Disease	Amendment 2	12/05/2016	12
15/SC/0548/AM01	STAR_PAC	SA1	30/08/2016	22
15/SC/0548/AM02	STAR_PAC	2	12/12/2016	18
15/SC/0550/AM10	A Single-Dose Open-Label Study of XOMA 358	8	09/12/2016	33
16/SC/0151/AM01	Endometrial Scratch Trial	SA1	09/05/2016	22
16/SC/0256/AM01	Open-Label Extn Study, Safety & Tolerability RVT-101 in AD patients V1	Amendment 1	12/05/2016	28
16/SC/0432/AM01	WOLVES	1	21/10/2016	25
16/SC/0617/AM01	Randomised Pilot Trial of Oxygen Targets in PICU (Oxy-PICU) v1.0	1	07/02/2017	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**
14/SC/0249/AM12/1	Symbicort in mild asthma	Modified Amendment to SA8	06/05/2016	7
14/SC/1206/AM07/1	ElaTION	3 (AM07/1)	08/12/2016	5
15/SC/0469/AM02/1	Genetic Basis of Motor Neurone Disease	Modified Amendment to SA2	05/07/2016	9
15/SC/0548/AM01/1	STAR_PAC	Modified to SA1	17/11/2016	1

15/SC/0548/AM02/1	STAR_PAC	2.0 (AM02/1)	12/01/2017	5
15/SC/0550/AM10/1	A Single-Dose Open-Label Study of XOMA 358	Amendment 8 - Modified version	10/02/2017	3
16/SC/0151/AM01/1	Endometrial Scratch Trial	1	03/06/2016	4
16/SC/0256/AM01/1	Open-Label Extn Study, Safety & Tolerability RVT-101 in AD patients V1	Modified Amendment to SA1	12/05/2016	14

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/0012	TUMMY-CD	22

SSAs (non Phase 1) over 25 day timeline		
REC Reference	**Title**	**Number of Days on Clock**
16/SC/0352	A Long-Term, Open-Label Extension Study of the Safety and Tolerability of RVT-101 in Subjects with Alzheimer's Disease	26
16/SC/0581	A Long-Term, Open-Label Extension Study of the Safety and Tolerability of RVT-101 in Subjects with Alzheimer's Disease	28
16/SC/0582	A Long-Term, Open-Label Extension Study of the Safety and Tolerability of RVT-101 in	28

	Subjects with Alzheimer's Disease	
17/SC/0050	A Multicentre Randomised Controlled Trial of Induced Endometrial Scratch in Women Undergoing First Time in Vitro Fertilisation (IVF)	29

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**

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