

**South Central - Berkshire Research Ethics
Committee**

Annual Report

01 April 2015 - 31 March 2016



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:	Ms Rae Granville (until 01/09/2015) Mr Mark Dawson (01/09//2015 to 01/02/2016) Mrs Claudia Bywater (01/03/2016 – ongoing)
REC Assistant:	Miss Lidia Gonzalez (until 01/09/2015) Mr. Stephan Ramey (01/03/2016 – ongoing)
Committee Address:	Bristol REC Centre Whitefriars Level 3, Block B Lewins Mead Bristol BS1 2NT
Telephone:	0207 104 8043
Email:	nrescommittee.southcentral-berkshire@nhs.net

Chair's overview of the past year:

Overall this has been a good year. We have seen quite a few changes of membership – most significantly the loss of Susan Tonks –Vice-Chair; we have however gained two new members and Mike Proven (Vice-Chair) and Ann Quin (Alternate Vice-Chair) are proving to be excellent officers. We still need at least one more practicing clinician and I hope that this will be addressed soon. Turnover of REC managers and assistants has been significant; but I'm delighted to welcome Claudia who has settled into the role very quickly.

The Committee continues to be busy – we have a fairly steady flow of challenging reviews at full committee and PRSC. Sub-Committee business is also steady – and I'm very grateful for the arrangement allowing us to deal with this business weekly.

I am very pleased with the Committee's performance in terms of the opinions it has given for full reviews; just a little more than a third of our opinions were provisional whereas nearly two thirds were favourable or favourable with conditions. We have not become any less rigorous – rather we have been increasingly aware of the need to focus on ethical issues. I am equally pleased with other data – exceeding any timeline is very rare and simple explanations are available in all cases.

I believe that Berkshire REC offers an excellent service and has the benefit of an excellent infrastructure provided by the HRA. I would like to thank HRA staff for all their help and support.

David Carpenter

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	
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	01/03/2012	
Dr Deborah Scholey	Managing Director	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	01/05/2007	30/06/2015
Mrs Helen Turner	Clinical Study Manager	Lay	01/09/2015	

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	University Ethics Adviser at the University of Portsmouth – sponsor's representative Member of the Ethics Executive Group at the Rowans Hospice – Portsmouth Vice- chair/Chair elect of AfRE Holds position of University Ethics Adviser at the Member of the British Psychological Society Ethics Committee Occasional advice to clinicians and researchers working in Portsmouth Hospitals Trust	31/01/2016
Dr Mike Emanuel	Consultant to Oragenic Inc and Kinapse (Health Care Management Consultancy) Owner of Sintopharm, Clinical Research Consultancy Shareholder in Johnson + Johnson and Triumph Research Consultancy	16/02/2016
Mrs Liz Hunter	None	29/01/2016
Dr Vandana Luthra	None	31/03/2016
Mr Daniel Charles Mace	None	30/01/2016
Mr Richard Merewood	None	16/06/2015
Dr Joanne Philpot	None	15/02/2016
Dr Mike Proven	Employed by the University of Reading, Academic and Governance Services Department. When required University's 'Sponsor representative' for research covered by the Department of Health's Research Governance Framework for Health and Social Care.	29/01/2016
Dr Deborah Scholey	Ownership, including part ownership of private companies, businesses or consultancies involved in or possibly seeking to be involved in the conduct of research. Best regulatory consulting ltd. Director and owner	14/12/2015
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.	02/09/2015
Dr John Andrew Sutton	Minor share holding in ReGen Therapeutics which has a treatment for brain damage and another diet supplement for Alzheimer's Dementia.	21/04/2015
Mrs Helen Turner	Clinical Study Manager at Cancer Research UK 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)	10/09/2015

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

Month	Date	Number of Members Present at Meeting
April	21/04/2015	12
May	19/05/2015	11
June	16/06/2015	11
August	18/08/2015	9
September	15/09/2015	12
November	17/11/2015	11
December	15/12/2015	14
February	16/02/2016	10
March	15/03/2016	11

9 full committee meetings were held during the reporting period.

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

Month	Date	Number of Members Present at Meeting
April	14/04/2015	3
May	12/05/2015	3
June	09/06/2015	3
August	13/08/2015	3
September	15/09/2015	3
October	13/10/2015	3
November	10/11/2015	3
December	15/12/2015	3
January	11/01/2016	3
February	10/02/2016	3
March	09/03/2016	3

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

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

Month	Date	Number of Members Present at Meeting
April	02/04/2015	2
April	10/04/2015	2
April	16/04/2015	2
April	24/04/2015	3
April	30/04/2015	2
May	08/05/2015	2
May	13/05/2015	3
May	15/05/2015	2
May	29/05/2015	3
June	12/06/2015	2
June	19/06/2015	2

June	26/06/2015	2
July	03/07/2015	2
July	10/07/2015	2
July	17/07/2015	2
July	24/07/2015	2
July	31/07/2015	3
August	07/08/2015	2
August	14/08/2015	2
August	21/08/2015	2
August	28/08/2015	2
September	04/09/2015	2
September	11/09/2015	2
September	18/09/2015	2
September	25/09/2015	2
October	02/10/2015	2
October	09/10/2015	2
October	23/10/2015	2
October	30/10/2015	2
November	06/11/2015	2
November	13/11/2015	2
November	27/11/2015	2
December	04/12/2015	3
December	07/12/2015	3
December	11/12/2015	2
December	18/12/2015	2
December	30/12/2015	2
January	06/01/2016	3
January	15/01/2016	2
January	22/01/2016	2
January	29/01/2016	2
February	05/02/2016	2
February	12/02/2016	2
February	26/02/2016	2
March	04/03/2016	2
March	11/03/2016	2
March	18/03/2016	2
March	25/03/2016	2

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

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

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

Name	Number of Meetings Attended
Mr David Carpenter	8
Dr Mike Emanuel	7
Mrs Liz Hunter	8
Dr Vandana Luthra	6
Mr Daniel Charles Mace	7
Mr Richard Merewood	7
Mr Neil Thomas O'Kane	7
Dr Joanne Philpot	8
Dr Mike Proven	8
Ms Ann Quinn	8
Dr Deborah Scholey	3
Mr Donald Scott-Collett	8
Dr John Andrew Sutton	8
Ms Susan Tonks	3
Mrs Helen Turner	5

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

Name	Number of Meetings Attended
Mr David Carpenter	11
Dr Vandana Luthra	2
Mr Richard Merewood	4
Mr Neil Thomas O'Kane	4
Dr Mike Proven	1
Ms Ann Quinn	6
Mr Donald Scott-Collett	1
Dr John Andrew Sutton	2
Ms Susan Tonks	1
Mrs Helen Turner	1

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

Name	Number of Meetings Attended
Mr David Carpenter	46
Dr Mike Emanuel	2
Mrs Liz Hunter	1
Mr Richard Merewood	1
Dr Mike Proven	1

Dr Mike Proven	39
Ms Ann Quinn	2
Mr Donald Scott-Collett	2
Ms Susan Tonks	9

Training 01 April 2015 - 31 March 2016

Name of Member	Date	Event(s) attended
Mr David Carpenter	01/05/2015	Virtue Ethics in the Practice and Review of Social Science Research
Mr David Carpenter	13/05/2015	UKRIO Annual Conference
Mr David Carpenter	03/06/2015	NREAP Chair's Meeting South Central
Mr David Carpenter	04/09/2015	Local Training Day - Joint Oxford
Mr David Carpenter	20/10/2015	Local Training - Berkshire & Berkshire B Research Ethics Committees Training Day
Mr David Carpenter	09/12/2015	Training - National Training Day for Committee Chairs
Dr Mike Emanuel	04/09/2015	Joint Oxford Training Day
Dr Mike Emanuel	20/10/2015	Berkshire & Berkshire B Research Ethics Committees Training Day
Mrs Liz Hunter	20/10/2015	Berkshire & Berkshire B Research Ethics Committees Training Day
Dr Vandana Luthra	20/10/2015	Berkshire & Berkshire B Research Ethics Committees Training Day
Mr Daniel Charles Mace	04/09/2015	Local training Day - Joint Oxford
Mr Daniel Charles Mace	20/10/2015	Berkshire & Berkshire B Research Ethics Committees Training Day
Mr Richard Merewood	20/10/2015	Berkshire & Berkshire B Research Ethics Committees Training Day
Mr Neil Thomas O'Kane	20/10/2015	Berkshire & Berkshire B Research Ethics Committees Training Day
Dr Mike Proven	20/10/2015	Joint Berkshire and Berkshire B Training Day
Dr Mike Proven	09/12/2015	National Training Day for Committee Chairs
Dr Mike Proven	05/02/2016	Local Training Day - Social Care REC
Ms Ann Quinn	04/09/2015	Local Training Day - Joint Oxford
Dr Deborah Scholey	10/02/2016	Training - Committee Members Induction
Mr Donald Scott-Collett	20/10/2015	Berkshire & Berkshire B Research Ethics Committees Training Day
Dr John Andrew Sutton	24/09/2015	Committee Members Induction
Dr John Andrew Sutton	20/10/2015	Berkshire & Berkshire B Research Ethics Committees

		Training Day
Mrs Helen Turner	20/10/2015	Berkshire & Berkshire B Research Ethics Committees Training Day
Mrs Helen Turner	03/12/2015	HRA Workshop: Pragmatic or Point of Care trials

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	19	38.78
Phase 1	3	6.12
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	0	0.00
Others	27	55.10
Total Applications Reviewed	49	100

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

Number of applications made invalid by the REC Manager	2
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	9
Number of paediatric applications reviewed	5
Number of device applications reviewed	3
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	2
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	7	14.29
Favourable Opinion with Additional Conditions	23	46.94
Unfavourable Opinion	1	2.04
Provisional Opinion	18	36.73
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	49	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	18	36.73
Further Information Favourable Opinion with Additional Conditions	0	0.00
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	7	14.29
Favourable Opinion with Additional Conditions	23	46.94
Unfavourable Opinion	1	2.04
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	49	100

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

Total Applications Reviewed	32
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Table 6: Breakdown of PRS applications and other activity during reporting period:

Number of applications made invalid by the REC Manager	10
Number of studies withdrawn prior to the meeting	0
Number of student applications reviewed	17
Number of paediatric applications reviewed	3
Number of device applications reviewed	1
Number of qualitative applications reviewed	5

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	7	21.88
Favourable Opinion with Additional Conditions	9	28.13
No Opinion transfer to full committee for review	4	12.50
Provisional Opinion	9	28.13
Unfavourable Opinion	3	9.38
Total	32	100

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

Average number of applications reviewed per full meeting	5.44
Number of completed applications for full ethical review	49
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	6.12%
Number of days taken to final decision – average (mean)	28
Number of completed proportionate review applications for ethical review	28
Number of completed proportionate review applications for ethical review over 14 days	1
Number of completed proportionate review applications over 14 days as a % of total	3.57%
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	4
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	134
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	2
Number of completed substantial amendments over 28 days as a % of total substantial amendments	1.49%
Number of modified amendments reviewed	9
Number of completed modified amendments over 14 days	1
Number of completed modified amendments over 14 days as a % of total modified amendments	11.11%
Number of minor amendments received	104
Number of substantial amendments received for information	0
Number of substantial amendments received for new sites/PIs	24
Number of annual progress reports received	68

Number of safety reports received	21
Number of Serious Adverse Events received	1
Number of final reports received	10

Table 9.1: Breakdown of current status of all full applications reviewed within the reporting period

Further Information Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
15/SC/0228	An investigation into distractibility in those reporting memory change	30
15/SC/0234	Improving the Oral Health of Older People Initiative (IOHOPI) study	32
15/SC/0295	D0816C00012 (ORZORA), Open Label, Phase IV, Ovarian Cancer (Olaparib)	24
15/SC/0469	Genetic Basis of Motor Neurone Disease	29
15/SC/0470	Abatacept-Methotrexate combo vs Methotrexate in adults with early RA	50
15/SC/0521	Phase 2 study with nab-Paclitaxel in patients with NSCLC	32
15/SC/0548	STAR_PAC	30
15/SC/0550	A Single-Dose Open-Label Study of XOMA 358	35
15/SC/0656	The unstable kneecap - the impact of anatomy on function	33
15/SC/0685	Phase 1 Study in Patients with Advanced Systemic Mastocytosis	38
15/SC/0694	KRN23 in Adults with X-linked Hypophosphatemia (XLH) -(Final Version)	40
15/SC/0714	Phase 3 study of RVT-101 versus placebo in AD patients. V1.0	26
15/SC/0724	PK & Scintigraphic Assessment of Colistimethate Sodium (QCL117619)	26
16/SC/0023	GSK COPD	53
16/SC/0047	A Phase 1b Study of FDL169 in Healthy Volunteers and CF Patients.	34
16/SC/0075	Evaluation of the Efficacy and Safety of MV140	40
16/SC/0149	Evaluation of PIPEs in Prisons and Approved Premises	29
16/SC/0153	The patient experience of conscious regional anaesthesia & surgery	26

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
15/SC/0207	Alarm fatigue in the ICU (v. 1.0)	27
15/SC/0306	RANGE - Ramucirumab in Advanced Bladder Cancer (JVDC Study)	23

15/SC/0356	POMAR	17
15/SC/0526	The English Longitudinal Study of Ageing - Wave 8	27
15/SC/0566	LEAK: Lipocalin in the ED for the diagnosis of Acute Kidney injury	24
15/SC/0754	Out of hours primary care – a high risk practice?	28
16/SC/0076	Quick+fire-P study	23

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/SC/0177	Advance care planning in the context of children's palliative care	29
15/SC/0224	InTeam Consortium	30
15/SC/0280	1160.204 RE-CIRCUIT: Dabigatran vs warfarin in AF Ablation	23
15/SC/0285	Measuring and comparing breath acetone and blood ketones	23
15/SC/0290	Exploring experience of MDO's in a vocational rehabilitation project	23
15/SC/0353	Task orientated training intervention: sitting balance	18
15/SC/0354	Processes of help seeking for people with PTSD from Domestic Violence	18
15/SC/0355	Baby Vaccine Study (Sched3)	13
15/SC/0359	A Phase 3 Veliparib plus Chemotherapy study in Ovarian Cancer	20
15/SC/0437	Fluciclovine (18F) PET/CT in biochemical recurrence of prostate cancer	24
15/SC/0456	MPDL3280A-Early phase study in patients with solid tumours	46
15/SC/0466	Bioavailability of MK-1439 nano formulations in healthy subjects	18
15/SC/0475	CA209-227 - Nivolumab or nivolumab plus ipilimumab vs SOC in NSCLC	37
15/SC/0553	Oxford Telehealth Qualitative Study version 1.2	24
15/SC/0676	ANNOUNCE - Olaratumab and Doxorubicin in Soft Tissue Sarcoma (JDGJ)	28
15/SC/0687	Traumatic Brain Injury Imaging Study	28
15/SC/0732	HAM neuroimaging	23
15/SC/0752	Cognition and psychological flexibility in multiple sclerosis - v1.0	23
15/SC/0759	MS and ME	21
16/SC/0089	The REST Study	21
16/SC/0150	Prostate Cancer UK Module2 - Phase 2: Post-operative continence care	17
16/SC/0151	Endometrial Scratch Trial	27
16/SC/0152	Simvastatin to prevent complications after oesophagectomy v1.0	27

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
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15/SC/0323	Are children's rights upheld during burns and plastic day surgery? v2	21
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Provisional Opinion

REC Reference	Title	Number of Days on Clock
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Provisional Opinion Pending Consultation with Referee

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

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

REC Reference	Title	Number of Days on Clock
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Table 9.2: Breakdown of current status of all PRS applications reviewed within the reporting period

Further Information Favourable Opinion with Standard Conditions

REC Reference	Title	Number of Days on Clock
15/SC/0238	PATIENT EXPERIENCE OF DONATING A KIDNEY (PEDaK) STUDY	9
15/SC/0304	peri-operative experience of parents	10
15/SC/0307	Does increasing morphine result in improved function in chronic pain?	14
15/SC/0309	Outpatient Occupational Therapy for type-1 diabetes: A pilot study	12
15/SC/0367	"OPTI-CLOT" goes United Kingdom (UK)	11
15/SC/0513	Patient Beliefs About Cholesterol Lowering	5
15/SC/0705	Development & Impact of Speech and Language Services (Young Offenders)	12
16/SC/0077	Reliability of an outcome measure in neurosurgical patients.	12
16/SC/0087	Feasibility of a calprotectin swab test to detect bacterial throats	7

Further Information Favourable Opinion with Additional Conditions

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

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

REC Reference	Title	Number of Days on Clock
15/SC/0360	BMP4, BMP7 and BMP receptor expression in ovaries of PCOS patients	4
15/SC/0515	Measuring response to immune stimuli in patients with CTD	8
15/SC/0581	'Together' promotion of healthy lifestyles	12
15/SC/0713	Biomarker validation of anti-TMUC1 antibody in breast cancer	11
15/SC/0773	Estimating community carriage of CPE in Manchester v1.	15
16/SC/0024	IMP2ART Qualitative Study	9
16/SC/0025	Reconceptualising PROMs - Feasibility	7

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/SC/0300	Experiences of people living with rosacea	8
15/SC/0363	Managing Aggression In Young Adults Through Group – Therapy	5
15/SC/0514	Investigation of Bone Marrow Macrophages	8
15/SC/0576	Effectiveness of Pilates exercise for chronic low back pain.	12
15/SC/0577	Exploring patients decision to participate in cardiac rehabilitation	14
15/SC/0632	Acoustic emission assessment of knee joint degeneration	10
15/SC/0707	Clinical and Evolutionary Consequences of Human Amylase Variation	11
15/SC/0711	Fit for Later Life v17	12
16/SC/0154	Heartmate III Registry	10

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
15/SC/0512	The unstable kneecap - the impact of anatomy on function	10
15/SC/0575	Pictorial aids and memory recall in head injury patients V2	8

16/SC/0093	Factors that increase sickle cell patient engagement with Dietitian	6
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Provisional Opinion

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

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

REC Reference	Title	Number of Days on Clock
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Table 10.1: Breakdown of current status of all substantial amendments reviewed within the reporting period

Favourable opinion				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
05/MRE12/8/AM06	T cell responses and multiple sclerosis (Version 1)	Version 6 , Protocol 10 June	10/06/2015	15
06/MRE12/11/AM20	The genetic analysis of multiple sclerosis V1.0	15	12/08/2015	6
07/H0607/101/AM13	Safer pre-natal diagnosis using free DNA in maternal blood test	6, 21st July 2015 (SA04)	21/07/2015	4
07/H0607/66/AM11	Cardiac energy metabolism during exercise spectroscopy	Version 10, 25th September 201	25/09/2015	17
07/H0607/74/AM07	The placenta and pre-eclampsia	NOSA 2	03/03/2015	17
07/H0607/74/AM11	The placenta and pre-eclampsia	3	01/09/2015	16
09/H0505/1/AM07	FOXFIRE - version 1	6	26/02/2015	13
09/H0505/121/AM06	Free 4 Flow (2)	Version: 1, 2014/12/22	23/10/2015	20
09/H0505/132/AM06	Ultrasound vs biopsy in diagnosis of GCA (TABUL)	Substantial Amendment 3	17/04/2015	19
09/H0505/73/AM14	Dominantly Inherited Alzheimer Network (DIAN)	10	08/07/2015	12
09/H0603/24/AM03	Safety of sports for patients with ICDs	2	10/08/2015	7
10/H0505/108/AM27	The CAROLINA Trial. Final Protocol, Version 1, 17 Aug 2010	21	16/03/2015	14
10/H0505/108/AM37	The CAROLINA Trial. Final Protocol, Version 1, 17 Aug 2010	23	20/01/2016	6
10/H0505/108/AM39	The CAROLINA Trial. Final Protocol, Version 1, 17 Aug 2010	25	18/03/2016	18
11/SC/0059/AM09	A Phase 1B study of INC424 in myelofibrosis with thrombocytopenia	Protocol Amendment 4	28/07/2015	7
11/SC/0059/AM10	A Phase 1B study of INC424 in myelofibrosis with thrombocytopenia	8	09/02/2016	28
11/SC/0488/AM06	Xenon lung imaging in COPD: a COPD Cohort sub-study Version 1.0	5	26/05/2015	6
11/SC/0488/AM08	Xenon lung imaging in COPD: a COPD Cohort sub-study Version 1.0	SA06	03/07/2015	8
12/SC/0149/AM10	LUX-Lung 8, Afatinib versus Erlotinib in Squamous NSCLC	10	14/08/2015	13
12/SC/0309/AM11	B1931022 Inotuzumab in Acute Lymphoblastic Leukaemia	January 2015	09/04/2015	19
12/SC/0437/AM09	Self management and support programme (EDGE) for COPD	5, 18/09/2015	23/09/2015	25
12/SC/0495/AM12	Narratives of health and illness for Healthtalkonline 2012 V1	1	01/07/2015	7

12/SC/0539/AM07	Intravenous iron in COPD	Substantial Amendment 7	30/03/2015	8
12/SC/0539/AM08	Intravenous iron in COPD	8	04/03/2016	20
13/SC/0003/AM06	A Phase I trial of DI-B4 in patients with advanced B-cell malignancies	Amendment 13, dated 02 Dec 201	13/01/2016	13
13/SC/0089/AM02	Mechanisms of Exercise Benefit with IV Iron in CHF ver 6	02	28/09/2015	4
13/SC/0124/AM03	Babies with Down syndrome in neonatal intensive care units v1	AM03 Substantial	29/07/2014	10
13/SC/0143/AM05	Psychological Intervention Alcohol Misuse Learning Disability	7	15/08/2014	5
13/SC/0206/AM06	(May) ACTIB	V4.0 Date 04/11/2015	04/11/2015	19
13/SC/0206/AM07	(May) ACTIB	V5.0 Date 19/11/2015	23/11/2015	10
13/SC/0264/AM12	Nivolumab or Nivolumab + Ipilimumab vs Ipilimumab in advanced melanoma	10	06/05/2015	5
13/SC/0264/AM13	Nivolumab or Nivolumab + Ipilimumab vs Ipilimumab in advanced melanoma	11	09/06/2015	17
13/SC/0264/AM14	Nivolumab or Nivolumab + Ipilimumab vs Ipilimumab in advanced melanoma	EC12	27/07/2015	3
13/SC/0264/AM15	Nivolumab or Nivolumab + Ipilimumab vs Ipilimumab in advanced melanoma	CA209-067 EC13 05-Oct-15 Nivol	05/10/2015	10
13/SC/0452/AM06	VX12-809-105 CF Rollover study	Lumacaftor/ivacaftor Investigator	16/06/2015	9
13/SC/0452/AM07	VX12-809-105 CF Rollover study	3.2	29/09/2015	16
13/SC/0452/AM08	VX12-809-105 CF Rollover study	5	22/12/2015	22
13/SC/0501/AM02	Urine Biomarkers in Overactive Bladder Syndrome	Number 2, 27/05/2015	22/06/2015	13
13/SC/0535/AM12	DIAN-TU-001: Ph. II/III Randomized, Double-blind, Placebo in Alzheimer's	8	13/05/2015	0
13/SC/0602/AM01	Ultrastructural and molecular studies in angiogenesis and permeability	1	18/05/2015	14
13/SC/0634/AM05	Cognitive Treatment of Depression in Schizophrenia	4	27/10/2015	16
13/SC/0634/AM06	Cognitive Treatment of Depression in Schizophrenia	5	27/11/2015	10
14/SC/0027/AM03	Nivolumab in Relapsed or Refractory Diffuse Large B-Cell Lymphoma	Substantial Amendment 3	23/04/2015	12
14/SC/0027/AM04	Nivolumab in Relapsed or Refractory Diffuse Large B-Cell	4	20/08/2015	14

	Lymphoma			
14/SC/0028/AM03	Nivolumab in Relapsed or Refractory Follicular Lymphoma	Nivolumab IB13 Addendum 02 & 0	30/06/2015	8
14/SC/0028/AM04	Nivolumab in Relapsed or Refractory Follicular Lymphoma	Substantial Amendment dated 11	11/09/2015	12
14/SC/0034/AM07	997HA307 - Previously Treated Subjects With Severe Haemophilia A	7	10/04/2015	25
14/SC/0074/AM03	Mechanisms underlying limb apraxia	1	15/12/2015	20
14/SC/0083/AM04	Advancing biomarkers in neurodegeneration	2	29/09/2015	16
14/SC/0092/AM12	Laminar Airflow in Severe Asthma for Exacerbation Reduction - LASER	5	13/05/2015	15
14/SC/0092/AM13	Laminar Airflow in Severe Asthma for Exacerbation Reduction - LASER	6, 24 June 2015	24/06/2015	11
14/SC/0128/AM04	CogBIAS - Mechanisms underlying Emotional Vulnerability & Resilience	5	20/05/2015	10
14/SC/0128/AM05	CogBIAS - Mechanisms underlying Emotional Vulnerability & Resilience	Amendment number six	03/12/2015	21
14/SC/0167/AM02	Prescription Of analgesia in Emergency Medicine (POEM)	2	04/06/2015	12
14/SC/0199/AM04	CheckMate 141: CHECKpoint pathway and nivoluMAb clinical Trial Evaluat	4	13/04/2015	15
14/SC/0199/AM05	CheckMate 141: CHECKpoint pathway and nivoluMAb clinical Trial Evaluat	CA209-141- UK SA EC05	24/07/2015	4
14/SC/0228/AM03	Minimally invasive surgery for ICH (MISTIE III)	Ethics 3, Protocol Version 4.0	14/04/2015	8
14/SC/0230/AM03	Tecfidera (dimethyl fumarate) Pregnancy Exposure Registry	3, Patient Brochure and PIS/ICF	07/08/2015	13
14/SC/0230/AM04	Tecfidera (dimethyl fumarate) Pregnancy Exposure Registry	4	01/02/2015	27
14/SC/0249/AM05	Symbicort in mild asthma	4 V1.0	03/07/2015	15
14/SC/0249/AM09	Symbicort in mild asthma	7 (Global Protocol Amendment 2	04/09/2015	16
14/SC/0277/AM04	RCT of physiotherapy informed by ACT for CLBP: the PACT study	4	12/05/2015	16
14/SC/0277/AM05	RCT of physiotherapy informed by ACT for CLBP: the PACT study	5	29/02/2016	14
14/SC/0283/AM03	Six Lead identification of Atrial Fibrillation (SL-AF Trial)	2	20/11/2015	13

14/SC/1032/AM01	Eosinophilic Oesophagitis in Adults	Substantial Amendment 1	14/04/2015	5
14/SC/1192/AM04	D5160C00008 - Phase I, Open Label, PK, Advanced Solid Tumour (Hepatic)	Substantial Amendment - V03GBR	20/03/2015	15
14/SC/1192/AM05	D5160C00008 - Phase I, Open Label, PK, Advanced Solid Tumour (Hepatic)	5 - SA5 ICF (V04GBR01) & IB (03/07/2015	11
14/SC/1203/AM02	Efficacy and safety of PF06410293 and Adalimumab in RA	Protocol Am 03	25/09/2014	17
14/SC/1203/AM04	Efficacy and safety of PF06410293 and Adalimumab in RA	Substantial Amendment 4	19/08/2015	9
14/SC/1203/AM05	Efficacy and safety of PF06410293 and Adalimumab in RA	5	06/11/2015	27
14/SC/1203/AM07	Efficacy and safety of PF06410293 and Adalimumab in RA	6	02/02/2016	17
14/SC/1206/AM02	ElaTION	Amendment 2 ³ / ₄ 09th July 2015	09/07/2015	10
14/SC/1235/AM05	Obstructive sleep apnoea and retinal vascular reactivity	SA4	17/02/2016	24
14/SC/1251/AM04	D5160C00009 - Phase I, Open Label, PK, NSCLC (Food Effect)	SA3 - V03GBR01	30/03/2015	14
14/SC/1251/AM05	D5160C00009 - Phase I, Open Label, PK, NSCLC (Food Effect)	SA4 ICF (V04GBR01) & IB (Ed 5)	03/06/2015	8
14/SC/1257/AM04	AM1030 - Single and Multiple dose study in Atopic dermatitis patients	4	28/07/2015	6
14/SC/1259/AM04	D5160C00013 - Phase I, Open Label, EGFRm positive NSCLC (Inducer)	3	20/03/2015	5
14/SC/1259/AM05	D5160C00013 - Phase I, Open Label, EGFRm positive NSCLC (Inducer)	SA4 ICF (V04GBR01) & IB (Ed 5)	16/07/2015	7
14/SC/1366/AM02	Therasphere treatment of liver metastases from colorectal cancer	1 IB V3.2	20/02/2015	4
14/SC/1376/AM01	Partial prostate Ablation versus Radical prosTatectomy (PART)	1	21/12/2015	28
14/SC/1376/AM02	Partial prostate Ablation versus Radical prosTatectomy (PART)	2	25/01/2016	15
14/SC/1429/AM03	Role of lung sounds in IPF - Version 1	2	27/01/2016	14
15/SC/0003/AM02	A Study on the Effect of E7438 in Patients with Advanced Tumors	2	30/04/2015	10
15/SC/0003/AM03	A Study on the Effect of E7438 in Patients with Advanced Tumors	Prot Am 8, 15 September 2015/	20/10/2015	10

15/SC/0011/AM06	Phase IIA study of Lanreotide PRF in subjects with Acromegaly	2	07/09/2015	16
15/SC/0011/AM14	Phase IIA study of Lanreotide PRF in subjects with Acromegaly	13	16/03/2016	19
15/SC/0038/AM01	Platelet function in paediatric cardiac patients on bypass and ECMO	Amendment 1 March 10th 2015	10/03/2015	25
15/SC/0076/AM02	Offender Personality Disorder Pathway – Feasibility Study	4, 10.06.15	10/06/2015	17
15/SC/0080/AM04	Study to Investigate the Use of Biotelemetry in Subjects with ALS	1	24/09/2015	21
15/SC/0080/AM06	Study to Investigate the Use of Biotelemetry in Subjects with ALS	2	10/12/2015	21
15/SC/0080/AM10	Study to Investigate the Use of Biotelemetry in Subjects with ALS	3	14/01/2016	12
15/SC/0133/AM01	RSV PED-001	1	21/05/2015	8
15/SC/0133/AM04	RSV PED-001	2	18/08/2015	12
15/SC/0133/AM05	RSV PED-001	3	08/10/2015	7
15/SC/0133/AM06	RSV PED-001	4	10/11/2015	23
15/SC/0172/AM01	Investigating Meningococcal Vaccines in Adults	SA1 dated 17th June 2015	17/06/2015	14
15/SC/0172/AM02	Investigating Meningococcal Vaccines in Adults	Substantial Amendment 2, dated	15/10/2015	15
15/SC/0228/AM01	An investigation into distractibility in those reporting memory change	Amendment 1 - 23/09/2015	24/09/2015	24
15/SC/0280/AM04	1160.204 RE-CIRCUIT: Dabigatran vs warfarin in AF Ablation	3	22/09/2015	23
15/SC/0280/AM07	1160.204 RE-CIRCUIT: Dabigatran vs warfarin in AF Ablation	4	29/01/2016	21
15/SC/0295/AM03	D0816C00012 (ORZORA), Open Label, Phase IV, Ovarian Cancer (Olaparib)	03	28/01/2016	13
15/SC/0300/AM01	Experiences of people living with rosacea	1	10/12/2015	18
15/SC/0306/AM01	RANGE - Ramucirumab in Advanced Bladder Cancer (JVDC Study)	1	15/06/2015	14
15/SC/0355/AM01	Baby Vaccine Study (Sched3)	3	14/07/2015	10
15/SC/0355/AM06	Baby Vaccine Study (Sched3)	4	22/02/2016	21
15/SC/0359/AM01	A Phase 3 Veliparib plus Chemotherapy study in Ovarian Cancer	1	06/08/2015	5
15/SC/0437/AM01	Fluciclovine (18F) PET/CT in biochemical recurrence of prostate cancer	1	03/12/2015	29
15/SC/0456/AM01	MPDL3280A-Early phase study in patients with solid tumours	1	19/11/2015	14

15/SC/0456/AM02	MPDL3280A-Early phase study in patients with solid tumours	02	13/01/2016	12
15/SC/0470/AM01	Abatacept-Methotrexate combo vs Methotrexate in adults with early RA	EC01	22/10/2015	21
15/SC/0470/AM02	Abatacept-Methotrexate combo vs Methotrexate in adults with early RA	EC02	23/11/2015	10
15/SC/0475/AM01	CA209-227 - Nivolumab or nivolumab plus ipilimumab vs SOC in NSCLC	CA209-227-EC SA-01	17/09/2015	24
15/SC/0475/AM03	CA209-227 - Nivolumab or nivolumab plus ipilimumab vs SOC in NSCLC	CA209-227 -EC SA-02	15/10/2015	14
15/SC/0475/AM04	CA209-227 - Nivolumab or nivolumab plus ipilimumab vs SOC in NSCLC	3	20/11/2015	9
15/SC/0475/AM05	CA209-227 - Nivolumab or nivolumab plus ipilimumab vs SOC in NSCLC	4	07/01/2016	9
15/SC/0521/AM05	Phase 2 study with nab-Paclitaxel in patients with NSCLC	5	30/11/2015	7
15/SC/0550/AM01	A Single-Dose Open-Label Study of XOMA 358	1	06/11/2015	27
15/SC/0566/AM01	LEAK: Lipocalin in the ED for the diagnosis of Acute Kidney injury	1	18/11/2015	19
15/SC/0577/AM01	Exploring patients decision to participate in cardiac rehabilitation	1	17/12/2015	20
15/SC/0752/AM01	Cognition and psychological flexibility in multiple sclerosis - v1.0	1	08/03/2016	9

Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
08/H0607/51/AM03	Novel immune correlates of HIV-1 control	3	24/09/2015	25
12/SC/0462/AM09	Crohn's Disease Biomarker Study	6	13/04/2015	22
13/SC/0183/AM15	Everolimus in patients who have TSC related seizures	15	20/05/2015	17
13/SC/0286/AM11	BAN2401-G000-201 BAN2401 in Early Alzheimer's Disease	7	24/09/2015	28
13/SC/0535/AM14	DIAN-TU-001: Ph. II/III Randomized,Double-blind,Placebo in Alzheimer's	SA10, PA4 and related document	25/06/2015	11
13/SC/0535/AM15	DIAN-TU-001: Ph. II/III Randomized,Double-blind,Placebo in Alzheimer's	11	28/07/2015	5
14/SC/0092/AM14	Laminar Airflow in Severe Asthma for Exacerbation Reduction - LASER	7	20/08/2015	15
14/SC/0283/AM01	Six Lead identification of Atrial Fibrillation (SL-AF Trial)	1	21/04/2015	21

14/SC/1203/AM08	Efficacy and safety of PF06410293 and Adalimumab in RA	7	09/03/2016	27
14/SC/1235/AM04	Obstructive sleep apnoea and retinal vascular reactivity	3	23/07/2015	4
14/SC/1429/AM01	Role of lung sounds in IPF - Version 1	Substantial Amendment 1	11/03/2015	18
15/SC/0456/AM03	MPDL3280A-Early phase study in patients with solid tumours	3	15/02/2016	23
15/SC/0469/AM01	Genetic Basis of Motor Neurone Disease	1	08/02/2015	35
15/SC/0550/AM02	A Single-Dose Open-Label Study of XOMA 358	02	02/02/2016	17

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/0183/AM15/1	Everolimus in patients who have TSC related seizures	15	20/11/2015	8
13/SC/0286/AM11/3	BAN2401-G000-201 BAN2401 in Early Alzheimer's Disease	7	10/02/2016	23
13/SC/0535/AM14/1	DIAN-TU-001: Ph. II/III Randomized, Double-blind, Placebo in Alzheimer's	SA10 Modified	06/08/2015	4
14/SC/0283/AM01/1	Six Lead identification of Atrial Fibrillation (SL-AF Trial)	1.0 dated 29th June 2015	29/06/2015	8
14/SC/1235/AM04/1	Obstructive sleep apnoea and retinal vascular reactivity	Modified Substantial Amendment	23/07/2015	2
14/SC/1429/AM01/1	Role of lung sounds in IPF - Version 1	Modified Substantial Amendment	11/03/2015	6
15/SC/0550/AM02/1	A Single-Dose Open-Label Study of XOMA 358	2	24/02/2016	14

Unfavourable opinion timeline				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
13/SC/0286/AM11/1	BAN2401-G000-201 BAN2401 in Early Alzheimer's Disease	7	03/11/2015	14
13/SC/0286/AM11/2	BAN2401-G000-201 BAN2401 in Early Alzheimer's Disease	7	01/12/2015	10

Table 11: Items exceeding timelines

Full applications for ethical review over 60 day timeline

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

REC Reference	Title	Number of Days on Clock
15/SC/0773	Estimating community carriage of CPE in Manchester v1.	15

SSAs (non Phase 1) over 25 day timeline

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

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

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

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
13/SC/0286/AM11/3	BAN2401-G000-201 BAN2401 in Early Alzheimer's Disease	7	10/02/2016	23

