

**South Central - Berkshire B Research Ethics
Committee**

Annual Report

01 April 2015 - 31 March 2016



Part 1 – Committee Membership and Training

Name of REC:	South Central - Berkshire B Research Ethics Committee
Type of REC:	RES Committee South Central - Berkshire B
Type of Flag:	Type III
Chair:	Dr John Sheridan
Vice-Chair:	Mr Mike Arnott
Alternate Vice-Chair:	Mr John Inman
REC Manager:	Miss Lauren Allen (until 31/04/2016) Mr Rajat Khullar (01/05/2016 – 31/09/2016) Miss Tina Cavaliere (01/10/2016 – ongoing)
REC Assistant:	Mr Wai Yeung(01/05/2016 – 31/09/2016) Claudia Bywater (01/10/2016 – 01/03/2016) Ms Helen Sivey (01/03/2016 – ongoing)
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Chair's overview of the past year:

I consider that the REC had a good year overall. The main objective of safeguarding the interests of the participants was fulfilled, discussions at meeting were productive and all members contributed well. I believe that the decisions reached were sound and that the REC interacted effectively with researchers. Timelines were generally good and the REC managers and their assistants in post during the year deserve credit for this.

The REC again reached a high proportion of provisional opinions but the points raised were generally resolved quickly, with the co-operation of the researchers, and final favourable opinions were issued relatively soon after the meetings. I also consider that, for some studies, considerable improvements in the PIS (in particular) were achieved following the input of the REC.

I consider that negative aspects were relatively minor. The REC considered to be hampered by a shortage of medically qualified members. The stricture concerning relative numbers of members in the different categories also continued to cause problems.

South Central - Berkshire B Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Mr Mike Arnott	Research Consultant	Lay Plus	01/06/2011	
Ms Sukhdip Boughan	Pharmacist	Expert	01/08/2014	
Dr Alan Clark	Pharmacist	Expert	01/09/2014	
Mrs Sue Harrison	Retired Managing Director of a Trade Association	Lay Plus	13/02/2013	
Mr John Inman	Retired Pharmacist	Lay	01/06/2011	
Dr Sandy McPherson	Consultant General Surgeon	Expert	17/12/2015	
Dr Joanne Milton	Project Manager	Lay	11/02/2013	
Mrs Rachael Quinn	Nurse Member	Expert	09/03/2015	09/09/2015
Dr John Sheridan	Consultant Toxicologist and Chemist	Lay	01/06/2011	
Mrs Mary Sneade	Clinical Trial manager	Expert	01/04/2014	
Mr Paul Soper	Research Manager	Lay Plus	01/06/2011	
Ms Decca Warrington	Volunteer Arts Coordinator	Lay Plus	09/07/2013	
Mr Stuart Young	Director	Lay	29/05/2013	

South Central - Berkshire B Research Ethics Committee: Deputy Members

Name	Profession	Status	Meeting date attended
Miss Elena Villarreal	Assistant Clinical Research Coordinator	Lay	01/12/2015
Mrs Nicola Adey	Regulatory Officer	Lay	02/12/2015

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

Name	Profession	Status	Meeting date attended
Dr Mike Proven	Coordinator for QAR (UREC Secretary)	Lay Plus	12/04/2016
Ms Stephanie Ellis	Civil Servant (Retired)	Lay Plus	13/10/2015
Mr Roy Sinclair	Pharmacist	Lay	11/08/2014
Mr Jeremy Butler	Former NHS Non-Executive Director	Lay	10/11/2015

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

Name	Declaration of Interest	Date
Mrs Nicola Adey	Senior Regulatory Officer at PSI CRO UK Ltd	12/01/2016
Mr Mike Arnott	Administrator, Vice Chair of Reading Independent REC	12/01/2016
Ms Sukhdip Boughan	Medical affairs manager at AstraZeneca	12/01/2016
Dr Alan Clark	Minor holdings in public companies GSK, Astrazeneca, Cardinal Health and Becton Dickinson Inc. Employed by Trudell Medical International, Europe Ltd. A Canadian medical device manufacturer.	12/01/2016
Mrs Sue Harrison	Trusteed of Re-solv.C Prevention of Volatile Substance, Abuse and Legal Highs.	28/02/2016
Mr John Inman	None	11/01/2016
Dr Sandy McPherson	None	31/03/2016
Dr Joanne Milton	Shareholdings in Oxford Biomedica Plc, Member of Reading Independent Ethics Committee, Employed as Clinical Trial Manager at University of Oxford currently involved in trails sponsored by Merck & Co. Inc. and Takeda Ltd.	12/01/2016
Dr John Sheridan	None	12/01/2016
Mrs Mary Sneade	Member of the Reading Independent Ethics Committee.	28/02/2016
Mr Paul Soper	None	28/02/2016
Miss Elena Villarreal	Employed by Division of Cardiovascular Medicine at University of Oxford	12/01/2016
Ms Decca Warrington	None	12/01/2016
Mr Stuart Young	None	12/01/2016

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

Month	Date	Number of Members Present at Meeting
April	14/04/2015	10
June	09/06/2015	8
July	07/07/2015	8
August	11/08/2015	11
September	08/09/2015	9
October	13/10/2015	8
November	10/11/2015	8
December	08/12/2015	12
January	12/01/2016	10
February	09/02/2016	12

10 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	28/04/2015	3
May	27/05/2015	3
June	23/06/2015	3
July	21/07/2015	3
August	25/08/2015	3
September	22/09/2015	3
October	27/10/2015	3
November	24/11/2015	3
December	08/12/2015	3
January	27/01/2016	3
February	23/02/2016	3
March	31/03/2016	3

12 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	03/04/2015	2
April	10/04/2015	2
April	24/04/2015	3
May	08/05/2015	3
May	22/05/2015	2
June	05/06/2015	2
June	19/06/2015	2
July	03/07/2015	2
July	17/07/2015	2

July	31/07/2015	2
August	14/08/2015	2
August	28/08/2015	2
September	25/09/2015	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	20/11/2015	2
December	04/12/2015	2
December	18/12/2015	2
January	04/01/2016	2
January	18/01/2016	2
February	01/02/2016	2
February	15/02/2016	2
March	04/03/2016	2
March	14/03/2016	3

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

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

None

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

Name	Number of Meetings Attended
Mrs Nicola Adey	2
Mr Mike Arnott	10
Ms Sukhdip Boughan	3
Mr Jeremy Butler	1
Dr Alan Clark	9
Mrs Sue Harrison	8
Mr John Inman	7
Dr Sandy McPherson	1
Dr Joanne Milton	8
Mrs Rachael Quinn	3
Dr John Sheridan	10
Mrs Mary Sneade	7
Mr Paul Soper	6
Miss Elena Villarreal	3
Ms Decca Warrington	10
Mr Stuart Young	6

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

Name	Number of Meetings Attended
Mr Mike Arnott	12
Dr Alan Clark	1
Mr John Inman	1
Mrs Rachael Quinn	1
Dr John Sheridan	11
Mrs Mary Sneade	10

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

Name	Number of Meetings Attended
Mr Mike Arnott	25
Mr John Inman	4
Dr Joanne Milton	1
Mrs Rachael Quinn	2
Dr John Sheridan	25

Training 01 April 2015 - 31 March 2016

Name of Member	Date	Event(s) attended
Mrs Nicola Adey	18/02/2016	National Members Training Day
Mrs Nicola Adey	10/03/2016	Committee Member Induction
Mr Mike Arnott	20/10/2015	Berkshire Training meeting
Mr Jeremy Butler	11/01/2016	Local Training Day
Dr Alan Clark	20/10/2015	Berkshire and Berkshire B REC Training Day
Mrs Sue Harrison	06/08/2015	Public Involvement in Health Research – To gain a better understanding of how the public can contribute to shaping health research.
Mrs Sue Harrison	06/08/2015	Ethical Issues in internet-based research: RCTs and qualitative approaches – To gain a better understanding of the ethical issues of undertaking internet based health research
Mrs Sue Harrison	06/08/2015	Where angels fear to tread? Research in Palliative Care – Can be done rigorously and ethically? - To gain an understanding of studies involving palliative care
Mrs Sue Harrison	06/08/2015	Changes to the European Clinical Trial Directive and their impact on research in the UK – To gain a better understanding of the legal framework under which the research ethics service operates
Mrs Sue Harrison	18/02/2016	National Members Training Day
Mrs Sue Harrison	18/02/2016	National Members Training Day
Mr John Inman	20/10/2015	Berkshire and Berkshire B REC training day 20.10.15
Dr Joanne Milton	07/10/2015	Introduction to Phase 1 Research - Trials & Regulation
Dr Joanne Milton	12/10/2015	Complex Cases
Dr John Sheridan	20/10/2015	Berkshire and Berkshire B Training Day
Mrs Mary Sneade	07/10/2015	Introduction to Phase 1 Research - Trials & Regulation
Mrs Mary Sneade	20/10/2015	Berkshire and Berkshire B Training Day
Mr Paul Soper	20/10/2015	Berkshire and Berkshire B REC Training Day
Miss Elena Villarreal	10/02/2016	National Members Training Day
Miss Elena Villarreal	22/02/2016	E&D
Ms Decca Warrington	19/10/2015	The Ethical Issues of Research Involving Children

Ms Decca Warrington	03/11/2015	E&D
Mr Stuart Young	20/10/2015	Berkshire and Berkshire B REC 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	26.00
Phase 1	18	36.00
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	0	0.00
Others	19	38.00
Total Applications Reviewed	50	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	11
Number of paediatric applications reviewed	5
Number of device applications reviewed	3
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	0
Number of applications reviewed that are funded by the US DHHS	1
Number of qualitative applications reviewed	0

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	0	0.00
Favourable Opinion with Additional Conditions	6	12.00
Unfavourable Opinion	0	0.00
Provisional Opinion	44	88.00
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	50	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	40	80.00
Further Information Favourable Opinion with Additional Conditions	4	8.00
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	6	12.00
Unfavourable Opinion	0	0.00
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	50	100

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

Total Applications Reviewed	29
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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	14
Number of studies withdrawn prior to the meeting	2
Number of student applications reviewed	11
Number of paediatric applications reviewed	1
Number of device applications reviewed	2
Number of qualitative applications reviewed	3

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

Decisions taken at proportionate review sub-committee meetings	Number	%
Favourable Opinion with Standard Conditions	10	34.48
Favourable Opinion with Additional Conditions	12	41.38
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	7	24.14
Unfavourable Opinion	0	0.00
Total	29	100

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

Average number of applications reviewed per full meeting	5.00
Number of completed applications for full ethical review	50
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	2
Number of completed applications over 40 days as a % of total	4.00%
Number of days taken to final decision – average (mean)	29
Number of completed proportionate review applications for ethical review	30
Number of completed proportionate review applications for ethical review over 14 days	0
Number of completed proportionate review applications over 14 days as a % of total	0.00%
Number of SSAs (non-Phase 1) reviewed	5
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	20
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	110
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	1
Number of completed substantial amendments over 28 days as a % of total substantial amendments	0.91%
Number of modified amendments reviewed	6
Number of completed modified amendments over 14 days	1
Number of completed modified amendments over 14 days as a % of total modified amendments	16.67%
Number of minor amendments received	100
Number of substantial amendments received for information	1
Number of substantial amendments received for new sites/PIs	13
Number of annual progress reports received	12

Number of safety reports received	17
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/0213	ABT494 in patients with Crohn's Disease	24
15/SC/0214	Babies' social development	26
15/SC/0221	A Randomised, SAD/MAD Study to Assess Safety & PK of DS102	23
15/SC/0225	BC Study of G7 cup used with compatible femoral stems	21
15/SC/0229	Neural effects of agomelatine on reward and aversion processing.	43
15/SC/0250	Effect of single doses MT-8554 with pain stimulus in healthy subjects	39
15/SC/0327	Polygraph with mentally disordered sex offenders	40
15/SC/0329	Leo - 32731 Phase I, Single-Blind, SAD/MAD study in healthy volunteers	26
15/SC/0331	A multi-centred study of the effectiveness of PEGASUS	33
15/SC/0345	The TROOPeR Study	29
15/SC/0357	PK, PD, safety and tolerability of CNP520 in healthy elderly subjects	33
15/SC/0386	A Phase I Study to Assess Malaria Vaccine R21 with Matrix-M1	29
15/SC/0402	Imagery Rescripting in Asylum Seekers	33
15/SC/0405	Emotion regulation in ADHD, anxiety and co-morbid ADHD/anxiety	32
15/SC/0407	CR4056-2-01	34
15/SC/0412	Safety, Tolerability & PK of TAK-831 as SAD & MAD in Healthy Subjects	30
15/SC/0443	CAIN457A3302 - OPTIMISE STUDY	29
15/SC/0450	SGLT2 inhibitors effect on Glucose Flux, Lipolysis and Ketogenesis	31
15/SC/0549	A PK and DP assessment of MR308 in Japanese and Caucasian subjects	30
15/SC/0552	Phase 1 Study of BLU-285 in Patients with GIST v1	33
15/SC/0554	UCB4940 as add-on to Certolizumab Pegol for Rheumatoid Arthritis	25
15/SC/0599	GS-US-218-1797 GS-5806 in Lung Transplant Recipients with RSV	26
15/SC/0608	IONA Twin Study, Version 1.0	28
15/SC/0637	Understanding barriers and outcomes of unspecified (altruistic) kidney	25
15/SC/0659	JNJ-54861911ALZ2003 - 'EARLY' - Alzheimer's Dementia Study	24
15/SC/0670	Memory and Executive Functioning in Adolescent Depression	26
15/SC/0679	Study of Trametinib in children and adolescent subjects with Cancer	24
15/SC/0688	Assess PK of AZD7986 alone & with VER, ITR or DIL in healthy subjects	19
15/SC/0690	Getting Down to Coping in Lanarkshire	24
15/SC/0747	EACH study follow-up	22
15/SC/0748	The Texture Study	27
16/SC/0009	First time in human study of oral anti-Serum Amyloid P (GSK3039294)	54

16/SC/0012	Atovaquone as Tumour HypOxia Modifier	33
16/SC/0013	Parent-Adolescent Interactions in Depressed Adolescents - Version 1	31
16/SC/0014	Safety & tolerability of MEDI9314 as SAD in healthy subjects	35
16/SC/0027	Safety & Tolerability of PC945 in healthy & subjects with mild asthma	28
16/SC/0033	PK of intranasal MR903 and i.m and i.v naloxone hydrochloride	29
16/SC/0034	Safety, tolerability and PK of IV MOTREM in healthy male volunteers	21
16/SC/0069	True NTH Exercise & Diet Project Phase 2	28
16/SC/0070	Creative bibliotherapy for post-traumatic stress disorder (PTSD)	25

Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/SC/0431	JVDE: The REACH-2 Study	29
15/SC/0522	Mindfulness for patients with difficult to manage asthma	28
15/SC/0603	MAESTRO-OL: Macitentan in Eisenmenger Syndrome OPEN LABEL AC-055-308	23
15/SC/0719	A SAD, MAD, safety, PK and PD study of AZD5718 in healthy subjects	24

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
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Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/SC/0216	RESCUE-COPD1 Version 1	17
15/SC/0404	OC000459 in Severe Asthma	32
15/SC/0449	Study to Evaluate PK Profiles of AF-219 (QCL117521)	28
15/SC/0516	A PET study to evaluate the effect of ABT-555 in subjects with MS	22
15/SC/0651	A study to investigate FDL169 in healthy female volunteers	22
16/SC/0001	DELP-04: Comparison of the effect of four emollients on skin hydration	30

Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock

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
15/SC/0188	International LEMTRADA Pregnancy Exposure Cohort in Multiple Sclerosis	7
15/SC/0349	Injury attributions, shame and self-criticism in ABI/TBI survivors	10
15/SC/0465	Motivational interviewing and compliance with oral hygiene methods	13
15/SC/0467	The STarT Back Programme: The Perspectives of 'Low Risk' Participants	13
15/SC/0667	CA209_116 LENS expansion study	6
15/SC/0669	Patient perceptions of the discharge process at the RLBUHT v1	7
15/SC/0761	Anatomical correlates of upper limb impairment after stroke	13
15/SC/0764	Dialysis and vascular access	13

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/0343	Role of ConfirmMDx for Prostate Cancer in prostate cancer detection	8
15/SC/0395	User Evaluation of the FreeStyle Optium BG Monitoring system	7
15/SC/0546	Anatomical variation of distal femoral rotational axes (1)	5
15/SC/0547	Epidemiology and Outcomes of Stab Injury in Children and Adolescents	5
15/SC/0590	Biomarker discovery in melanoma: case-control study	7
15/SC/0672	Characterising de novo donor-specific antibodies by IgG subclass	5
15/SC/0736	Role of endogenous transposable elements in the pathogenesis of MND	6
15/SC/0738	Patients' online access and interpretation of lab test results	6
15/SC/0742	Pathological analysis of glioblastoma tissue in elderly patients	4
16/SC/0132	REMARK	8

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
15/SC/0277	TABI	8
15/SC/0278	Supporting children's participation by targeting parental self-efficacy	8
15/SC/0279	Imaging of digital arteries in patients with systemic sclerosis	8
15/SC/0281	A trial to investigate the effect of fluids on sodium and fluid status	9
15/SC/0341	ADDITION Plus - 10 year	8
15/SC/0346	Aflibercept (Eylea) Risk Minimisation Study	8
15/SC/0398	TENS for Overactive bladder symptoms in females	6
15/SC/0400	TRANSBACCHUS	8
15/SC/0464	Clinical Evaluation of Two Daily Disposable Contact Lenses	7
15/SC/0543	High Density Mapping for WACA Completion	2
16/SC/0059	Correlation between DAS and PROs in RA. V1	10
16/SC/0118	3D vs 2D laparoscopic rectal surgery: randomised controlled trial	6

Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock

Provisional Opinion		
REC Reference	Title	Number of Days on Clock

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

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

Table 10.1: Breakdown of current status of all substantial amendments reviewed within the reporting period

Favourable opinion				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
12/SC/0024/AM09	Ranibizumab in visual impaired patients due to macular edema (CRVO).	IB Edition 13 2015/01/21	09/04/2015	3
12/SC/0025/AM09	Ranibizumab in visual impaired patients due to macular edema(BRVO)	IB's Edition 13 2015/01/21	10/04/2015	3
12/SC/0472/AM12	BMS-936558 vs Docetaxel in metastatic Non Small Cell Lung Cancer	9	30/03/2015	3
12/SC/0482/AM02	Atrial Fibrillation Ablation Registry (Protocol Date: 10th May 2012)	2	10/08/2015	11
12/SC/0482/AM03	Atrial Fibrillation Ablation Registry (Protocol Date: 10th May 2012)	3	08/09/2015	6
12/SC/0570/AM12	CFTY720D2406: long-term observational fingolimod study	SA5: Protocol v03	16/12/2015	7
12/SC/0630/AM14	GSK systemic amyloidosis	5	26/08/2015	9
12/SC/0649/AM03	Development and implantation of normal human preimplantation embryos	SA3	17/12/2015	6
13/SC/0073/AM10	COSMIC-HF A dose escalation study in patients with heart failure	7	01/06/2015	8
13/SC/0530/AM06	ORANGE II PLUS	7	28/04/2015	1
13/SC/0530/AM07	ORANGE II PLUS	08	05/08/2015	6
13/SC/0569/AM05	Dopamine and Choice in Depression	Amendment 4 26/9/2015	15/10/2015	6
13/SC/0583/AM02	Matchpoint	Substantial amendment dated 20	20/08/2015	8
14/SC/0011/AM02	Egg activation and cytoplasmic movements	2	06/05/2015	1
14/SC/0043/AM03	Parental Responses to Child Experiences of Trauma	3	18/05/2015	15
14/SC/0079/AM01	MAT-IA	Amendment No 1, 29.06.2015	29/06/2015	10
14/SC/0126/AM05	Rare diseases of the bone, joint and vessels Study (RUDY)	3	29/06/2015	10
14/SC/0127/AM02	The psychological impact of chronic leg ulceration on caregivers	2 29/ 04/2015	07/05/2015	5
14/SC/0172/AM02	Measuring cognitive processes in CFS.	1	07/03/2016	13

14/SC/0181/AM07	Elagolix in Endometriosis Associated Pain - Extension Study	Protocol Amendment 1 - 6/09/20	19/05/2015	11
14/SC/0181/AM08	Elagolix in Endometriosis Associated Pain - Extension Study	SA2	24/09/2015	4
14/SC/0181/AM10	Elagolix in Endometriosis Associated Pain - Extension Study	Protocol Amendment 2 24/09/201	10/02/2016	7
14/SC/0262/AM07	SAFARI	SA 5 Amended Protocol v01	20/04/2015	9
14/SC/0262/AM08	SAFARI	SA 6 Change in CI	19/06/2015	3
14/SC/0287/AM01	Predictors of bowel scope screening participation, version 1.4	1	01/04/2015	7
14/SC/0290/AM04	ECLIPSE: Exploring the Current Landscape of IV Infusion Practices v.1	1.3 (10 September 2015)	10/09/2015	11
14/SC/1028/AM04	CTC in pancreatic cancer	Version 9, 29th May 2015	31/05/2015	8
14/SC/1059/AM13	28431754DNE3001: The CREDENCE Trial	8	13/04/2015	2
14/SC/1059/AM16	28431754DNE3001: The CREDENCE Trial	11	11/08/2015	14
14/SC/1059/AM19	28431754DNE3001: The CREDENCE Trial	Substantial Amendment 14	30/10/2015	6
14/SC/1059/AM22	28431754DNE3001: The CREDENCE Trial	UK EC Substantial Amendment #S	04/02/2016	5
14/SC/1059/AM24	28431754DNE3001: The CREDENCE Trial	UK EC Substantial Amendment #1	18/02/2016	13
14/SC/1214/AM04	Effects of regional ischaemia and light on NO and Sulphide signalling	Amendment 3, 21/10/2015	21/10/2015	5
14/SC/1226/AM01	Treatment of dental plaque biofilms using photodynamic therapy (ver.1)	1	16/04/2015	4
14/SC/1252/AM04	NEXUS- 24 week Study to investigate new medicine Namilumab in patients	Protocol Amendment 3	12/05/2015	1
14/SC/1252/AM07	NEXUS- 24 week Study to investigate new medicine Namilumab in patients	Recruitment Materials -2015/08	27/08/2015	11
14/SC/1252/AM09	NEXUS- 24 week Study to investigate new medicine Namilumab in patients	SA6 - Notification of recruitm	04/01/2016	2
14/SC/1294/AM02	Case-control study for Campylobacter in the under 5s. Version 1	02	21/04/2015	8
14/SC/1317/AM02	ACP-196 in subjects with Relapsed or Refractory de Novo ABC	1	12/05/2015	0

	DLBCL			
14/SC/1317/AM03	ACP-196 in subjects with Relapsed or Refractory de Novo ABC DLBCL	2	22/06/2015	11
14/SC/1317/AM05	ACP-196 in subjects with Relapsed or Refractory de Novo ABC DLBCL	SA3	25/02/2016	35
14/SC/1329/AM03	STRIVE - Intravenous immunoglobulin vs standard therapy for TM	2	09/07/2015	1
14/SC/1329/AM05	STRIVE - Intravenous immunoglobulin vs standard therapy for TM	SA3	22/12/2015	14
14/SC/1342/AM01	MAD PK study of CD5789 in Japanese and non-Japanese healthy subjects	1	29/04/2015	1
14/SC/1342/AM02	MAD PK study of CD5789 in Japanese and non-Japanese healthy subjects	Substantial amendment dated 12	12/06/2015	10
14/SC/1355/AM03	Health literacy assessment in community pharmacies	1.2 22nd October 2015	22/10/2015	4
14/SC/1413/AM01	Faecal s-RAGE	1 9/12/15	14/12/2015	4
15/SC/0006/AM02	Phase1a, Safety, Randomized, Placebo-controlled, SAD Study of MEDI7836	SA2	30/11/2015	3
15/SC/0008/AM01	Portsmouth Birth Cohort Registry	1	06/05/2015	5
15/SC/0008/AM02	Portsmouth Birth Cohort Registry	Substantial Amendment 2	28/10/2015	6
15/SC/0008/AM03	Portsmouth Birth Cohort Registry	Substantial Amendment 3	12/11/2015	7
15/SC/0008/AM04	Portsmouth Birth Cohort Registry	4	04/12/2015	19
15/SC/0008/AM05	Portsmouth Birth Cohort Registry	5:22/01/16	22/01/2016	6
15/SC/0008/AM06	Portsmouth Birth Cohort Registry	Amendment 6	02/03/2016	14
15/SC/0020/AM01	MT203-2004 TELLUS: Namilumab & Adalimumab in Rheumatoid Arthritis	Amendment #1	07/05/2015	5
15/SC/0020/AM02	MT203-2004 TELLUS: Namilumab & Adalimumab in Rheumatoid Arthritis	2	04/01/2016	3
15/SC/0079/AM03	Study Protocol ACI-35 in patients with mild to moderate Alzheimer's.	ECSA# 3UK (Protocol v 5.0 Am 8	07/07/2015	3
15/SC/0079/AM05	Study Protocol ACI-35 in patients with mild to moderate Alzheimer's.	SA#5	08/10/2015	12

15/SC/0079/AM07	Study Protocol ACI-35 in patients with mild to moderate Alzheimer's.	SA#7	01/12/2015	12
15/SC/0081/AM01	Cognitive and behavioural processes in anxious children/adolescents V1	SA1	16/12/2015	5
15/SC/0100/AM01	Clinical trial of topical GTN for treatment of Erectile dysfunction	Amendment 1 Protocol V3.0	19/06/2015	9
15/SC/0100/AM02	Clinical trial of topical GTN for treatment of Erectile dysfunction	Substantial Amendment 2 - v1.0	07/07/2015	4
15/SC/0119/AM04	Safety, Tolerability, PK and PD study of ASP6282 in Healthy Subjects	Sub Amendment 1 - Temp halt	07/07/2015	2
15/SC/0119/AM05	Safety, Tolerability, PK and PD study of ASP6282 in Healthy Subjects	Sub Amendment 2 - Restart of t	28/09/2015	10
15/SC/0123/AM05	PGRx Information System for Epidemiological Research	1	19/06/2015	3
15/SC/0123/AM07	PGRx Information System for Epidemiological Research	2	17/07/2015	7
15/SC/0123/AM08	PGRx Information System for Epidemiological Research	substantial amendment 3 dated	15/10/2015	2
15/SC/0141/AM02	DELP-05: Comparison of two emollients in patients with dry skin	Substantial amendment 13/05/2105	13/05/2015	4
15/SC/0213/AM01	ABT494 in patients with Crohn's Disease	1	22/06/2015	17
15/SC/0213/AM02	ABT494 in patients with Crohn's Disease	2	17/08/2015	15
15/SC/0213/AM03	ABT494 in patients with Crohn's Disease	ABT494 Annual IB Update, Ed.5	11/09/2015	7
15/SC/0213/AM04	ABT494 in patients with Crohn's Disease	SA4	11/12/2015	6
15/SC/0213/AM05	ABT494 in patients with Crohn's Disease	Protocol Amendment 3	05/02/2016	25
15/SC/0216/AM03	RESCUE-COPD1 Version 1	SA2	09/07/2015	4
15/SC/0221/AM02	A Randomised, SAD/MAD Study to Assess Safety & PK of DS102	3	02/07/2015	6
15/SC/0221/AM03	A Randomised, SAD/MAD Study to Assess Safety & PK of DS102	4	12/08/2015	14
15/SC/0225/AM01	BC Study of G7 cup used with compatible femoral stems	1	11/08/2015	14
15/SC/0225/AM03	BC Study of G7 cup used with compatible femoral stems	SA2	18/12/2015	2
15/SC/0229/AM03	Neural effects of agomelatine on reward and aversion	Version 3,	19/10/2015	11

	processing.	24/09/2015		
15/SC/0329/AM02	Leo - 32731 Phase I, Single-Blind, SAD/MAD study in healthy volunteers	Protocol v 2 - 2015/09/25	06/10/2015	16
15/SC/0345/AM01	The TROOPeR Study	1	08/09/2015	1
15/SC/0357/AM01	PK, PD, safety and tolerability of CNP520 in healthy elderly subjects	1	26/08/2015	9
15/SC/0357/AM05	PK, PD, safety and tolerability of CNP520 in healthy elderly subjects	SA3	04/02/2016	1
15/SC/0386/AM01	A Phase I Study to Assess Malaria Vaccine R21 with Matrix-M1	1	13/08/2015	15
15/SC/0386/AM02	A Phase I Study to Assess Malaria Vaccine R21 with Matrix-M1	SA 002	28/08/2015	4
15/SC/0386/AM03	A Phase I Study to Assess Malaria Vaccine R21 with Matrix-M1	SA003	26/11/2015	18
15/SC/0402/AM01	Imagery Rescripting in Asylum Seekers	SA1	08/12/2015	6
15/SC/0402/AM02	Imagery Rescripting in Asylum Seekers	SA2	20/12/2015	2
15/SC/0404/AM02	OC000459 in Severe Asthma	Amendment 1 - 2015/08/19	19/08/2015	10
15/SC/0404/AM03	OC000459 in Severe Asthma	Amendment 2 - 2015/11/19	10/12/2015	8
15/SC/0404/AM04	OC000459 in Severe Asthma	1 - Substantial Amendment 3, T	15/03/2016	14
15/SC/0407/AM01	CR4056-2-01	Amendment 2 (Amending Protocol	21/09/2015	7
15/SC/0407/AM03	CR4056-2-01	SA2	07/12/2015	9
15/SC/0412/AM05	Safety, Tolerability & PK of TAK-831 as SAD & MAD in Healthy Subjects	Amendment 04	17/02/2016	21
15/SC/0443/AM01	CAIN457A3302 - OPTIMISE STUDY	1	17/09/2015	8
15/SC/0464/AM02	Clinical Evaluation of Two Daily Disposable Contact Lenses	1	02/09/2015	4
15/SC/0516/AM01	A PET study to evaluate the effect of ABT-555 in subjects with MS	Substantial Amendment - 09.12.	05/01/2016	1
15/SC/0522/AM01	Mindfulness for patients with difficult to manage asthma	Amendment 1, 15 Jan 2016	15/01/2016	9
15/SC/0552/AM01	Phase 1 Study of BLU-285 in Patients with GIST v1	BLU-285-1101_SA#01	22/01/2016	6
15/SC/0554/AM01	UCB4940 as add-on to Certolizumab Pegol for Rheumatoid Arthritis	SA #1	17/11/2015	8
15/SC/0670/AM01	Memory and Executive Functioning in Adolescent Depression	amendment 1	28/01/2016	6

		22/01/16		
15/SC/0679/AM01	Study of Trametinib in children and adolescent subjects with Cancer	SA1	18/12/2015	15
15/SC/0690/AM02	Getting Down to Coping in Lanarkshire	SA1	04/02/2016	4
16/SC/0014/AM01	Safety & tolerability of MEDI9314 as SAD in healthy subjects	Substantial Amendment 1 (Proto	10/02/2016	9

Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
14/SC/1252/AM08	NEXUS- 24 week Study to investigate new medicine Namilumab in patients	Protocol Amendment 5	25/11/2015	19
15/SC/0100/AM03	Clinical trial of topical GTN for treatment of Erectile dysfunction	3 (v1.0)	24/07/2015	10
15/SC/0187/AM01	Midwives' communication, womens' cognitive ability & understanding	v1.8 17092015	17/09/2015	14
15/SC/0357/AM02	PK, PD, safety and tolerability of CNP520 in healthy elderly subjects	Substantial Amendment 2	09/09/2015	14
15/SC/0431/AM01	JVDE: The REACH-2 Study	SA1	30/11/2015	11
15/SC/0599/AM03	GS-US-218-1797 GS-5806 in Lung Transplant Recipients with RSV	Protocol Amendment 1, ICF V2,	25/01/2016	3

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

Favourable opinion timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
15/SC/0100/AM03/1	Clinical trial of topical GTN for treatment of Erectile dysfunction	2.0	04/08/2015	1
15/SC/0187/AM01/1	Midwives' communication, womens' cognitive ability & understanding	Modified v1.9 28/10/2015	02/11/2015	16
15/SC/0357/AM02/1	PK, PD, safety and tolerability of CNP520 in healthy elderly subjects	Substantial Amendment 2	07/10/2015	9

15/SC/0431/AM01/2	JVDE: The REACH-2 Study	Modified amendment to the 30th	05/01/2016	2
15/SC/0599/AM03/1	GS-US-218-1797 GS-5806 in Lung Transplant Recipients with RSV	MODIFIED Protocol Amendment 1	01/03/2016	8

Unfavourable opinion timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
15/SC/0431/AM01/1	JVDE: The REACH-2 Study	Modified 30/11/15	22/12/2015	2

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
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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
15/SC/0187/AM01/1	Midwives' communication, womens' cognitive ability & understanding	Modified v1.9 28/10/2015	02/11/2015	16

