

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

Annual Report

01 April 2016 - 31 March 2017



Part 1 – Committee Membership and Training

Name of REC:	South Central - Berkshire B 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:	Phase 1 in Healthy Volunteers, Phase 1 in Patients
Chair:	Dr John Sheridan
Vice-Chair:	Mr Mike Arnott (until 04/10/2016) Miss Elena Villarreal (from 05/10/2016)
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 – 19/12/2016) Miss Lucy Roberts (19/12/2016-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 – 03/01/2017) Mr Stephan Ramey (03/01/2017- 27/04/2017)
Committee Address:	Whitefriars Level 3, Block B Lewins Mead Bristol BS1 2NT
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Chair's overview of the past year:

Overall, a good year for the REC, in my view. The members worked well together and timescales were generally good. Membership increased over the period and we eventually no longer needed the much appreciated help from Mike Proven, which tided us over time when we were short on numbers.

Mike Arnott resigned as Vice Chair after several years of excellent performance in the role but I am pleased that he stayed on as a member. Elena Villarreal has already proved effective as Mike's replacement. We were sorry to lose Decca Warrington, who had made a very valued contribution to the work of the REC.

The changes in Management staff over the period were greater than I would have liked to see but I am pleased that Lucy Roberts is now in post. Helen Sivey was excellent as REC assistant and fully deserved her promotion to manager of another REC.

South Central - Berkshire B Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Mrs Nicola Adey	Regulatory Officer	Lay	02/12/2015	
Mr Mike Arnott	Research Consultant	Lay Plus	01/06/2011	
Ms Sukhdip Boughan	Pharmacist	Expert	01/08/2014	
Dr Joseph Chiesa	Consultant in pharmaceutical medicine	Expert	13/07/2016	
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	01/05/2016
Dr Joanne Milton	Project Manager	Lay	11/02/2013	
Dr Mike Proven	Coordinator for QAR (UREC Secretary)	Lay Plus	01/05/2016	01/12/2016
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	31/05/2016
Miss Elena Villarreal	Clinical Trial Manager	Lay	01/12/2015	
Dr Thomas Edward Woodcock	Retired Consultant - Intensive Care Unit	Expert	26/05/2016	
Mr Stuart Young	Director	Lay	29/05/2013	

South Central - Berkshire B Research Ethics Committee: Deputy Members

Name	Profession	Status	Meeting date attended
Mrs Nicola Adey	Regulatory Officer	Lay	08/11/2016
Mrs Nicola Adey	Regulatory Officer	Lay	12/04/2016
Mrs Nicola Adey	Regulatory Officer	Lay	13/09/2016
Mrs Nicola Adey	Regulatory Officer	Lay	13/12/2016
Mrs Nicola Adey	Regulatory Officer	Lay	09/08/2016
Miss Elena Villarreal	Clinical Trial Manager	Lay	13/12/2016
Miss Elena Villarreal	Clinical Trial Manager	Lay	12/07/2016
Miss Elena Villarreal	Clinical Trial Manager	Lay	14/06/2016
Miss Elena Villarreal	Clinical Trial Manager	Lay	11/10/2016

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

Name	Profession	Status	Meeting date attended
Ms Stephanie Ellis	Former Civil Servant	Lay Plus	14/06/2016
Dr Mike Proven	Coordinator for QAR (UREC Secretary)	Lay Plus	12/04/2016

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	28/02/2017
Mr Mike Arnott	Administrator, Reading Independent REC	14/06/2016
Ms Sukhdip Boughan	Medical affairs manager at AstraZeneca	31/03/2017
Dr Joseph Chiesa	Transcrip partnership. Reading-UK. Fellow of the Faculty of Pharmaceutical Medicine. Visiting Professor of Salvador University (Argentina).	09/08/2016
Dr Alan Clark	Minor holdings in public companies GSK, Astrazeneca, Cardinal Health and Becton Dickinson Inc. Employed by Trudell Medical Internationa, Europe Ltd. A Canadian medical device manufacturer.	31/03/2017
Mrs Sue Harrison	Trustee Re-Solv- Prevention of volatile substance abuse and legal highs	13/03/2017
Mr John Inman	Small number of Pfizer shares	01/03/2017
Dr Joanne Milton	Member of Reading Independent Ethics Committee. Shares in Oxford Biomedica plc. Employed as a Project Manager by the University of Oxford.	31/03/2017
Dr John Sheridan	None	13/05/2016
Mrs Mary Sneade	None	01/03/2017
Mr Paul Soper	None	01/07/2016
Miss Elena Villarreal	Employed as a Trial Manager within the Surgical Interventions Trials Unit and Oxford Clinical Trials Unit at the University of Oxford.	31/03/2017
Dr Thomas Edward Woodcock	Lectures on medical and legal topics and provide web-based education	14/06/2016
Mr Stuart Young	None	31/03/2017

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

Month	Date	Number of Members Present at Meeting
April	12/04/2016	8
June	14/06/2016	9
July	12/07/2016	10
August	09/08/2016	11
September	13/09/2016	8
October	11/10/2016	10
November	08/11/2016	12
December	13/12/2016	10
January	17/01/2017	10

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	26/04/2016	3
June	28/06/2016	3
September	26/09/2016	3
October	31/10/2016	3
November	28/11/2016	4
December	19/12/2016	3
January	24/01/2017	3
February	27/02/2017	4
March	27/03/2017	3

9 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	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	3
May	20/05/2016	3
June	03/06/2016	2
June	10/06/2016	4
June	17/06/2016	3
June	24/06/2016	2
July	01/07/2016	4
July	08/07/2016	4

July	15/07/2016	4
July	22/07/2016	2
July	29/07/2016	3
August	05/08/2016	3
August	12/08/2016	2
August	19/08/2016	2
August	26/08/2016	2
September	02/09/2016	3
September	05/09/2016	2
September	16/09/2016	2
September	30/09/2016	2
October	07/10/2016	2
October	14/10/2016	2
October	24/10/2016	2
October	31/10/2016	2
November	11/11/2016	2
November	18/11/2016	3
November	25/11/2016	2
November	30/11/2016	3
December	02/12/2016	2
December	16/12/2016	2
December	30/12/2016	2
January	13/01/2017	2
January	20/01/2017	2
January	27/01/2017	2
February	01/02/2017	2
February	10/02/2017	2
February	24/02/2017	2
February	27/02/2017	2
March	10/03/2017	2
March	24/03/2017	2
March	27/03/2017	2

45 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
Dr Joseph Chiesa	5
Mrs Nicola Adey	5
Mr Mike Arnott	9
Dr Alan Clark	7
Mrs Sue Harrison	6
Mr John Inman	6
Dr Joanne Milton	6
Dr Mike Proven	4
Dr John Sheridan	8
Mrs Mary Sneade	7
Mr Paul Soper	6
Miss Elena Villarreal	5
Ms Decca Warrington	1
Dr Thomas Edward Woodcock	8
Mr Stuart Young	4

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

Name	Number of Meetings Attended
Dr Joseph Chiesa	1
Mr Mike Arnott	6
Mrs Sue Harrison	2
Dr Mike Proven	1
Dr John Sheridan	7
Mrs Mary Sneade	7
Miss Elena Villarreal	3
Dr Thomas Edward Woodcock	2

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

Name	Number of Meetings Attended
Mr Mike Arnott	24
Dr Alan Clark	6
Mrs Sue Harrison	4
Mr John Inman	3
Dr Joanne Milton	2
Dr Mike Proven	7
Dr John Sheridan	38

Mrs Mary Sneade	3
Miss Elena Villarreal	16
Dr Thomas Edward Woodcock	3

Training 01 April 2016 - 31 March 2017

Name of Member	Date	Event(s) attended
Mrs Nicola Adey	14/10/2016	Training - Genetic and Genomic Research (previously HTA Advanced)
Mrs Nicola Adey	16/02/2017	Training - National Members Training Day
Dr Joseph Chiesa	18/10/2016	Local Training Day- Berkshire B & Berkshire
Dr Alan Clark	18/10/2016	Local Training - Berkshire & Berkshire B Research Ethics Committees Training Day
Mrs Sue Harrison	18/10/2016	Local Training - Berkshire & Berkshire B Research Ethics Committees Training Day
Dr Joanne Milton	16/02/2017	Training - National Members Training Day
Dr John Sheridan	18/10/2016	Local Training - Berkshire & Berkshire B Research Ethics Committees Training Day
Dr John Sheridan	28/03/2017	Introduction of Chair appraisals teleconference
Mrs Mary Sneade	18/10/2016	Local Training - Berkshire & Berkshire B Research Ethics Committees Training Day
Mrs Mary Sneade	16/02/2017	Training - National Members Training Day
Mr Paul Soper	18/10/2016	Local Training - Berkshire & Berkshire B Research Ethics Committees Training Day
Miss Elena Villarreal	09/11/2016	Training - Training for New REC Chairs
Miss Elena Villarreal	22/03/2017	Training - National Members Training Day
Dr Thomas Edward Woodcock	05/09/2016	Local Training Day- Riverside
Dr Thomas Edward Woodcock	15/09/2016	Training - Committee Members Induction
Dr Thomas Edward Woodcock	18/10/2016	Local Training - Berkshire & Berkshire B Research Ethics Committees Training Day
Mr Stuart Young	18/10/2016	Local Training - Berkshire & Berkshire B Research Ethics Committees 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	29.55
Phase 1	15	34.09
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	1	2.27
Others	15	34.09
Total Applications Reviewed	44	100

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

Number of applications made invalid by the REC Manager	1
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	8
Number of paediatric applications reviewed	0
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	0
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	3	6.82
Favourable Opinion with Additional Conditions	15	34.09
Unfavourable Opinion	0	0.00
Provisional Opinion	26	59.09
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	44	100
Number of studies sent back to full committee meeting for final opinion	0	

Table 4: Summary of current status of applications reviewed during the reporting period

Status of applications at date of generation of report	Number	%
Further Information Favourable Opinion with Standard Conditions	24	54.55
Further Information Favourable Opinion with Additional Conditions	2	4.55
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	3	6.82
Favourable Opinion with Additional Conditions	15	34.09
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	44	100

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

Total Applications Reviewed	22
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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	4
Number of studies withdrawn prior to the meeting	1
Number of student applications reviewed	10
Number of paediatric applications reviewed	2
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	7	31.82
Favourable Opinion with Additional Conditions	7	31.82
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	8	36.36
Unfavourable Opinion	0	0.00
Total	22	100

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

Average number of applications reviewed per full meeting	4.89
Number of completed applications for full ethical review	44
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	6.82%
Number of days taken to final decision – average (mean)	27
Number of completed proportionate review applications for ethical review	21
Number of completed proportionate review applications for ethical review over 14 days (Please note, the timeline for review of PR applications was extended from 14 to 21 calendar days in December 2016)	4
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	19.05%
Number of SSAs (non-Phase 1) reviewed	6
Number of completed applications for SSA review over 25 days	2
Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs	33.33%
Number of SSAs (Phase 1) reviewed	17
Number of completed applications for SSA review over 14 days	1
Number of completed applications for SSA review over 14 days as % of all Phase 1 SSAs	5.88%
Number of substantial amendments reviewed	138
Number of completed substantial amendments over 35 days	1
Number of completed substantial amendments over 35 days as a % of total substantial amendments	0.72%
Number of completed substantial amendments over 28 days	4
Number of completed substantial amendments over 28 days as a % of total substantial amendments	2.90%
Number of modified amendments reviewed	1
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	80

Number of substantial amendments received for information	2
Number of substantial amendments received for new sites/PIs	21
Number of annual progress reports received	37
Number of safety reports received	20
Number of Serious Adverse Events received	3
Number of final reports received	14

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/0202	Low dose Glibenclamide in Diabetes - Part A (LEGEND-A)	32
16/SC/0203	Safety and efficacy of BGS649 in male obese patients with HH	35
16/SC/0205	Risk-reducing surgery in women with a family history of breast cancer	30
16/SC/0248	Safety, tolerability, PK & PD of UCB4019 as SAD in healthy subjects	26
16/SC/0280	A Phase 1 SAD, MAD & Food Effect, PK & PD of OBE022 in healthy women	27
16/SC/0281	Safety & PK of OBE022 & MgSO ₄ , Atosiban, Nifedipine or Betamethasone	23
16/SC/0304	CaNCaP03 - Cambridge Neoadjuvant Cancer of the Prostate 3	31
16/SC/0329	A Phase 1, Safety, Tolerability, PK & PD study of SC and IV ALXN1210	21
16/SC/0348	Effect of Personality on Neural Reward and Aversion Processing	30
16/SC/0374	Perioperative Quality Improvement Programme (PQIP)	20
16/SC/0375	A FIH study to investigate the safety, tolerability and PK of P218	42
16/SC/0422	105GTN201: TRC105 in Refractory Gestational Trophoblastic Neoplasia	56
16/SC/0455	Use of NIR imaging to detect and sample early liver metastases.	39
16/SC/0478	CXCR2 inhibition and coronary heart disease / CICADA	28
16/SC/0497	VX-695 Bioavailability Study in Healthy and Cystic Fibrosis Subjects	23
16/SC/0498	Effects and safety of anti-SAP therapy in patients with amyloidosis;v1	50
16/SC/0538	M14-327 Ph 2 study in Crohn's Disease Extension study	22
16/SC/0558	Yoga and Mindfulness for Addiction - Version 1.0	37
16/SC/0574	Blood Collection	27
16/SC/0575	A Phase 1, Food & Proton Pump Inhibitor Effect on GED-0301 PK study	16
16/SC/0590	Depletion of Serum Amyloid P Component in Alzheimer's Disease (v1.0)	29
16/SC/0608	Study to compare the PK of sc Mepolizumab from safety syringe vs AI	23
17/SC/0028	CA209-714	32
17/SC/0030	A High Security Hospital in Transition	26

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
16/SC/0632	Patient's Views on Pain Management- Qualitative	24
17/SC/0005	SIDS version	28

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
16/SC/0204	Guidelines for inpatient group music therapy	22
16/SC/0480	Selective uptake of cervical cancer screening	21
17/SC/0014	OPEN WATER Registry	26

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/SC/0158	ALLIKAT (All Ligaments Left In Knee Arthroplasty Trial)	22
16/SC/0303	Safety, PK and food effect of RV521 in healthy male volunteers	21
16/SC/0349	Epidemiology of Critical Care provision after Surgery (EpiCCS)	20
16/SC/0384	16976A - bioequivalence commercial and clinical tablet comparison	22
16/SC/0403	PK,PD & Safety Trial of CAM2047, CAM2048 & CAM2058 in Healthy Subjects	17
16/SC/0436	Jazz 15-006: Efficacy and Safety Study in Cataplexy and Narcolepsy	27
16/SC/0461	Bioavailability of symbicort with & without spacer in healthy subjects	21
16/SC/0472	REDUCE WS2	21
16/SC/0508	The GRASP Trial	24
16/SC/0515	VX-659 Bioavailability study in Cystic Fibrosis subjects - Part D	20
16/SC/0543	A FIH, SAD, MAD and FE study of AZD0284 in healthy subjects	22
16/SC/0568	Bioavailability, PK, DDI & Food Effect of AZD5718 in healthy subjects	15
16/SC/0671	M15-531: ABT-199 in MDS	21
17/SC/0003	Does compassion for self or others predict violent behaviour?	27
17/SC/0027	hsCRP assay in post-myocardial infarction patients	28

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
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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

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
16/SC/0366	Visual Performance & Satisfaction with Multifocal Contact Lenses	17
16/SC/0606	Acceptability and tolerability of MACE compared to gastroscopy	23
16/SC/0663	Cardiorespiratory fitness of patients with glycogen storage diseases	12
16/SC/0691	Reliability of the TAL in positioning the Acetabular Component in THA	14
17/SC/0053	Psychological Impact of Notification Exercises - Version 4.0	18
17/SC/0104	PIBD-NET - Inception cohort and safety registry	14
17/SC/0155	Tumour infiltrating lymphocyte therapy for paediatric malignancies	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
16/SC/0234	Whole genome sequencing for the diagnosis of infections	7
16/SC/0373	Fatigue in psoriatic arthritis	7
16/SC/0609	Return to sport following the Latarjet procedure	11
16/SC/0659	The role of biomarkers in inherited cardiac conditions	17
17/SC/0036	The development of assays to study immuno-oncology (DAIO) – V03	8
17/SC/0054	Oral cancer risk assessment, examination and prevention Version 2.0	11
17/SC/0103	Congenital Heart Disease in Northern Ireland:Data Linkage Cohort Study	11

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
16/SC/0238	Impact of anaphylaxis on the quality of life of adults	2
16/SC/0240	ADR-gene study (v1)	7
16/SC/0369	Rheumatoid Arthritis Risk Survey v1	14
16/SC/0496	Models of Antenatal Care: a pilot quality care framework evaluation v1	10
16/SC/0528	Prehospital 12-lead electrocardiograms in acute stroke patients	14
16/SC/0541	Does preparation influence anxiety following total knee arthroplasty?	12
16/SC/0648	How is living with diabetes experienced following a course in MBCT?	13

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

16/SC/0603	LA with EMLA cream	14
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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
13/SC/0054/AM12	Global Registry in Patients with Atrial Fibrillation	4	20/02/2017	16
13/SC/0311/AM13	GP2013 in patients with previously untreated, advanced lymphoma.	6.0	05/10/2016	8
13/SC/0311/AM14	GP2013 in patients with previously untreated, advanced lymphoma.	Urgent Safety Measure	10/01/2017	6
13/SC/0583/AM03	Matchpoint	3	23/05/2016	8
13/SC/0583/AM05	Matchpoint	4.0	05/10/2016	27
14/SC/0126/AM06	Rare diseases of the bone, joint and vessels Study (RUDY)	5	16/11/2015	11
14/SC/0181/AM11	Elagolix in Endometriosis Associated Pain - Extension Study	15	26/05/2016	15
14/SC/0262/AM11	SAFARI	8	25/05/2016	9
14/SC/0262/AM12	SAFARI	9.0	08/06/2016	8
14/SC/0262/AM14	SAFARI	10.0	25/11/2016	12
14/SC/0262/AM17	SAFARI	12	27/02/2017	14
14/SC/0290/AM05	ECLIPSE: Exploring the Current Landscape of IV Infusion Practices v.1	1	21/03/2016	10
14/SC/1024/AM05	Pazopanib-Surgically Unresectable or Metastatic Chondrosarcoma_V1.0	4	26/04/2016	24
14/SC/1028/AM14	CTC in pancreatic cancer	10	27/04/2016	11
14/SC/1059/AM26	28431754DNE3001: The CREDENCE Trial	18	12/04/2016	7
14/SC/1059/AM29	28431754DNE3001: The CREDENCE Trial	20.0	09/06/2016	8
14/SC/1059/AM30	28431754DNE3001: The CREDENCE Trial	21	12/07/2016	13
14/SC/1059/AM32	28431754DNE3001: The CREDENCE Trial	22.0	02/11/2016	14
14/SC/1059/AM33	28431754DNE3001: The CREDENCE Trial	23	03/02/2017	10
14/SC/1180/AM02	Reconstructive septorhinoplasty to improve olfaction	2.0	12/04/2016	9
14/SC/1180/AM04	Reconstructive septorhinoplasty to improve olfaction	3	03/03/2017	29
14/SC/1252/AM10	NEXUS- 24 week Study to investigate new medicine Namilumab in patients	1	09/03/2016	15
14/SC/1252/AM11	NEXUS- 24 week Study to investigate new medicine Namilumab in patients	5.0	25/04/2016	22
14/SC/1252/AM12	NEXUS- 24 week Study to investigate new medicine Namilumab in patients	PGx issue	16/06/2016	20

14/SC/1355/AM04	Health literacy assessment in community pharmacies	1.3	12/04/2016	3
15/SC/0008/AM08	Portsmouth Birth Cohort Registry	7	27/04/2016	12
15/SC/0008/AM09	Portsmouth Birth Cohort Registry	8	17/06/2016	14
15/SC/0008/AM10	Portsmouth Birth Cohort Registry	9.0	05/10/2016	19
15/SC/0008/AM11	Portsmouth Birth Cohort Registry	10	18/11/2016	11
15/SC/0008/AM12	Portsmouth Birth Cohort Registry	11	08/02/2017	21
15/SC/0008/AM13	Portsmouth Birth Cohort Registry	12	03/03/2017	10
15/SC/0013/AM02	Making Sense of Voices: Case Series	3.0	07/07/2016	8
15/SC/0079/AM09	Study Protocol ACI-35 in patients with mild to moderate Alzheimer's.	8	19/10/2016	8
15/SC/0081/AM02	Cognitive and behavioural processes in anxious children/adolescents V1	2.0	25/05/2016	13
15/SC/0081/AM03	Cognitive and behavioural processes in anxious children/adolescents V1	3.0	25/07/2016	6
15/SC/0081/AM04	Cognitive and behavioural processes in anxious children/adolescents V1	4.0	06/10/2016	8
15/SC/0123/AM10	PGRx Information System for Epidemiological Research	4	15/04/2016	4
15/SC/0123/AM14	PGRx Information System for Epidemiological Research	5.0	04/07/2016	11
15/SC/0123/AM15	PGRx Information System for Epidemiological Research	6.0	01/08/2016	11
15/SC/0123/AM18	PGRx Information System for Epidemiological Research	7.0	31/08/2016	23
15/SC/0123/AM19	PGRx Information System for Epidemiological Research	8	10/10/2016	1
15/SC/0123/AM20	PGRx Information System for Epidemiological Research	9.0	14/11/2016	10
15/SC/0123/AM22	PGRx Information System for Epidemiological Research	10	20/01/2017	21
15/SC/0123/AM23	PGRx Information System for Epidemiological Research	11	24/02/2017	26
15/SC/0182/AM01	Educational needs for spinal cord stimulation surgery	2.0	27/05/2016	12
15/SC/0213/AM06	ABT494 in patients with Crohn's Disease	4	24/05/2016	7
15/SC/0213/AM07	ABT494 in patients with Crohn's Disease	5	31/01/2017	20
15/SC/0229/AM05	Neural effects of agomelatine on reward and aversion processing.	5.0	19/08/2016	5
15/SC/0229/AM06	Neural effects of agomelatine on reward and aversion processing.	6.0	30/10/2016	4
15/SC/0279/AM02	Imaging of digital arteries in patients with systemic sclerosis	1	03/03/2017	7
15/SC/0341/AM03	ADDITION Plus - 10 year	1	11/03/2016	9
15/SC/0386/AM05	A Phase I Study to Assess Malaria Vaccine R21 with Matrix-M1	4.0	15/06/2016	6
15/SC/0386/AM06	A Phase I Study to Assess Malaria Vaccine R21 with Matrix-M1	5.0	22/07/2016	6
15/SC/0402/AM03	Imagery Rescripting in Asylum Seekers	3	26/04/2016	7

15/SC/0404/AM05	OC000459 in Severe Asthma	4	10/05/2016	6
15/SC/0404/AM06	OC000459 in Severe Asthma	5.0	28/11/2016	10
15/SC/0405/AM01	Emotion regulation in ADHD, anxiety and co-morbid ADHD/anxiety	1	03/05/2016	16
15/SC/0405/AM03	Emotion regulation in ADHD, anxiety and co-morbid ADHD/anxiety	2.0	09/06/2016	18
15/SC/0412/AM06	Safety, Tolerability & PK of TAK-831 as SAD & MAD in Healthy Subjects	05	28/04/2016	5
15/SC/0412/AM07	Safety, Tolerability & PK of TAK-831 as SAD & MAD in Healthy Subjects	Amendment 3	15/06/2016	14
15/SC/0431/AM04	JVDE: The REACH-2 Study	I4T-MC-JVDE	09/09/2016	27
15/SC/0431/AM05	JVDE: The REACH-2 Study	3	12/01/2017	10
15/SC/0449/AM02	Study to Evaluate PK Profiles of AF-219 (QCL117521)	2.0	22/09/2016	26
15/SC/0522/AM02	Mindfulness for patients with difficult to manage asthma	2	06/04/2016	7
15/SC/0522/AM04	Mindfulness for patients with difficult to manage asthma	3.0	06/07/2016	22
15/SC/0543/AM01	High Density Mapping for WACA Completion	1.0	02/08/2016	2
15/SC/0552/AM05	Phase 1 Study of BLU-285 in Patients with GIST v1	03	16/03/2017	21
15/SC/0554/AM05	UCB4940 as add-on to Certolizumab Pegol for Rheumatoid Arthritis	3	13/01/2017	5
15/SC/0590/AM01	Biomarker discovery in melanoma: case-control study	1.0	01/07/2016	7
15/SC/0599/AM04	GS-US-218-1797 GS-5806 in Lung Transplant Recipients with RSV	ERT Handheld Spirometry Material	03/05/2016	6
15/SC/0599/AM06	GS-US-218-1797 GS-5806 in Lung Transplant Recipients with RSV	PA2	12/09/2016	21
15/SC/0603/AM03	MAESTRO-OL: Macitentan in Eisenmenger Syndrome OPEN LABEL AC-055-308	14	04/11/2016	25
15/SC/0608/AM01	IONA Twin Study, Version 1.0	01	14/04/2016	13
15/SC/0608/AM03	IONA Twin Study, Version 1.0	1.0	03/09/2016	27
15/SC/0608/AM04	IONA Twin Study, Version 1.0	SA03	14/02/2017	12
15/SC/0637/AM01	Understanding barriers and outcomes of unspecified (altruistic) kidney	1.0	20/06/2016	10
15/SC/0659/AM01	JNJ-54861911ALZ2003 - 'EARLY' - Alzheimer's Dementia Study	1.0	10/06/2016	34
15/SC/0659/AM04	JNJ-54861911ALZ2003 - 'EARLY' - Alzheimer's Dementia Study	2	16/09/2016	20
15/SC/0659/AM06	JNJ-54861911ALZ2003 - 'EARLY' - Alzheimer's Dementia	4	16/12/2016	18

	Study			
15/SC/0659/AM07	JNJ-54861911ALZ2003 - 'EARLY' - Alzheimer's Dementia Study	5	22/12/2016	28
15/SC/0670/AM02	Memory and Executive Functioning in Adolescent Depression	2.0	10/06/2016	18
15/SC/0670/AM03	Memory and Executive Functioning in Adolescent Depression	3.0	07/11/2016	6
15/SC/0679/AM03	Study of Trametinib in children and adolescent subjects with Cancer	2	20/05/2016	33
15/SC/0679/AM04	Study of Trametinib in children and adolescent subjects with Cancer	3	25/01/2017	14
15/SC/0719/AM01	A SAD, MAD, safety, PK and PD study of AZD5718 in healthy subjects	1	20/04/2016	8
15/SC/0719/AM02	A SAD, MAD, safety, PK and PD study of AZD5718 in healthy subjects	1.0	26/05/2016	21
15/SC/0738/AM01	Patients' online access and interpretation of lab test results	1	07/04/2016	0
15/SC/0761/AM01	Anatomical correlates of upper limb impairment after stroke	1	24/11/2016	14
16/SC/0009/AM01	First time in human study of oral anti-Serum Amyloid P (GSK3039294)	2	13/12/2016	16
16/SC/0012/AM02	Atovaquone as Tumour HypOxia Modifier	Protocol V3.0	18/10/2016	9
16/SC/0012/AM03	Atovaquone as Tumour HypOxia Modifier	Protocol v4	06/03/2017	8
16/SC/0013/AM01	Parent-Adolescent Interactions in Depressed Adolescents - Version 1	1.0	08/06/2016	8
16/SC/0013/AM03	Parent-Adolescent Interactions in Depressed Adolescents - Version 1	2.0	27/07/2016	1
16/SC/0013/AM04	Parent-Adolescent Interactions in Depressed Adolescents - Version 1	3.0	06/10/2016	20
16/SC/0013/AM05	Parent-Adolescent Interactions in Depressed Adolescents - Version 1	4	02/03/2017	25
16/SC/0014/AM03	Safety & tolerability of MEDI9314 as SAD in healthy subjects	2.0	10/08/2016	3
16/SC/0014/AM04	Safety & tolerability of MEDI9314 as SAD in healthy subjects	3.0	15/09/2016	15
16/SC/0027/AM03	Safety & Tolerability of PC945 in healthy & subjects with mild asthma	1	30/11/2016	6
16/SC/0069/AM01	True NTH Exercise & Diet Project Phase 2	1.0	26/05/2016	3
16/SC/0069/AM02	True NTH Exercise & Diet Project Phase 2	2.0	23/09/2016	19
16/SC/0069/AM03	True NTH Exercise & Diet Project Phase 2	3	04/01/2017	4
16/SC/0070/AM01	Creative bibliotherapy for post-traumatic stress disorder (PTSD)	1	01/04/2016	4

16/SC/0158/AM01	ALLIKAT (All Ligaments Left In Knee Arthroplasty Trial)	1.0	24/10/2016	11
16/SC/0202/AM02	Low dose Glibenclamide in Diabetes - Part A (LEGEND-A)	2.0	16/08/2016	7
16/SC/0203/AM01	Safety and efficacy of BGS649 in male obese patients with HH	3.0	25/07/2016	7
16/SC/0203/AM03	Safety and efficacy of BGS649 in male obese patients with HH	4.0	28/10/2016	12
16/SC/0203/AM04	Safety and efficacy of BGS649 in male obese patients with HH	1.0	30/11/2016	40
16/SC/0203/AM06	Safety and efficacy of BGS649 in male obese patients with HH	5	26/01/2017	25
16/SC/0203/AM07	Safety and efficacy of BGS649 in male obese patients with HH	4	02/03/2017	11
16/SC/0205/AM02	Risk-reducing surgery in women with a family history of breast cancer	1	08/09/2016	15
16/SC/0248/AM01	Safety, tolerability, PK & PD of UCB4019 as SAD in healthy subjects	1.0	04/08/2016	12
16/SC/0248/AM02	Safety, tolerability, PK & PD of UCB4019 as SAD in healthy subjects	2.0	19/08/2016	11
16/SC/0280/AM01	A Phase 1 SAD, MAD & Food Effect, PK & PD of OBE022 in healthy women	1.0	21/07/2016	18
16/SC/0303/AM02	Safety, PK and food effect of RV521 in healthy male volunteers	Amendment 2	25/11/2016	3
16/SC/0304/AM01	CaNCaP03 - Cambridge Neoadjuvant Cancer of the Prostate 3	1	04/01/2017	4
16/SC/0348/AM01	Effect of Personality on Neural Reward and Aversion Processing	4	12/01/2017	8
16/SC/0349/AM02	Epidemiology of Critical Care provision after Surgery (EpiCCS)	1.5	26/10/2016	13
16/SC/0349/AM04	Epidemiology of Critical Care provision after Surgery (EpiCCS)	1.6	02/02/2017	10
16/SC/0403/AM04	PK,PD & Safety Trial of CAM2047, CAM2048 & CAM2058 in Healthy Subjects	2	13/01/2017	11
16/SC/0403/AM05	PK,PD & Safety Trial of CAM2047, CAM2048 & CAM2058 in Healthy Subjects	3	28/02/2017	7
16/SC/0403/AM06	PK,PD & Safety Trial of CAM2047, CAM2048 & CAM2058 in Healthy Subjects	4	01/03/2017	19
16/SC/0422/AM01	105GTN201: TRC105 in Refractory Gestational Trophoblastic Neoplasia	2.0	27/09/2016	25
16/SC/0436/AM01	Jazz 15-006: Efficacy and Safety Study in Cataplexy and Narcolepsy	SA1	15/11/2016	6
16/SC/0436/AM04	Jazz 15-006: Efficacy and Safety Study in Cataplexy and Narcolepsy	2.0	01/12/2016	11
16/SC/0436/AM05	Jazz 15-006: Efficacy and Safety Study in Cataplexy and Narcolepsy	3	23/12/2016	17
16/SC/0436/AM08	Jazz 15-006: Efficacy and Safety Study in Cataplexy and	4	07/02/2017	10

	Narcolepsy			
16/SC/0497/AM02	VX-695 Bioavailability Study in Healthy and Cystic Fibrosis Subjects	1	21/12/2016	14
16/SC/0497/AM03	VX-695 Bioavailability Study in Healthy and Cystic Fibrosis Subjects	2	21/12/2016	10
16/SC/0497/AM05	VX-695 Bioavailability Study in Healthy and Cystic Fibrosis Subjects	SA3	24/02/2017	10
16/SC/0508/AM01	The GRASP Trial	1.0	20/01/2017	6
16/SC/0515/AM02	VX-659 Bioavailability study in Cystic Fibrosis subjects - Part D	1	15/02/2017	7
16/SC/0538/AM01	M14-327 Ph 2 study in Crohn's Disease Extension study	1	27/09/2016	21
16/SC/0543/AM02	A FIH, SAD, MAD and FE study of AZD0284 in healthy subjects	3.0	09/12/2016	5
16/SC/0543/AM04	A FIH, SAD, MAD and FE study of AZD0284 in healthy subjects	Substantial Amendment 3 - Prot	21/02/2017	10

Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
15/SC/0552/AM03	Phase 1 Study of BLU-285 in Patients with GIST v1	1.0	12/08/2016	10

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/0552/AM03/1	Phase 1 Study of BLU-285 in Patients with GIST v1	1.0	29/08/2016	10

Unfavourable opinion timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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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 21 day timeline

REC Reference	Title	Number of Days on Clock
16/SC/0606	Acceptability and tolerability of MACE compared to gastroscopy	23

SSAs (non Phase 1) over 25 day timeline

REC Reference	Title	Number of Days on Clock
16/SC/0226	Safety and Pharmacokinetics of PL265 in healthy males (QCL117989)	34
16/SC/0689	Safety and Pharmacokinetics of PL265 in healthy males (QCL117989)	43

SSAs (Phase 1) over 14 day timeline

REC Reference	Title	Number of Days on Clock
16/SC/0564	Safety and Pharmacokinetics of PL265 in healthy males (QCL117989)	56

Substantial Amendments over 35 day timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
16/SC/0203/AM04	Safety and efficacy of BGS649 in male obese patients with HH	1.0	30/11/2016	40

Modified Amendments over 14 day timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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