

**South West - Central Bristol Research Ethics  
Committee**

**Annual Report**

**01 April 2017 - 31 March 2018**



## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	South West - Central Bristol Research Ethics Committee
<b>Type of REC:</b>	III, Recognised
<b>Type of Flag:</b>	RD, RTB, IRB
<b>Chair:</b>	Dr Julie Woodley
<b>Vice-Chair:</b>	Mr Brian Pixton
<b>Alternate Vice-Chair:</b>	Dr Margaret Saunders
<b>REC Manager:</b>	Mrs Naazneen Nathoo
<b>REC Assistant:</b>	Miss Lidia Gonzalez (from 01/05/2017 to present)
<b>Committee Address:</b>	Whitefriars Level 3, Block B Lewin's Mead Bristol BS1 2NT Email: nrescommittee.southwest-bristol@nhs.net
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## Chair's overview of the past year:

Two members (one expert and one lay) stepped down and were replaced by two expert members during the reporting period.

A Training Day on CTIMPs was organized by the REC Manager on 23 March 2018: this had 100% attendance.

Our committee continues to receive good feedback from researchers and many choose to return and submit additional applications because they have found the committee to be rigorous but supportive.

As Chair I enjoy chairing this committee as all members are friendly and between them have a wealth of knowledge and opinions. All discussions are always very well natured and everyone feels their opinions will be valued.

We are also supported by an excellent administrative team who work very hard to manage an ever increasing workload

Dr Julie Woodley

### South West - Central Bristol Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Dr Robert Beetham	Retired Consultant Clinical Biochemist	Lay	01/02/2014	
Ms Susan Bradford	Solicitor	Lay Plus	18/02/2016	
Dr Elizabeth Coates	Research Governance Coordinator	Lay	01/09/2016	
Dr Ian Davies	Consultant in Cardiac Anaesthesia & Intensive Care	Expert	01/05/2011	
Mr Richard Gibson	Administrator	Lay Plus	01/02/2016	06/10/2017
Mr Alexander Howard	Humanist Funeral Celebrant	Lay Plus	08/08/2014	
Mr Mike Howell	Medical Devices Design Engineer	Expert	10/11/2017	
Dr Adrian Kendrick	Consultant Clinical Scientist	Expert	20/01/2013	
Mrs Liz McCullagh	Clinical Trials Pharmacist	Expert	11/08/2017	
Ms Sally Morgan-Fletcher	Clinical Scientist	Expert	01/05/2015	
Mr Brian Pixton	Retired solicitor	Lay Plus	11/03/2013	
Dr Colette Reid	Consultant in Palliative Medicine	Expert	01/08/2013	14/06/2017
Dr Margaret Saunders	Consultant Clinical Scientist	Expert	01/05/2015	
Dr Julie Woodley	Senior Lecturer/ Chair of Faculty Ethics Committee	Expert	08/08/2014	

### South West - Central Bristol Research Ethics Committee: Deputy Members

Name	Profession	Status	Meeting date attended
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### South West - Central Bristol Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended
Miss Helen Moore	Pharmacist	Expert Member	PRSC 18/09/2017
Canon Ian Ainsworth-Smith	Retired Hospital Chaplain	Lay Member	Sub Committee 20/10/2017

## South West - Central Bristol Research Ethics Committee: Members' Declarations of

Name	Declaration of Interest	Date
Dr Robert Beetham	Shareholding in Smith & Nephew plc	31/03/2018
Ms Susan Bradford	Associate Non-Executive Director, South Western Ambulance Service NHS Foundation Trust	31/01/2018
Dr Elizabeth Coates	Head of Governance at Public Health England	31/01/2018
Dr Ian Davies	None	31/01/2018
Mr Alexander Howard	None	31/03/2018
Mr Mike Howell	Snr Design engineer at Renishaw. Involved in clinical trials for medical devices for Renishaw; possible involvement in pharmaceutical co and their clinical trials.	06/11/2017
Dr Adrian Kendrick	<p>Institute of Clinical Science &amp; Technology (Cardiff &amp; London) – Course Director (MSc in Sleep Medicine) and Co-Lead of Research through the ICST.</p> <p>Rett UK – Member of Medical Advisory Panel. Rett UK – Member of National/International Clinical Trials Group.</p> <p>Rett Alliance (Rett UK &amp; Reverse Rett) – Member of working group for position statements for the assessment and management of patients with Rett Syndrome and associated disorders. Probably will include areas for further research.</p> <p>NIHR – Reviewer for Grant Applications.</p> <p>European Respiratory Society – College of Experts: reviewer for grant applications to the various ERS research programmes.</p> <p>Institute of Clinical Science &amp; Technology – see above</p> <p>Association for Respiratory Technology &amp; Physiology – Research Committee member</p> <p>Non-Disclosure Agreements: Pharmaceutical Industry x2 Manufacturing Industry x1</p>	31/03/2018
Mrs Liz McCullagh	CTIMP Advice to NHS and University sponsored studies. UHBristol employee.	31/01/2018
Ms Sally Morgan-Fletcher	None	31/03/2018
Mr Brian Pixton	None	31/01/2018
Dr Margaret Saunders	Head of D&T Divisional Research & Innovation Group, UHB NHS FT	31/01/2018
Dr Julie Woodley	Lecturer and Chair of ethics committee at UWE. Senior fellow at University of Bristol (so may know some researchers).	31/01/2018

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

Month	Date	Number of Members Present at Meeting
April	28/04/2017	10
May	26/05/2017	8
July	28/07/2017	7
August	25/08/2017	10
September	29/09/2017	10
October	27/10/2017	7
November	24/11/2017	11
January	26/01/2018	9
February	23/02/2018	11

9 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	10/04/2017	3
May	16/05/2017	3
June	14/06/2017	3
July	17/07/2017	3
August	21/08/2017	3
September	18/09/2017	3
October	16/10/2017	3
November	20/11/2017	3
December	18/12/2017	3
January	15/01/2018	3
February	19/02/2018	3
March	19/03/2018	3

12 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	19/04/2017	2
May	05/05/2017	2
May	19/05/2017	3
June	02/06/2017	2
June	16/06/2017	2
June	30/06/2017	2
July	14/07/2017	2

July	28/07/2017	2
August	11/08/2017	2
August	25/08/2017	2
September	08/09/2017	2
September	22/09/2017	2
September	26/09/2017	3
October	06/10/2017	2
October	20/10/2017	2
November	03/11/2017	2
November	17/11/2017	2
December	01/12/2017	2
December	05/12/2017	2
December	15/12/2017	2
December	20/12/2017	2
January	12/01/2018	2
January	26/01/2018	2
February	16/02/2018	2
March	02/03/2018	2
March	16/03/2018	2

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

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

None

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

Name	Number of Meetings Attended
Dr Robert Beetham	9
Ms Susan Bradford	7
Dr Elizabeth Coates	8
Dr Ian Davies	6
Mr Richard Gibson	4
Mr Alexander Howard	7
Mr Mike Howell	3
Dr Adrian Kendrick	6
Mrs Liz McCullagh	5
Ms Sally Morgan-Fletcher	5
Mr Brian Pixton	7
Dr Colette Reid	2
Dr Margaret Saunders	7
Dr Julie Woodley	7

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

Name	Number of Meetings Attended
Dr Robert Beetham	2
Ms Susan Bradford	3
Dr Elizabeth Coates	2
Dr Ian Davies	3
Mr Richard Gibson	1
Mr Alexander Howard	4
Dr Adrian Kendrick	2
Ms Sally Morgan-Fletcher	3
Mr Brian Pixton	7
Dr Colette Reid	1
Dr Margaret Saunders	3
Dr Julie Woodley	4

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

Name	Number of Meetings Attended
Dr Robert Beetham	3
Ms Susan Bradford	8



Dr Elizabeth Coates	4
Dr Ian Davies	1
Mr Richard Gibson	1
Mr Alexander Howard	2
Ms Sally Morgan-Fletcher	3
Mr Brian Pixton	10
Dr Margaret Saunders	11
Dr Julie Woodley	13

## Training 01 April 2017 - 31 March 2018

Name of Member	Date	Event(s) attended
Dr Robert Beetham	12/12/2017	National Members Training Day
Dr Robert Beetham	25/01/2018	COMPLEX CASES
Ms Susan Bradford	23/03/2018	Local Training Day
Dr Elizabeth Coates	14/06/2017	Equality Diversity & Human Rights
Dr Elizabeth Coates	23/03/2018	LTD
Dr Ian Davies	23/03/2018	Local Training Day
Mr Richard Gibson	21/09/2017	Committee Member Induction
Mr Alexander Howard	23/03/2018	Local Training Day
Mr Mike Howell	06/11/2017	Induction
Mr Mike Howell	21/12/2017	Equality & Diversity
Mr Mike Howell	23/03/2018	Local Training Day
Dr Adrian Kendrick	23/03/2018	Local Training Day
Mrs Liz McCullagh	25/08/2017	Equality, Diversity & Human Rights
Mrs Liz McCullagh	06/10/2017	Induction for new RES committee members - online
Mrs Liz McCullagh	27/10/2017	Members' Induction
Mrs Liz McCullagh	23/03/2018	Local Training Day
Mr Brian Pixton	25/01/2018	Complex Cases
Mr Brian Pixton	23/03/2018	Local Training Day
Dr Margaret Saunders	09/11/2017	Equality, Diversity & Human Rights
Dr Margaret Saunders	07/12/2017	Local Training Day - Exeter
Dr Margaret Saunders	23/03/2018	Local Training Day
Dr Julie Woodley	26/06/2017	Equality & Diversity
Dr Julie Woodley	26/09/2017	Assessing the Consequences (benefits and harms) of Research: a Health Research Authority workshop
Dr Julie Woodley	24/11/2017	HRA National Chairs' Day and Policy Event
Dr Julie Woodley	25/01/2018	COMPLEX CASES
Dr Julie Woodley	23/03/2018	Local 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:**

<b>Applications for full ethical review – Study Type</b>	<b>Number</b>	<b>%</b>
Clinical Trial of Investigational Medicinal Product	14	32.56
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	2	4.65
Research Database (including renewals)	2	4.65
Others	25	58.14
<b>Total Applications Reviewed</b>	<b>43</b>	<b>100</b>

**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	12
Number of paediatric applications reviewed	10
Number of device applications reviewed	1
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	2
Number of qualitative applications reviewed	3

**Table 3: Decisions given at meetings held within the reporting period**

<b>Decisions taken at meetings following review of applications</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	4	9.30
Favourable Opinion with Additional Conditions	6	13.95
Unfavourable Opinion	0	0.00
Provisional Opinion	33	76.74
Provisional Opinion Pending Consultation with Referee	0	0.00
<b>Total</b>	<b>43</b>	<b>100</b>
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**

<b>Status of applications at date of generation of report</b>	<b>Number</b>	<b>%</b>
Further Information Favourable Opinion with Standard Conditions	32	74.42
Further Information Favourable Opinion with Additional Conditions	0	0.00
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	4	9.30
Favourable Opinion with Additional Conditions	6	13.95
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	1	2.33
<b>Total</b>	<b>43</b>	<b>100</b>

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

<b>Total Applications Reviewed</b>	<b>28</b>
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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	0
Number of student applications reviewed	13
Number of paediatric applications reviewed	4
Number of device applications reviewed	2
Number of qualitative applications reviewed	2

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

<b>Decisions taken at proportionate review sub-committee meetings</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	8	28.57
Favourable Opinion with Additional Conditions	4	14.29
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	16	57.14
Unfavourable Opinion	0	0.00
<b>Total</b>	<b>28</b>	<b>100</b>

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

<b>Average number of applications reviewed per full meeting</b>	4.78
<b>Number of completed applications for full ethical review</b>	42
<b>Number of completed applications for full ethical review over 60 days</b>	0
<b>Number of completed applications over 60 days as a % of total</b>	0.00%
<b>Number of completed applications for full ethical review over 40 days</b>	2
<b>Number of completed applications over 40 days as a % of total</b>	4.65%
<b>Number of days taken to final decision – average (mean)</b>	27
<b>Number of completed proportionate review applications for ethical review</b>	28
<b>Number of completed proportionate review applications for ethical review over 21 days</b>	1
<b>Number of completed proportionate review applications over 21 days as a % of total</b>	3.57%
<b>Number of SSAs (non-Phase 1) reviewed</b>	9
<b>Number of completed applications for SSA review over 25 days</b>	0
<b>Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs</b>	0.00%
<b>Number of SSAs (Phase 1) reviewed</b>	0
<b>Number of completed applications for SSA review over 14 days</b>	0
<b>Number of completed applications for SSA review over 14 days as % of all Phase 1 SSAs</b>	0.00%
<b>Number of substantial amendments reviewed</b>	133
<b>Number of completed substantial amendments over 35 days</b>	3
<b>Number of completed substantial amendments over 35 days as a % of total substantial amendments</b>	2.26%
<b>Number of completed substantial amendments over 28 days</b>	11
<b>Number of completed substantial amendments over 28 days as a % of total substantial amendments</b>	8.27%
<b>Number of modified amendments reviewed</b>	1
<b>Number of completed modified amendments over 14 days</b>	0
<b>Number of completed modified amendments over 14 days as a % of total modified amendments</b>	0.00%
<b>Number of non substantial amendments received</b>	100
<b>Number of substantial amendments received for information</b>	5
<b>Number of substantial amendments received for new sites/PIs</b>	37
<b>Number of annual progress reports received</b>	86

<b>Number of safety reports received</b>	32
<b>Number of Serious Adverse Events received</b>	1
<b>Number of final reports received</b>	11

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

<b>Further Information Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
17/SW/0089	Best Emollient for Eczema	41
17/SW/0107	Barts Health:NICOR - Extended Use of Data Version 1.1-2017	27
17/SW/0121	Hip and KnEe study of SPHERE (HEmiSPHERE) Version 1	27
17/SW/0127	FLIGHT Study, V1.0	29
17/SW/0142	FAST MRI Data Study	25
17/SW/0151	The Rejuvenate Training Study v1	43
17/SW/0163	Responses to physical exertion in Chronic Fatigue Syndrome / ME	35
17/SW/0174	A Phase 2 Clinical Trial in Patients with AML version amend 4	29
17/SW/0186	Bone Health Improvement in Individuals with SCI	17
17/SW/0200	Optimising pacemaker therapy using multi-point pacing (OPT-MPP)	25
17/SW/0201	MiBRVO	34
17/SW/0202	MiCRVO	34
17/SW/0219	Substrate use during prolonged exercise with ingestion of ethanol (v1)	23
17/SW/0221	(CAIN457K2340) Secukinumab compared with GP2017 in Active AS	33
17/SW/0243	Pilot evaluation of integrated CBT for depression (INTERACT Phase 2)	27
17/SW/0247	NP39403-RO6870810 as monotherapy and in combination in advanced MM	37
17/SW/0248	BioClin - B-701-U21 - B-701 vs Placebo in Urothelial Cell Carcinoma	19
17/SW/0250	Conventional versus minimally invasive extra-corporeal circulation	36
17/SW/0252	Managing the wait for first treatment in CAMHS	27
17/SW/0261	Understanding OCD that occurs in the context of complex trauma	23
17/SW/0269	Body Composition and Lipid Metabolism at Rest and During Exercise	21
17/SW/0273	SB11-G31-AMD-Comparison of efficacy&safety of SB11 and Lucentis in AMD	13
17/SW/0279	MO39171 - Atezolizumab in locally advanced or metastatic NSCLC	26
18/SW/0013	A feasibility study of the Fluency Trust Residential Course	23
18/SW/0020	What can be learnt from brief therapeutic work with parents & infants?	27
18/SW/0021	PUMA - Paediatric OsseoUs Marrow Assessment - study	23
18/SW/0023	228PD201 Phase 2a study testing BIIB054 for Parkinson's Disease	36
18/SW/0045	Mistletoe And Breast Cancer (MAB)	36
18/SW/0049	Phase 1B/2 Study of Avelumab combined with Standard Care Chemotherapy	28
18/SW/0050	A3921288 Phase 3B/4 Study of Tofacitinib in Subjects with UC	27
18/SW/0051	BPSU survey of severe Chronic Fatigue Syndrome/Myalgic Encephalopathy	26
18/SW/0053	STARSHIP v 2	38



**Further Information Favourable Opinion with Additional Conditions**

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

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

REC Reference	Title	Number of Days on Clock
17/SW/0067	MINOH-HF. Evaluating the potential role of minocycline in chronic heart failure	25
17/SW/0162	BEACON LUNG	27
17/SW/0223	Trial of physical Activity assisted Reduction of Smoking (TARS)	20
17/SW/0268	Collaboration in I(L)D services	20

**Favourable Opinion with Additional Conditions**

REC Reference	Title	Number of Days on Clock
17/SW/0099	Could Pre-Rehabilitation Commence before Diagnosis?	25
17/SW/0157	Southampton Eye Biobank (SEB)	24
17/SW/0178	A pilot study of the use of supported SLEEPIO for young people	19
17/SW/0253	Two vs. four SWI for low back pain in labour. Version 1.0	20
18/SW/0022	Harnessing plasticity to treat brain tumours	16
18/SW/0029	(duplicate) South West Dementia Brain Bank and DNA Bank (v3)	21

**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
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**Further information response not complete**

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

REC Reference	Title	Number of Days on Clock
17/SW/0161	Train for the Brain: Online exercise for over 50s	24

**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/SW/0097	Text messages for pressure ulcer prevention in spinal cord injury	15
17/SW/0134	Thermal Imaging of Breast Vasculature - v.1.0	13
17/SW/0137	Models of Child Health Appraised - UK study of 8 exemplar conditions	9
17/SW/0188	Impact of visual difficulties on quality of life in monocular children	27
17/SW/0217	Wearable Sensor Based Rehabilitation for Shoulder Pain	11
17/SW/0218	Small bowel and colonic ion channels in non-CF and CF patients	16
17/SW/0220	Immune responses to BK virus in kidney transplant patients	14
17/SW/0222	In vivo human motor unit imaging	18
17/SW/0237	LV mechanics in MR	13
17/SW/0293	MCG Post MI study	13
18/SW/0016	LEQ Development & Pretesting	20
18/SW/0018	Echocardiography comparison between athletes & controls	14
18/SW/0055	Better measuring quality of life in people with DMD (v1)	16
18/SW/0074	Body perception and cortical reorganisation in CRPS (Version 1)	19
18/SW/0076	Self-regulation during a pain management programme	20
18/SW/0077	Superficial wound infection in Hepatopancreatobiliary (HPB) surgery	12

**Further Information Favourable Opinion with Additional Conditions**

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

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

REC Reference	Title	Number of Days on Clock
17/SW/0096	ENABLE-Imperial	12
17/SW/0154	Audio recording of consent: attitudes of patients and healthcare staff	10
17/SW/0189	Bioprocessing of Gene and Cell Therapies	19
17/SW/0191	Fibromyalgia as predictor of bad outcome after spinal injection	19
17/SW/0241	Psychophysiological responses to stress in individuals with IBD	11
17/SW/0289	Unexplained visual loss following removal of silicone oil	13
17/SW/0291	An exploration of routine Primary Care consultations for skin problems	8
18/SW/0052	GLACIER and ICICLE update; survival outcomes	14

**Favourable Opinion with Additional Conditions**

REC Reference	Title	Number of Days on Clock
17/SW/0113	FaPIA V.1	14
17/SW/0239	MAPS Study	11
17/SW/0263	Multi compartment comparisons in Haematological malignancies.	14
17/SW/0265	What do patients need to manage Early Persistent Abdominal Pain V1	7

**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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**Further information response not complete**

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

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

<b>Favourable opinion</b>				
<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>
04/Q2006/102/AM16	Natural History Study of the development of Type 1 Diabetes - May 2004	16	27/06/2017	5
04/Q2006/102/AM19	Natural History Study of the development of Type 1 Diabetes - May 2004	18 - 28 NOV 2017	28/11/2017	13
06/Q2002/101/AM05	Cultured Glomerular Cells	5 (Substantial)	13/09/2017	17
09/H0106/80/AM11	National Study of Steroid Resistant Nephrotic Syndrome in Childhood	9	23/08/2017	25
09/H0106/83/AM14	TrialNet Oral Insulin Study	10, 2017/03/24	13/04/2017	25
10/H0106/1/AM05	VeRDICT: volume replacement vs. usual care in diabetics having CABG	5	10/11/2017	8
11/SW/0036/AM30	TABLET	RG_10_004 Amendment 26	04/10/2017	28
11/SW/0122/AM03	THERMIC-2: Normothermic v Hypothermic Perfusion in Paediatric CPB v1.0	4	21/07/2017	14
11/SW/0345/AM03	Bristol Bladder Trial	3 Protocol v8.0	01/03/2017	11
12/SW/0055/AM12	COCO90s Version 1.0	11 03/04/2017	03/04/2017	21
12/SW/0361/AM20	COMBI-AD. COMBIlation study in treatment of ADjuvant melanoma	6	22/02/2017	32
12/SW/0361/AM22	COMBI-AD. COMBIlation study in treatment of ADjuvant melanoma	DRB436F2301 (BRF115532)	31/05/2017	6
12/SW/0361/AM25	COMBI-AD. COMBIlation study in treatment of ADjuvant melanoma	ICF amendment for extension of	07/02/2018	20
13/SW/0015/AM05	The EQUAL Study	Major amendment 3	04/08/2017	7
13/SW/0078/AM01	Assessment of RV Function in CHD using Exercise Echocardiography	1	17/01/2017	22
13/SW/0159/AM10	NN304-4016 Diabetes Pregnancy Registry	Substantial Amendment 5, dated	21/12/2017	21
13/SW/0163/AM02	The Veteran Athlete's Heart (Version 2)	2	06/11/2017	15
13/SW/0199/AM07	EVRA (Early Venous Reflux Ablation) Ulcer trial Version 1.0	6	06/04/2017	12

13/SW/0230/AM01	Changes in Taste Perception and Preference Following ENT Surgery	Sub Am 1	25/10/2017	7
14/SW/0030/AM06	Feeding and Autoimmunity in Down's syndrome Evaluation Study (FADES)	SA7	25/07/2017	13
14/SW/0075/AM07	REDUCE Trial	SA 5	01/06/2017	20
14/SW/0091/AM17	A Phase 3 Veliparib plus Chemotherapy Study in Adv/Met squamous NSCLC	Veliparib IB Edition 11	22/06/2017	21
14/SW/0091/AM18	A Phase 3 Veliparib plus Chemotherapy Study in Adv/Met squamous NSCLC	Veliparib IB Ed 11 Addendum	02/10/2017	7
14/SW/1050/AM05	The Pulses Study	ME/2011/3709 V5	01/08/2017	30
14/SW/1061/AM06	TrialNet TN18 Abatacept Prevention	5	02/06/2017	22
14/SW/1061/AM08	TrialNet TN18 Abatacept Prevention	Amendment 6	17/10/2017	8
14/SW/1061/AM10	TrialNet TN18 Abatacept Prevention	Amendment 7	19/01/2018	5
14/SW/1084/AM04	Newborn Hearing Screening and the risk of SIDS	3	03/07/2017	11
14/SW/1085/AM10	Placebo controlled Radium-223, plus exemestane and everolimus in mBC	Global protocol Amendment 8	23/05/2017	9
14/SW/1088/AM03	National Registry for Rare Kidney Diseases (RaDaR)	RaDaR Protocol v11	20/09/2017	2
14/SW/1141/AM13	1289.5 BI409306 compared to placebo in Alzheimer's Disease	SA9	23/03/2017	14
14/SW/1141/AM15	1289.5 BI409306 compared to placebo in Alzheimer's Disease	SA11	28/07/2017	11
14/SW/1144/AM05	ARENA study	3	17/03/2017	22
14/SW/1144/AM06	ARENA study	4	23/01/2018	17
14/SW/1148/AM02	University of Birmingham Dentistry Research Tissue Bank	AM02	04/07/2017	12
14/SW/1163/AM02	LOTUS: long term follow up study of triple negative breast cancer	SA1	25/05/2017	10
14/SW/1164/AM15	MEDI4736 in Recurrent or Metastatic PD-L1 Positive SCCHN	SA#11 Updated durvalumab Inves	02/06/2017	10
14/SW/1164/AM17	MEDI4736 in Recurrent or Metastatic PD-L1 Positive SCCHN	SA#12	02/11/2017	18
14/SW/1164/AM18	MEDI4736 in Recurrent or Metastatic PD-L1 Positive SCCHN	SA#13	25/01/2018	17
15/SW/0004/AM02	Examining mechanisms underlying the anti-cancer effect of exercise-v1	2, dated 14.02.17	10/03/2017	27
15/SW/0084/AM04	PUMA-Paediatric early warning systems: Utility and Mortality Avoidance	3	07/12/2017	42
15/SW/0086/AM10	Daratumumab + rd vs rd in subjects with previously untreated MM	4.0	22/06/2017	14
15/SW/0144/AM03	Energy Expenditure Study Version 1.0	#3	18/04/2017	14

15/SW/0194/AM17	Phase III study with Finerenone in Type II Diabetes and DKD, Renal	11	17/03/2017	20
15/SW/0194/AM19	Phase III study with Finerenone in Type II Diabetes and DKD, Renal	#12	01/06/2017	28
15/SW/0194/AM21	Phase III study with Finerenone in Type II Diabetes and DKD, Renal	Substantial Amendment#14	22/09/2017	14
15/SW/0194/AM26	Phase III study with Finerenone in Type II Diabetes and DKD, Renal	Substantial#15	21/02/2018	15
15/SW/0196/AM05	GO29431 Phase III Study of MPDL3280A in Stage IV Non-Squamous NSCLC	GO29431 Protocol Version 6	14/03/2017	8
15/SW/0196/AM08	GO29431 Phase III Study of MPDL3280A in Stage IV Non-Squamous NSCLC	SA 11	11/12/2017	3
15/SW/0220/AM04	Ustekinumab in Subjects With Nonradiographic Axial Spondyloarthritis	SA# 3	02/06/2017	12
15/SW/0230/AM02	Bristol Twin (BRIT) Study	2	10/12/2017	17
15/SW/0248/AM08	VX14-661-110 Cystic Fibrosis	SA6 Protocol v3.2	21/07/2017	26
15/SW/0248/AM09	VX14-661-110 Cystic Fibrosis	SA8 - IB combo V1	08/11/2017	13
15/SW/0270/AM01	The attitudes to ageing questionnaire for young adults version 1.0	1.1	13/03/2017	25
15/SW/0270/AM02	The attitudes to ageing questionnaire for young adults version 1.0	Study Protocol v 1.2 27/10/201	27/10/2017	3
15/SW/0274/AM16	TITAN, Protocol 56021927PCR3002	TITAN Amendment 10: IB ED10 AD	21/08/2017	6
15/SW/0275/AM02	Inflammatory Dendritic Cells in Arthritis	SA#3	09/05/2017	7
15/SW/0289/AM05	RHINO: Respiratory Health Outcomes in Neonates	4 dated 14.03.17	14/03/2017	23
15/SW/0289/AM07	RHINO: Respiratory Health Outcomes in Neonates	5	27/07/2017	6
15/SW/0289/AM08	RHINO: Respiratory Health Outcomes in Neonates	SA06	07/12/2017	7
15/SW/0300/AM11	ARTIC PC	SA07	27/04/2017	5
15/SW/0300/AM16	ARTIC PC	11	08/09/2017	8
15/SW/0309/AM01	SPARKS	1	28/02/2016	30
15/SW/0312/AM07	KARE: Ketamine for reduction of Alcoholic Relapse Version 1	4	08/08/2017	15
15/SW/0312/AM08	KARE: Ketamine for reduction of Alcoholic Relapse Version 1	5	06/10/2017	14
15/SW/0326/AM07	ATLAS: JNJ56021927 (ARN509)	ATLAS Amendment 7	08/05/2017	10
15/SW/0326/AM09	ATLAS: JNJ56021927 (ARN509)	ATLAS	21/08/2017	6

		Amendment 9: IB ED10 ADD		
15/SW/0326/AM10	ATLAS: JNJ56021927 (ARN509)	ATLAS Amendment 9 (Numbering C	14/02/2018	33
15/SW/0333/AM04	Sentinel Skin Flaps in Pancreas Transplantation	Amendment no 3 (SSF Protocol V	10/04/2017	10
15/SW/0333/AM05	Sentinel Skin Flaps in Pancreas Transplantation	no 4 (SSF Protocol V5 )	01/10/2017	7
16/SW/0028/AM02	DOPAMIND	SUBAM2	15/06/2017	11
16/SW/0028/AM03	DOPAMIND	SUBAM3	07/07/2017	32
16/SW/0028/AM04	DOPAMIND	SUBAM4 REC	21/08/2017	24
16/SW/0038/AM01	Exploring the feasibility of an electronic prompting tool for dementia	01/11/2017	01/11/2017	24
16/SW/0090/AM05	Ustekinumab in Subjects with Radiographic Axial Spondyloarthritis	SA#4	02/06/2017	12
16/SW/0112/AM01	BAP1 and Histone Deacetylase Expression in Uveal Melanoma V1	2	30/06/2017	9
16/SW/0115/AM01	The LiBRA (Loss of implant breast reconstruction evaluation) study.	1	07/11/2017	14
16/SW/0120/AM04	EKOS and r-tPA thrombolysis in Pulmonary Embolism (OPTALYSE STUDY)	EKOS-12 UK Version 6	10/05/2017	16
16/SW/0154/AM03	STAR trial	Substantial amendment 2, 01- 03	21/03/2017	15
16/SW/0154/AM04	STAR trial	3	22/06/2017	12
16/SW/0154/AM05	STAR trial	4	23/01/2018	17
16/SW/0160/AM03	CHALLENGE-UK: A UK cohort of the CHALLENGE trial	Substantial Amendment 3.0 23/0	23/05/2017	35
16/SW/0161/AM01	TUDOR V1.0	SA Number 01: May 2017	08/05/2017	25
16/SW/0165/AM03	Exploring ways to support parents to look after their babies' teeth v1	4	25/04/2017	29
16/SW/0186/AM02	Peacock - A Paediatric Cortisol Study	2	20/12/2017	20
16/SW/0194/AM01	The UK Multiple Sclerosis Register	1	02/02/2018	15



16/SW/0201/AM02	CENTERA	2	21/03/2017	16
16/SW/0201/AM04	CENTERA	New Investigator Poster	02/06/2017	9
16/SW/0202/AM05	A Clinical Trial in subjects with active Ankylosing Spondylitis	Protocol V01 and vendor update	01/02/2018	17
16/SW/0205/AM02	DopaCon	2	11/08/2017	19
16/SW/0232/AM01	R-RID - Rifaximin to Reduce Infection in Decompensated Cirrhosis	SA Protocol Amendment Vs 3.0	01/08/2017	20
16/SW/0245/AM01	Quality of life and support needs in families with cleft lip/palate	1	03/08/2017	17
16/SW/0251/AM01	Superior capsule reconstruction using graft jacket- a case series	SA01	15/08/2017	7
16/SW/0267/AM01	Optic Nerves in Children born Early (ONCE) Study	SA1	15/08/2017	14
16/SW/0273/AM01	Bristol Imperial MDMA in Alcoholism Study (BIMA)	1	28/03/2017	13
16/SW/0290/AM01	An evaluation of the BHF's exercise DVD in cardiac rehabilitation	1	09/07/2017	15
16/SW/0297/AM03	Implementation of Mental Practice after Stroke: a novel method	1	27/04/2017	5
16/SW/0331/AM02	Natural adaptive immunity to high risk human papillomavirus (HR HPV)	2	29/03/2017	13
16/SW/0331/AM03	Natural adaptive immunity to high risk human papillomavirus (HR HPV)	3	02/11/2017	8
16/SW/0332/AM08	DIAPASS: Ayendi Observational Study	A07	19/09/2017	17
16/SW/0333/AM01	Sensory attenuation in functional movement disorders	SAM01	25/01/2017	7
17/SW/0011/AM02	Bruton's Tyrosine Kinase Inhibitor, Treatment for Follicular Lymphoma	Global Amd Pack 1 - Patient Vi	13/04/2017	15
17/SW/0019/AM02	ASSESS-meso	1.4	25/01/2018	16
17/SW/0020/AM01	The cancer therapy experience study. Version one.	number one	11/05/2017	11
17/SW/0048/AM01	FLEX-HD	1	20/09/2017	41
17/SW/0078/AM01	CheckMate 915	SA: EC02	16/06/2017	19
17/SW/0078/AM03	CheckMate 915	EC04	08/11/2017	8
17/SW/0078/AM04	CheckMate 915	EC05	08/02/2018	13
17/SW/0080/AM01	TILT	3850 V1.0	30/10/2017	6
17/SW/0080/AM02	TILT	3850 2.0	05/03/2018	23
17/SW/0089/AM03	Best Emollient for Eczema	1	10/11/2017	10
17/SW/0099/AM03	Could Pre-Rehabilitation Commence before Diagnosis?	4	06/09/2017	20
17/SW/0113/AM01	FaPIA V.1	1.2	14/11/2017	17
17/SW/0121/AM01	Hip and KnEe study of SPHERE (HEmiSPHERE) Version 1	1	21/11/2017	11

17/SW/0127/AM02	FLIGHT Study, V1.0	FLIGHT SA No. 1	20/07/2017	28
17/SW/0127/AM05	FLIGHT Study, V1.0	SA3	24/10/2017	6
17/SW/0162/AM01	BEACON LUNG	1	22/12/2017	19
17/SW/0174/AM01	A Phase 2 Clinical Trial in Patients with AML version amend 4	002	18/10/2017	11
17/SW/0174/AM04	A Phase 2 Clinical Trial in Patients with AML version amend 4	SA-004 - Protocol amendment, A	06/10/2017	23
17/SW/0201/AM01	MiBRVO	RVO-Sub1	29/01/2018	5
17/SW/0202/AM01	MiCRVO	RVO-Sub1	29/01/2018	16
17/SW/0217/AM01	Wearable Sensor Based Rehabilitation for Shoulder Pain	1.0	27/09/2017	8
17/SW/0221/AM01	(CAIN457K2340) Secukinumab compared with GP2017 in Active AS	Substantial Amendment (change	08/12/2017	20
17/SW/0221/AM03	(CAIN457K2340) Secukinumab compared with GP2017 in Active AS	Substantial Amendment (amendme	31/01/2018	14
17/SW/0221/AM04	(CAIN457K2340) Secukinumab compared with GP2017 in Active AS	Substantial Amendment (amendme	18/12/2017	60
17/SW/0223/AM01	Trial of physical Activity assisted Reduction of Smoking (TARS)	1	26/10/2017	9
17/SW/0223/AM02	Trial of physical Activity assisted Reduction of Smoking (TARS)	2	08/12/2017	10
17/SW/0223/AM05	Trial of physical Activity assisted Reduction of Smoking (TARS)	Amendment 3, 6th February 2018	06/02/2018	12
17/SW/0247/AM01	NP39403-RO6870810 as monotherapy and in combination in advanced MM	1 - SA: IB v5 and updated part	17/01/2018	17
17/SW/0248/AM01	BioClin - B-701-U21 - B-701 vs Placebo in Urothelial Cell Carcinoma	ICF update – Master V5.0 dated	12/02/2018	9
17/SW/0279/AM02	MO39171 - Atezolizumab in locally advanced or metastatic NSCLC	1 (substantial) - Protocol v3,	09/02/2018	8

Unfavourable opinion				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
11/SW/0230/AM04	Vascular endothelial cell growth factor (VEGF) in lung disease	amendment 3	13/01/2017	30
15/SW/0289/AM09	RHINO: Respiratory Health Outcomes in Neonates	7	13/02/2018	16

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

<b>Favourable opinion timeline</b>				
<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>
15/SW/0289/AM09/1	RHINO: Respiratory Health Outcomes in Neonates	1.0	13/03/2018	7

<b>Unfavourable opinion timeline</b>				
<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>

**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
17/SW/0188	Impact of visual difficulties on quality of life in monocular children	27

**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/SW/0084/AM04	PUMA-Paediatric early warning systems: Utility and Mortality Avoidance	3	07/12/2017	42
17/SW/0048/AM01	FLEX-HD	1	20/09/2017	41
17/SW/0221/AM04	(CAIN457K2340) Secukinumab compared with GP2017 in Active AS	Substantial Amendment (amendme	18/12/2017	60

**Modified Amendments over 14 day timeline**

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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