

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

Annual Report

01 April 2017 - 31 March 2018



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:	Miss Elena Villarreal
Alternate Vice-Chair:	Mr John Inman
REC Manager:	Miss Charlotte Ferris (06/02/2018 to present) Miss Lucy Roberts (until 05/02/2018)
REC Assistant:	Miss Kat Hogg (from 19/02/2018) Mrs Stacey Bamford (From 12/05/2017 until 05/02/2018) Mr Stephan Ramey (from 01/12/2016 until 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:

A good year overall, in which the members cooperated well to progress the business of the REC in a generally efficient and timely manner.

We were all greatly saddened when Dr Joseph Chiesa died suddenly on the day of our September meeting. Joseph had proved himself to be an effective and very conscientious member; he had even done REC work on the day prior to his death.

During the review period, we changed our meeting venue from Reading University campus to a location in central Reading. The main reason for the move was that the University had not been accommodating enough to our needs, particularly with respect to parking. The new venue has been a success, although some members have found it easier to get there than others.

We had a number of changes of manager and also administrative assistant during the review period. Although all the post holders performed very well, this was a little disruptive.

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	24/04/2018
Dr Joseph Chiesa	Consultant in pharmaceutical medicine	Expert	13/07/2016	12/09/2017
Dr Alan Clark	Pharmacist	Expert	01/09/2014	
Dr Miranda Davies	Senior Research Analyst	Lay Plus	15/01/2018	
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 Joanne Milton	Head of Clinical Research	Expert	11/02/2013	
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	
Miss Elena Villarreal	Clinical Trial Manager	Lay	05/10/2016	
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	14/11/2017, 08/08/2017, 11/07/2017, 11/04/2017

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

Name	Profession	Status	Meeting date attended
Ms Stephanie Ellis BEM	Former Civil Servant	Lay Plus	12/09/2017

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

Name	Declaration of Interest	Date
Mr Mike Arnott	Member of Administrator Reading Independent Ethics Committee.	20/03/2018
Dr Miranda Davies	Senior Research Analyst at the Nuffield trust. Chartered member of the British Psychological Society. Occasionally peer review journal articles.	23/01/2018
Mrs Sue Harrison	Trustee Re-Solv- Prevention of harm from volatile substance abuse and psychoactive	13/02/2018
Mr John Inman	None	25/01/2018
Dr Joanne Milton	Member of Reading Independent Ethics Committee. Shares in Oxford Biomedica plc. Employed as a Project Manager by the University of Oxford.	10/06/2017
Dr Joanne Milton	Member of Reading Independent Ethics Committee. Shares in Oxford Biomedica. Employed as Head of Clinical Research Diabetic Trials Unit, University of Oxford.	13/02/2018
Dr John Sheridan	None	02/02/2018
Mrs Mary Sneade	None	02/02/2018
Mr Paul Soper	None	31/03/2018
Miss Elena Villarreal	Employed as a Clinical Trial Manager for the University of Oxford	28/03/2018
Dr Thomas Edward Woodcock	None	12/02/2018
Mr Stuart Young	None	13/06/2017
Mr Stuart Young	None	13/02/2018
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.	31/03/2018

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

Month	Date	Number of Members Present at Meeting
April	11/04/2017	11
June	13/06/2017	8
July	11/07/2017	10
August	08/08/2017	11
September	12/09/2017	7
September	19/09/2017	9
October	10/10/2017	9
November	14/11/2017	11
December	12/12/2017	9
January	16/01/2018	10
February	13/02/2018	10

11 full committee meetings were held during the reporting period.

Proportionate Review Sub-Committee Meetings held during 01 April 2017 - 31 March 2018:

Month	Date	Number of Members Present at Meeting
April	24/04/2017	3
May	29/05/2017	3
June	26/06/2017	3
August	22/08/2017	3
September	25/09/2017	3
October	24/10/2017	3
November	28/11/2017	3
December	19/12/2017	3
January	23/01/2018	4
February	27/02/2018	3
March	27/03/2018	3

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

Sub-Committee Meetings held during 01 April 2017 - 31 March 2018:

Month	Date	Number of Members Present at Meeting
April	07/04/2017	3
April	14/04/2017	2
April	21/04/2017	2
April	24/04/2017	2
April	28/04/2017	2
May	05/05/2017	2
May	12/05/2017	2
May	19/05/2017	2
May	26/05/2017	2

June	02/06/2017	2
June	09/06/2017	2
June	16/06/2017	2
June	30/06/2017	2
July	14/07/2017	2
July	21/07/2017	2
August	04/08/2017	2
August	11/08/2017	2
August	18/08/2017	2
September	01/09/2017	2
September	08/09/2017	2
September	15/09/2017	2
September	22/09/2017	2
September	29/09/2017	2
October	06/10/2017	2
October	13/10/2017	2
October	20/10/2017	2
October	27/10/2017	2
November	03/11/2017	2
November	10/11/2017	2
November	17/11/2017	2
November	24/11/2017	2
December	01/12/2017	2
December	08/12/2017	2
December	15/12/2017	2
December	22/12/2017	2
January	05/01/2018	3
January	12/01/2018	2
January	19/01/2018	2
January	26/01/2018	2
February	02/02/2018	2
February	09/02/2018	2
February	16/02/2018	2
February	23/02/2018	2
March	02/03/2018	2
March	09/03/2018	2
March	16/03/2018	4
March	23/03/2018	2
March	30/03/2018	2

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

Details of inquorate meeting held: 01 April 2017 - 31 March 2018

Date	Reason	Action taken
12/09/2017	Become inquorate due to no expert being present as Dr Joseph Chiesa could not attend due to illness.	Telephone conference with quorate number of members was established to review the applications on 19/09/2017.

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

Name	Number of Meetings Attended
Mrs Nicola Adey	4
Mr Mike Arnott	10
Dr Joseph Chiesa	4
Dr Alan Clark	8
Dr Miranda Davies	1
Mrs Sue Harrison	10
Mr John Inman	9
Dr Joanne Milton	9
Dr John Sheridan	11
Mrs Mary Sneade	9
Mr Paul Soper	7
Miss Elena Villarreal	6
Dr Thomas Edward Woodcock	7
Mr Stuart Young	8

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

Name	Number of Meetings Attended
Dr Joseph Chiesa	3
Dr Alan Clark	3
Professor Test Member	1
Dr John Sheridan	11
Mrs Mary Sneade	3
Miss Elena Villarreal	11
Dr Thomas Edward Woodcock	2

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

Name	Number of Meetings Attended
Mr Mike Arnott	13
Dr Joseph Chiesa	3
Mrs Sue Harrison	9
Mr John Inman	1
Professor Test Member	1
Dr John Sheridan	48
Mrs Mary Sneade	12
Miss Elena Villarreal	13

Training 01 April 2017 - 31 March 2018

Name of Member	Date	Event(s) attended
Mr Mike Arnott	16/01/2018	HARP Portal Training
Mr Mike Arnott	23/03/2018	Research Involving Human Tissue
Mr Mike Arnott	31/03/2018	Equality and Diversity
Dr Alan Clark	18/10/2017	Review HRA guidance on research involving medical devices
Dr Alan Clark	12/12/2017	Review of HRA Portal for ethical assessment
Dr Alan Clark	16/01/2018	HARP Portal Training
Dr Miranda Davies	05/02/2018	Induction for new Research Ethics Service Committee members
Dr Miranda Davies	07/02/2018	Equality Diversity and Human Rights
Mrs Sue Harrison	16/01/2018	HARP Portal Training
Mrs Sue Harrison	18/03/2018	Equality and Diversity
Mrs Sue Harrison	28/03/2018	Review Research Design CTIMPS
Mrs Sue Harrison	29/03/2018	Confidentiality Info Governance
Mrs Sue Harrison	30/03/2018	Human Tissue Act
Mr John Inman	16/01/2018	HARP Portal Training
Mr John Inman	20/03/2018	Research Involving Human Tissue
Mr John Inman	25/03/2018	Research Involving Participants Lacking Mental Capacity
Mr John Inman	25/03/2018	Equality, Diversity and Human Rights
Mr John Inman	26/03/2018	Research Involving Exposure to Ionising Radiation
Dr Joanne Milton	26/09/2017	Training - Assessing the Consequences (benefits and harms) of Research: a Health Research Authority workshop
Dr Joanne Milton	16/01/2018	HARP Portal Training
Dr John Sheridan	27/07/2017	PPI Workshop
Dr John Sheridan	16/01/2018	Harp Portal Training
Dr John Sheridan	27/03/2018	Equality Diversity and Human Rights
Mrs Mary Sneade	10/08/2017	accredited researcher course for NHS Digital
Mrs Mary Sneade	16/01/2018	HARP Portal Training
Mrs Mary Sneade	28/02/2018	Ethical Issues in Phase One Research: An Advanced Training Course
Mr Paul Soper	16/01/2018	HARP Portal Training
Mr Paul Soper	31/03/2018	Equality and Diversity
Mr Paul Soper	31/03/2018	Research Involving Participants Lacking Mental Capacity
Miss Elena Villarreal	03/12/2017	Read articles on vulnerability

		and pregnancy prior to REC Chairs' meeting on 6th December 2018
Miss Elena Villarreal	13/12/2017	Read Reviewing Research Website section on Consent. Given as further reading after the REC Chairs' Meeting
Miss Elena Villarreal	16/12/2017	Read the article Vulnerability in Research Subjects: A Bioethical Taxonomy, Kipnis, Date unknown
Miss Elena Villarreal	02/03/2018	Equality and Diversity
Miss Elena Villarreal	22/03/2018	Good Clinical Practice Training
Miss Elena Villarreal	28/03/2018	Read RES Informed Consent in CTIMPs Information note.
Miss Elena Villarreal	28/03/2018	MRC Experimental Medicine Tool Kit (Protocol Development)
Miss Elena Villarreal	30/03/2018	Reviewing research that uses quantitative methods
Miss Elena Villarreal	30/03/2018	Reviewing research website page on reviewing quantitative design
Miss Elena Villarreal	30/03/2018	Reviewing CTIMPs e-learning module
Miss Elena Villarreal	30/03/2018	Reviewing the Research Design of Clinical
Dr Thomas Edward Woodcock	11/04/2017	Local Training Day - London - Harrow
Dr Thomas Edward Woodcock	16/01/2018	HARP Portal Training
Dr Thomas Edward Woodcock	25/03/2018	Equality Diversity and Human Rights
Mr Stuart Young	01/04/2017	Futurelearn Online Course on Liver Disease
Mr Stuart Young	01/06/2017	Futurelearn Online Course on Cancer Treatment
Mr Stuart Young	01/12/2017	Futurelearn Online Course on Dementia
Mr Stuart Young	16/01/2018	HARP Portal Training

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	12	25.53
Phase 1	18	38.30
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	0	0.00
Others	17	36.17
Total Applications Reviewed	47	100

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

Number of applications made invalid by the REC Manager	1
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	9
Number of paediatric applications reviewed	6
Number of device applications reviewed	4
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	2

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	14	29.79
Unfavourable Opinion	0	0.00
Provisional Opinion	33	70.21
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	47	100
Number of studies sent back to full committee meeting for final opinion	5	

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	32	68.09
Further Information Favourable Opinion with Additional Conditions	1	2.13
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	14	29.79
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	47	100

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

Total Applications Reviewed	21
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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	6
Number of studies withdrawn prior to the meeting	0
Number of student applications reviewed	9
Number of paediatric applications reviewed	1
Number of device applications reviewed	2
Number of qualitative applications reviewed	1

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	4	19.05
Favourable Opinion with Additional Conditions	5	23.81
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	12	57.14
Unfavourable Opinion	0	0.00
Total	21	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	4.27
Number of completed applications for full ethical review	47
Number of completed applications for full ethical review over 60 days	0
Number of completed applications over 60 days as a % of total	0.00%
Number of completed applications for full ethical review over 40 days	2
Number of completed applications over 40 days as a % of total	4.26%
Number of days taken to final decision – average (mean)	23
Number of completed proportionate review applications for ethical review	21
Number of completed proportionate review applications for ethical review over 21 days	0
Number of completed proportionate review applications over 21 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	17
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	106
Number of completed substantial amendments over 35 days	1
Number of completed substantial amendments over 35 days as a % of total substantial amendments	0.94%
Number of completed substantial amendments over 28 days	4
Number of completed substantial amendments over 28 days as a % of total substantial amendments	3.77%
Number of modified amendments reviewed	0
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	71
Number of substantial amendments received for information	0
Number of substantial amendments received for new sites/PIs	18
Number of annual progress reports received	51
Number of safety reports received	77
Number of Serious Adverse Events received	2

Number of final reports received	19
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Table 9.1: Breakdown of current status of all full applications reviewed within the reporting period

Further Information Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
17/SC/0184	SINGLED	24
17/SC/0185	BGB-3111 and Ibrutinib in Waldenström's Macroglobulinemia	24
17/SC/0186	Switching from TDF to TAF	25
17/SC/0273	Social media use and facial satisfaction (Version 1)	31
17/SC/0283	A CFit Study: Baseline	31
17/SC/0294	WO39392 IMpassion 031 ATEZOLIZUMAB or PLACEBO + NAB-PACLITAXEL + CHEMO	31
17/SC/0298	GSK3640254 FTIH study in healthy participants	31
17/SC/0334	A CFit Study: Acute Exercise	20
17/SC/0337	First Time in Human Study of GSK3335065 in Healthy Adults	28
17/SC/0341	Being in a Seclusion Room: The Forensic Inpatient Perspective	15
17/SC/0390	Safety, tolerability, PK, PD, food-effect of SAD and MAD of TRK-750	19
17/SC/0404	PK of Modified Release formulations of GSK2982772 (QCL117918)	32
17/SC/0408	GRAVITAS-301 Treatment of First-Line Acute Graft Versus-Host Disease	19
17/SC/0409	PK of Sublingual Formulations of FLD169 (QCL117615)	23
17/SC/0412	Treatment of Anxiety Disorder in Adolescents (TAD-A) Version 1.0	21
17/SC/0413	Safety, tolerability and PK, of SAD and MAD of XEN1101 in HV	17
17/SC/0420	CiVi007- Phase 1 safety tolerability PK PD study	11
17/SC/0492	Fluorescence targeted lymphatic mapping in colonic cancer	25
17/SC/0493	M16-109 Phase 2 Single Arm Study on Patients with Myelofibrosis	25
17/SC/0501	Rare and Undiagnosed Diseases Study (RUDY)	16
17/SC/0542	Safety, tolerability, PK, transcranial magnetic stimulation of XEN1101	26
17/SC/0592	BA, PK & Food Effect of different formulations of AZD5718 in HV	17
17/SC/0606	Efficacy and Safety of TAK-653 in Treatment-Resistant Depression	25
17/SC/0610	iTIND RCT	24
17/SC/0612	Using an MRI scan to explore the Bowditch phenomenon in CHF	24
17/SC/0643	CA017-055 Nivolumab and BMS-986205 in melanoma	23
18/SC/0002	A MAD study to determine the safety, tolerability and PK of AZD9977	12
18/SC/0010	Effects of VX-659 triple combination on Oral contraceptives in Females	18
18/SC/0013	Safety, tolerability, PK and PD of LU AF76432 in healthy, young men	48
18/SC/0022	BMS-986224 in Healthy Subjects and Chronic Heart Failure Patients	20
18/SC/0065	INTICO study	32
18/SC/0080	NARRATIVES OF ASSERTIVE OUTREACH TEAM MENTAL HEALTH PATIENTS	32

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
17/SC/0482	VERIFY	27

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

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
17/SC/0127	Safety, Tolerability and PK of AZD8871 in Healthy Japanese Subjects	16
17/SC/0178	Testing the efficacy of image enhancement for visual impairment	23
17/SC/0179	A Rollover Study of PBI-4050 in Subjects with Alström Syndrome	23
17/SC/0339	A Phase I study to show how different formulations of HLD400 perform	20
17/SC/0343	SAD/MAD Phase 1 of the Safety, PK & PD of AST-008 in Healthy Subjects	24
17/SC/0465	SAD and MAD study to assess the PK of MR311 in healthy volunteers	11
17/SC/0490	The FORECAST Trial	23
17/SC/0540	Measuring the effect of physical activity on people living with HIV	21
17/SC/0624	Phase 1 PK study in healthy adult subjects (QCL118137)	16
17/SC/0653	HATRIC	20
17/SC/0662	Voices in Borderline Personality Disorder Explored (ViBE)	20
18/SC/0024	Nail bed INJury Analysis (NINJA)	20
18/SC/0055	Be on the TEAM: Teenagers Against Meningitis	41
18/SC/0070	mySARAH Proof-of-concept study	22

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
17/SC/0202	Validation of C3d assay	20
17/SC/0212	Neurofilaments for NEDA assessing in MS	13
17/SC/0446	Glucose lowering and pre-eclampsia: the role of vascular function (v1)	16
17/SC/0519	PHOTO: Health Economics Time Trade-off Study	7
17/SC/0521	The relationship between iron levels and healing in venous leg ulcers	9
17/SC/0645	The GATASS study	7
17/SC/0646	Therapy interventions for developing self-care in children Version 1.5	14
17/SC/0647	Herbal medicines in pregnancy and the postnatal period study	10
18/SC/0053	TPoTS Study	11
18/SC/0056	Flexible endoscopic treatment for ZD with SB knife	17
18/SC/0134	Amgen_20170129_ Osteoporosis	15
18/SC/0167	Association between periodontal disease and diabetic foot ulcer	17

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

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

Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
17/SC/0204	Mechanisms of change in psychological therapies	10
17/SC/0672	Eye movement tracking to monitor change in ocular nerve palsy	5
17/SC/0675	TREMERA - BIO study	8
18/SC/0112	Factors influencing polypharmacy and inappropriate prescribing in NI	9

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
17/SC/0323	Factors affecting patients' use of electronic personal health records	13
17/SC/0579	Quality of life, mobility and diabetic foot ulcer treatment with casts	8
18/SC/0057	A study of web and tablet-based interactive audiometry in adult CF.	8
18/SC/0110	A novel MRI scoring system for Crohn's Perianal fistula	17
18/SC/0166	BMN 270-901: Prospective Laboratory Study in Haemophilia A Patients	14

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
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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
12/SC/0649/AM05	Development and implantation of normal human preimplantation embryos	4	07/03/2017	17
13/SC/0311/AM15	GP2013 in patients with previously untreated, advanced lymphoma.	7.0	23/02/2017	6
13/SC/0530/AM08	ORANGE II PLUS	AM09	05/04/2017	2
13/SC/0580/AM04	Imaging in peripheral neuropathies	2	04/09/2017	3
13/SC/0583/AM06	Matchpoint	SA6	07/11/2017	7
14/SC/0172/AM03	Measuring cognitive processes in CFS.	3	08/08/2017	7
14/SC/0240/AM01	Couple Dynamics and Maternal Smoking Cessation during Pregnancy	1	26/01/2017	7
14/SC/1024/AM06	Pazopanib-Surgically Unresectable or Metastatic Chondrosarcoma_V1.0	5	03/02/2017	3
14/SC/1059/AM36	28431754DNE3001: The CREDENCE Trial	25	29/01/2018	32
14/SC/1317/AM09	ACP-196 in subjects with Relapsed or Refractory de Novo ABC DLBCL	5	30/03/2017	11
14/SC/1317/AM10	ACP-196 in subjects with Relapsed or Refractory de Novo ABC DLBCL	6	07/11/2017	12
14/SC/1349/AM01	Urban Health Centers Europe 2.0	1	24/01/2017	7
15/SC/0008/AM14	Portsmouth Birth Cohort Registry	13	24/11/2017	2
15/SC/0081/AM05	Cognitive and behavioural processes in anxious children/adolescents V1	AM004	15/03/2018	7
15/SC/0123/AM25	PGRx Information System for Epidemiological Research	12	26/04/2017	9
15/SC/0188/AM01	International LEMTRADA Pregnancy Exposure Cohort in Multiple Sclerosis	Protocol AM 2	16/11/2016	6
15/SC/0225/AM04	BC Study of G7 cup used with compatible femoral stems	3	15/06/2017	6
15/SC/0229/AM08	Neural effects of agomelatine on reward and aversion processing.	Version 7	25/09/2017	1
15/SC/0402/AM04	Imagery Rescripting in Asylum Seekers	4	22/11/2017	5
15/SC/0404/AM07	OC000459 in Severe Asthma	6	06/06/2017	5
15/SC/0404/AM10	OC000459 in Severe Asthma	Amendment 7	12/09/2017	3
15/SC/0404/AM12	OC000459 in Severe Asthma	8	03/01/2018	1

15/SC/0431/AM06	JVDE: The REACH-2 Study	6	29/03/2017	7
15/SC/0431/AM07	JVDE: The REACH-2 Study	7	28/04/2017	6
15/SC/0552/AM06	Phase 1 Study of BLU-285 in Patients with GIST v1	4	30/05/2017	8
15/SC/0552/AM07	Phase 1 Study of BLU-285 in Patients with GIST v1	BLU-285-1101_SA#05	15/09/2017	10
15/SC/0552/AM08	Phase 1 Study of BLU-285 in Patients with GIST v1	BLU-285-1101_SA#06	11/12/2017	3
15/SC/0552/AM09	Phase 1 Study of BLU-285 in Patients with GIST v1	BLU-285-1101_SA#07 Version 1	14/03/2018	9
15/SC/0603/AM04	MAESTRO-OL: Macitentan in Eisenmenger Syndrome OPEN LABEL AC-055-308	Investigator Brochure version	01/06/2017	6
15/SC/0637/AM02	Understanding barriers and outcomes of unspecified (altruistic) kidney	2	07/02/2018	13
15/SC/0659/AM08	JNJ-54861911ALZ2003 - 'EARLY' - Alzheimer's Dementia Study	6	20/03/2017	6
15/SC/0659/AM09	JNJ-54861911ALZ2003 - 'EARLY' - Alzheimer's Dementia Study	7	27/03/2017	27
15/SC/0659/AM10	JNJ-54861911ALZ2003 - 'EARLY' - Alzheimer's Dementia Study	8	24/03/2017	24
15/SC/0659/AM12	JNJ-54861911ALZ2003 - 'EARLY' - Alzheimer's Dementia Study	10	18/12/2017	13
15/SC/0670/AM04	Memory and Executive Functioning in Adolescent Depression	4	31/03/2017	1
15/SC/0679/AM05	Study of Trametinib in children and adolescent subjects with Cancer	4	12/09/2017	36
15/SC/0764/AM01	Dialysis and vascular access	1.0	09/02/2018	4
16/SC/0009/AM03	First time in human study of oral anti-Serum Amyloid P (GSK3039294)	4	16/05/2017	6
16/SC/0012/AM04	Atovaquone as Tumour HypOxia Modifier	4	10/08/2017	10
16/SC/0012/AM05	Atovaquone as Tumour HypOxia Modifier	ATOM_Amendment005	09/11/2017	4
16/SC/0118/AM02	3D vs 2D laparoscopic rectal surgery: randomised controlled trial	1	19/12/2017	2
16/SC/0158/AM02	ALLIKAT (All Ligaments Left In Knee Arthroplasty Trial)	2	10/03/2017	11
16/SC/0158/AM04	ALLIKAT (All Ligaments Left In Knee Arthroplasty Trial)	4.0	06/03/2018	31

16/SC/0203/AM08	Safety and efficacy of BGS649 in male obese patients with HH	6.0	10/03/2017	13
16/SC/0203/AM11	Safety and efficacy of BGS649 in male obese patients with HH	10.0	13/12/2017	2
16/SC/0234/AM02	Whole genome sequencing for the diagnosis of infections	2	06/02/2018	8
16/SC/0303/AM03	Safety, PK and food effect of RV521 in healthy male volunteers	1.0	16/06/2017	6
16/SC/0304/AM02	CaNCaP03 - Cambridge Neoadjuvant Cancer of the Prostate 3	2	25/05/2017	11
16/SC/0369/AM01	Rheumatoid Arthritis Risk Survey v1	1	10/04/2017	7
16/SC/0375/AM02	A FIH study to investigate the safety, tolerability and PK of P218	3	31/10/2017	5
16/SC/0403/AM07	PK,PD & Safety Trial of CAM2047, CAM2048 & CAM2058 in Healthy Subjects	5	07/04/2017	10
16/SC/0422/AM02	105GTN201: TRC105 in Refractory Gestational Trophoblastic Neoplasia	3	30/03/2017	32
16/SC/0436/AM09	Jazz 15-006: Efficacy and Safety Study in Cataplexy and Narcolepsy	5	11/05/2017	8
16/SC/0436/AM10	Jazz 15-006: Efficacy and Safety Study in Cataplexy and Narcolepsy	6	23/06/2017	3
16/SC/0436/AM12	Jazz 15-006: Efficacy and Safety Study in Cataplexy and Narcolepsy	SA8	21/09/2017	1
16/SC/0436/AM13	Jazz 15-006: Efficacy and Safety Study in Cataplexy and Narcolepsy	9	31/01/2018	20
16/SC/0478/AM01	CXCR2 inhibition and coronary heart disease / CICADA	Substantial Amendment 1	27/09/2017	3
16/SC/0497/AM08	VX-695 Bioavailability Study in Healthy and Cystic Fibrosis Subjects	4	25/05/2017	14
16/SC/0497/AM09	VX-695 Bioavailability Study in Healthy and Cystic Fibrosis Subjects	5	25/05/2017	1
16/SC/0498/AM05	Effects and safety of anti-SAP therapy in patients with amyloidosis;v1	2	14/03/2017	5
16/SC/0498/AM06	Effects and safety of anti-SAP therapy in patients with amyloidosis;v1	3	20/04/2017	8
16/SC/0508/AM05	The GRASP Trial	2	13/02/2017	20
16/SC/0508/AM13	The GRASP Trial	7	01/02/2018	17
16/SC/0515/AM03	VX-659 Bioavailability study in Cystic Fibrosis subjects - Part D	2	31/03/2017	10
16/SC/0515/AM07	VX-659 Bioavailability study in Cystic Fibrosis subjects - Part D	3	19/06/2017	7
16/SC/0543/AM05	A FIH, SAD, MAD and FE study of AZD0284 in healthy subjects	SA4	18/08/2017	5

16/SC/0590/AM01	Depletion of Serum Amyloid P Component in Alzheimer's Disease (v1.0)	AM02	16/08/2017	7
16/SC/0590/AM04	Depletion of Serum Amyloid P Component in Alzheimer's Disease (v1.0)	3	23/11/2017	11
16/SC/0590/AM05	Depletion of Serum Amyloid P Component in Alzheimer's Disease (v1.0)	AM04 07 March 18	07/03/2018	6
16/SC/0671/AM01	M15-531: ABT-199 in MDS	1	15/02/2017	13
16/SC/0671/AM03	M15-531: ABT-199 in MDS	2	30/05/2017	8
16/SC/0671/AM04	M15-531: ABT-199 in MDS	Protocol Amendment 1	25/08/2017	8
17/SC/0005/AM01	SIDS version	1	01/11/2016	6
17/SC/0028/AM01	CA209-714	1	10/04/2017	1
17/SC/0028/AM02	CA209-714	2.0	24/07/2017	13
17/SC/0028/AM04	CA209-714	3.0	14/11/2017	2
17/SC/0053/AM01	Psychological Impact of Notification Exercises - Version 4.0	SA1	17/08/2017	8
17/SC/0178/AM02	Testing the efficacy of image enhancement for visual impairment	1	18/10/2017	2
17/SC/0179/AM01	A Rollover Study of PBI-4050 in Subjects with Alström Syndrome	Amendment 2	20/07/2017	1
17/SC/0179/AM02	A Rollover Study of PBI-4050 in Subjects with Alström Syndrome	3	07/02/2018	22
17/SC/0184/AM01	SINGLED	1	22/03/2017	7
17/SC/0184/AM02	SINGLED	2	01/11/2017	0
17/SC/0185/AM01	BGB-3111 and Ibrutinib in Waldenström's Macroglobulinemia	1	03/08/2017	22
17/SC/0185/AM03	BGB-3111 and Ibrutinib in Waldenström's Macroglobulinemia	Substantial Amendment 2	16/10/2017	1
17/SC/0185/AM05	BGB-3111 and Ibrutinib in Waldenström's Macroglobulinemia	4	13/03/2017	20
17/SC/0186/AM01	Switching from TDF to TAF	1	09/08/2017	5
17/SC/0204/AM01	Mechanisms of change in psychological therapies	1	27/07/2017	7
17/SC/0204/AM02	Mechanisms of change in psychological therapies	Substantial Amendment V1.3	27/10/2017	2
17/SC/0283/AM01	A CFit Study: Baseline	1	11/10/2017	5
17/SC/0294/AM02	WO39392 IMpassion 031 ATEZOLIZUMAB or PLACEBO + NAB-PACLITAXEL + CHEMO	Amendment No.2 Updated PIS ICF	05/12/2017	10
17/SC/0298/AM01	GSK3640254 FTIH study in healthy participants	1	03/08/2017	16
17/SC/0298/AM02	GSK3640254 FTIH study in healthy participants	Substantial	05/12/2107	4

17/SC/0334/AM01	A CFit Study: Acute Exercise	Amendment 2 Substantial Amendment 2	11/10/2017	1
17/SC/0337/AM01	First Time in Human Study of GSK3335065 in Healthy Adults	SA01	21/08/2017	6
17/SC/0337/AM02	First Time in Human Study of GSK3335065 in Healthy Adults	201570 SA2	29/11/2017	7
17/SC/0337/AM03	First Time in Human Study of GSK3335065 in Healthy Adults	3	23/02/2018	10
17/SC/0343/AM01	SAD/MAD Phase 1 of the Safety, PK & PD of AST-008 in Healthy Subjects	Amendment 6, Version 1.0, 19 F	19/02/2018	3
17/SC/0390/AM01	Safety, tolerability, PK, PD, food-effect of SAD and MAD of TRK-750	2	06/11/2017	2
17/SC/0390/AM02	Safety, tolerability, PK, PD, food-effect of SAD and MAD of TRK-750	1.0	14/03/2018	14
17/SC/0413/AM02	Safety, tolerability and PK, of SAD and MAD of XEN1101 in HV	1	06/11/2017	2
17/SC/0413/AM05	Safety, tolerability and PK, of SAD and MAD of XEN1101 in HV	4	22/12/2017	6
17/SC/0446/AM01	Glucose lowering and pre-eclampsia: the role of vascular function (v1)	1	19/02/2018	4
17/SC/0465/AM01	SAD and MAD study to assess the PK of MR311 in healthy volunteers	Protocol Am 2	18/01/2018	1
17/SC/0492/AM01	Fluorescence targeted lymphatic mapping in colonic cancer	AM001	13/03/2018	18
17/SC/0624/AM01	Phase 1 PK study in healthy adult subjects (QCL118137)	SA01	09/02/2018	3
18/SC/0010/AM01	Effects of VX-659 triple combination on Oral contraceptives in Females	AM01	14/03/2018	20

Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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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
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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
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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
15/SC/0679/AM05	Study of Trametinib in children and adolescent subjects with Cancer	4	12/09/2017	36

Modified Amendments over 14 day timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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