

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

**Annual Report**

**01 April 2015 - 31 March 2016**



## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	South Central - Oxford B Research Ethics Committee
<b>Type of REC:</b>	RECs recognised to review CTIMPS in patients - type iii
<b>Type of Flag:</b>	IRB Registered, Phase 1 Studies in Patients
<b>Chair:</b>	Mr Chris Foy
<b>Vice-Chair:</b>	Dr Kim Cheetham
<b>Alternate Vice-Chair:</b>	Dr Liesl Osman
<b>REC Manager:</b>	Mrs Siobhan Bawn (until 01/09/2015) Mr Mark Dawson (01/09/2015 – 01/02/2016) Mrs Claudia Bywater (01/02/2016 - present)
<b>REC Assistant:</b>	Lidia Gonzalez (until 01/09/2015) Mr Stephan Ramey (01/09/2016 - present)
<b>Committee Address:</b>	Whitefriars Level 3, Block B Lewin's Mead Bristol BS1 2NT
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## Chair's overview of the past year:

2015/16 was a year of steady achievement for the Oxford B Research Ethics Committee. For most of the year, membership was stable, and we had no quorum difficulties, or any need to co-opt, for any of our meetings.

In February 2016, we had to say goodbye to our excellent pharmacist, Paul Windscheif, who returned to live in Germany for family reasons. His wise and careful counsel will be much missed. Rose Wharton also decided her workload was making a regular commitment difficult, so she stepped down in March 2016, with an invitation to consider renewed REC work in the future.

The Joint Oxford Training Day in September 2015 was a success – Kim Cheetham and I were two of the four speakers.

During the year we had three REC managers in succession – Siobhan Bawn for a second spell, then Mark Dawson, who left us for a new role in Oxford's Joint Research Office, and now Claudia Bywater. I am grateful for the very professional support we have had from all of them, together with our REC Assistant, Stephan Ramey.

Chris Foy

## South Central - Oxford B Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Mr Peter Brown	Emeritus Professor of Classics, Trinity College	Lay Plus	01/09/2011	
Dr Kim Cheetham	Retired Consultant Paediatrician	Expert	01/09/2010	
Dr Richard Philip Craven	Senior lecturer in physiology	Lay Plus	28/05/2013	
Mr Chris Foy	Medical Statistician	Expert	14/05/2013	
Miss Nicola Joseph	Student, Reading Reproductive and Developmental Biology	Lay Plus	01/01/2015	
Dr Wilhelm Kuker	Consultant Neuroradiologist	Expert	01/12/2010	
Dr Pamela Laurie	Retired Consultant Anaesthetist	Expert	05/06/2006	
Mr Ian MacKenzie	Retired Consultant / Reader Emeritus in Obstetrics and Gynaecology	Expert	09/11/2010	
Dr Liesl Osman	Retired Research Advisor	Lay	10/10/2009	
Rev Emma Percy	College Chaplain, Trinity College	Lay Plus	01/09/2011	
Dr Iveta Simera	Head of Programme Development, EQUATOR Network, Centre for Statistics in Medicine	Lay	21/09/2011	
Mrs Kate Thompson	Retired In patient and day hospice manager	Lay	10/03/2009	
Ms Rose Wharton	Medical Statistician	Lay	27/09/2012	11/03/2016
Mr Paul Windscheif	Pharmacist	Expert	08/05/2008	29/02/2016

## South Central - Oxford B Research Ethics Committee: Deputy Members

Name	Profession	Status	Meeting date attended

## South Central - Oxford B Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended

**South Central - Oxford B Research Ethics Committee: Members' Declarations of Interest:**

<b>Name</b>	<b>Declaration of Interest</b>	<b>Date</b>
Mr Peter Brown	None	30/01/2016
Dr Kim Cheetham	Vice Chair of Adoption Panel of PACT (Parents and Children together)	30/01/2016
Dr Richard Philip Craven	None	12/05/2015
Mr Chris Foy	Employed by NIHR Research Design Service to provide advice to NHS staff and other researchers in South West England on how to make grant applications. For projects sponsored by an NHS body in Gloucestershire contributes to the peer review as part of a Committee.	01/03/2016
Miss Nicola Joseph	None	12/05/2015
Dr Wilhelm Kuker	None	31/03/2016
Dr Pamela Laurie	Volunteer at the Anaesthesia Heritage Museum, London.	06/03/2016
Mr Ian MacKenzie	Director, Elliott Smith Vasectomy Clinic	16/02/2016
Dr Liesl Osman	Small number of shares at GSK	10/02/2016
Rev Emma Percy	None	12/05/2015
Dr Iveta Simera	Deputy Director of the UK EQUATOR Centre and Programme Manager of the EQUATOR Network.	12/02/2016
Mrs Kate Thompson	Miscellaneous shares via bank, which might include Pharmaceutical Companies. £1500 worth of GSK shares.	31/03/2016
Mr Paul Windscheif	Minor number of shares in Procter & Gamble due to past employment. Member of more than 20 scientific (mainly chemistry) pharmaceutical and medical organisations, societies and associations (national UK & Germany & US, and international (incl. European), - but no direct interests with any companies who may sponsor conferences, a congress, training, annual meetings of these organisations.	05/05/2015

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

Month	Date	Number of Members Present at Meeting
May	12/05/2015	10
June	09/06/2015	12
July	14/07/2015	9
September	08/09/2015	11
October	13/10/2015	10
November	10/11/2015	12
December	08/12/2015	9
January	12/01/2016	13
March	08/03/2016	10

9 full committee meetings were held during the reporting period.

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

Month	Date	Number of Members Present at Meeting
April	28/04/2015	3
May	26/05/2015	3
July	28/07/2015	3
September	22/09/2015	3
October	27/10/2015	5
December	23/12/2015	3
January	29/01/2016	3
February	26/02/2016	3
March	24/03/2016	3

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

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

Month	Date	Number of Members Present at Meeting
April	03/04/2015	2
April	03/04/2015	2
April	17/04/2015	2
May	01/05/2015	2
May	15/05/2015	2
May	29/05/2015	2
June	12/06/2015	2
June	26/06/2015	2
July	10/07/2015	2
July	24/07/2015	2
August	07/08/2015	2
August	17/08/2015	2
August	21/08/2015	2

September	02/09/2015	2
September	04/09/2015	2
September	09/09/2015	2
September	11/09/2015	2
September	23/09/2015	2
September	25/09/2015	2
September	25/09/2015	2
September	30/09/2015	3
October	02/10/2015	2
October	16/10/2015	2
October	22/10/2015	3
October	23/10/2015	2
October	30/10/2015	2
November	05/11/2015	2
November	13/11/2015	3
November	20/11/2015	2
November	23/11/2015	2
November	24/11/2015	2
November	25/11/2015	2
November	27/11/2015	2
November	30/11/2015	3
December	11/12/2015	2
December	23/12/2015	2
December	24/12/2015	3
January	07/01/2016	2
January	08/01/2016	2
January	15/01/2016	3
January	16/01/2016	3
January	22/01/2016	2
February	01/02/2016	2
February	05/02/2016	2
February	09/02/2016	3
February	10/02/2016	4
February	19/02/2016	3
February	19/02/2016	2
March	04/03/2016	2
March	15/03/2016	2
March	18/03/2016	2
March	22/03/2016	2
March	23/03/2016	2

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

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Mr Peter Brown	6
Dr Kim Cheetham	7
Dr Richard Philip Craven	8
Mr Chris Foy	9
Miss Nicola Joseph	6
Dr Wilhelm Kuker	5
Dr Pamela Laurie	9
Mr Ian MacKenzie	7
Dr Liesl Osman	8
Rev Emma Percy	6
Dr Iveta Simera	6
Mrs Kate Thompson	6
Ms Rose Wharton	5
Mr Paul Windscheif	8

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Mr Peter Brown	4
Dr Kim Cheetham	5
Dr Richard Philip Craven	2
Mr Chris Foy	3
Dr Wilhelm Kuker	1
Dr Pamela Laurie	2
Mr Ian MacKenzie	3
Dr Liesl Osman	2
Rev Emma Percy	2
Dr Iveta Simera	3
Mrs Kate Thompson	1
Mr Paul Windscheif	1

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Mr Peter Brown	2
Dr Kim Cheetham	13
Dr Richard Philip Craven	5
Mr Chris Foy	32



Miss Nicola Joseph	2
Dr Wilhelm Kuker	4
Dr Pamela Laurie	7
Mr Ian MacKenzie	4
Dr Liesl Osman	18
Rev Emma Percy	7
Dr Iveta Simera	2
Mrs Kate Thompson	4
Ms Rose Wharton	1
Mr Paul Windcheif	2
Mr Paul Windscheif	12

**Training 01 April 2015 - 31 March 2016**

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Mr Peter Brown	04/09/2015	Joint Oxford Training Day
Dr Kim Cheetham	17/04/2015	Equality and Diversity E module
Dr Kim Cheetham	04/09/2015	Joint Oxford Training Day
Dr Kim Cheetham	29/09/2015	Genetics and Genomics training day 29/09/2015 in Bristol
Dr Kim Cheetham	14/10/2015	Bioethics' Guidance on Research Involving Children
Dr Richard Philip Craven	04/09/2015	Joint Oxford Training Day
Dr Richard Philip Craven	07/10/2015	Introduction to Phase 1 Research - Trials & Regulation
Mr Chris Foy	05/05/2015	E and D (online)
Mr Chris Foy	04/09/2015	Joint Oxford Training Day
Mr Chris Foy	03/12/2015	Training - HRA Workshop: Pragmatic or Point of Care trials
Mr Chris Foy	09/12/2015	Training - National Training Day for Committee Chairs
Mr Chris Foy	17/12/2015	RSS/HRA co-sponsored workshop for statistician members of Research Ethics Committees
Miss Nicola Joseph	10/03/2016	Committee Members Induction
Dr Pamela Laurie	18/02/2016	National Members Training Day
Mr Ian MacKenzie	03/12/2015	HRA Workshop: Pragmatic or Point of Care trials
Dr Liesl Osman	08/04/2015	Ethics & GCP Forum ICR
Dr Liesl Osman	09/12/2015	National Training Day for Committee Chairs
Rev Emma Percy	04/09/2015	Joint Oxford Training Day
Dr Iveta Simera	04/09/2015	Joint Oxford Training Day
Mrs Kate Thompson	04/09/2015	Joint Oxford Training Day
Mrs Kate Thompson	27/11/2015	CTIMP 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:**

<b>Applications for full ethical review – Study Type</b>	<b>Number</b>	<b>%</b>
Clinical Trial of Investigational Medicinal Product	19	38.00
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	0	0.00
Others	31	62.00
<b>Total Applications Reviewed</b>	<b>50</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	14
Number of paediatric applications reviewed	3
Number of device applications reviewed	2
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	0
Number of applications reviewed that are funded by the US DHHS	1
Number of qualitative applications reviewed	4

**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	2	4.00
Favourable Opinion with Additional Conditions	7	14.00
Unfavourable Opinion	1	2.00
Provisional Opinion	40	80.00
Provisional Opinion Pending Consultation with Referee	0	0.00
<b>Total</b>	<b>50</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	31	62.00
Further Information Favourable Opinion with Additional Conditions	8	16.00
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	2	4.00
Favourable Opinion with Additional Conditions	7	14.00
Unfavourable Opinion	1	2.00
Provisional Opinion	1	2.00
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
<b>Total</b>	<b>50</b>	<b>100</b>

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

<b>Total Applications Reviewed</b>	<b>14</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	7
Number of studies withdrawn prior to the meeting	0
Number of student applications reviewed	3
Number of paediatric applications reviewed	1
Number of device applications reviewed	0
Number of qualitative applications reviewed	4

**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	6	42.86
Favourable Opinion with Additional Conditions	2	14.29
No Opinion transfer to full committee for review	1	7.14
Provisional Opinion	4	28.57
Unfavourable Opinion	1	7.14
<b>Total</b>	<b>14</b>	<b>100</b>

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

<b>Average number of applications reviewed per full meeting</b>	5.56
<b>Number of completed applications for full ethical review</b>	50
<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>	1
<b>Number of completed applications over 40 days as a % of total</b>	2.00%
<b>Number of days taken to final decision – average (mean)</b>	27
<b>Number of completed proportionate review applications for ethical review</b>	13
<b>Number of completed proportionate review applications for ethical review over 14 days</b>	1
<b>Number of completed proportionate review applications over 14 days as a % of total</b>	7.69%
<b>Number of SSAs (non-Phase 1) reviewed</b>	18
<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>	139
<b>Number of completed substantial amendments over 35 days</b>	0
<b>Number of completed substantial amendments over 35 days as a % of total substantial amendments</b>	0.00%
<b>Number of completed substantial amendments over 28 days</b>	6
<b>Number of completed substantial amendments over 28 days as a % of total substantial amendments</b>	4.32%
<b>Number of modified amendments reviewed</b>	6
<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 minor amendments received</b>	87
<b>Number of substantial amendments received for information</b>	3
<b>Number of substantial amendments received for new sites/Pis</b>	62
<b>Number of annual progress reports received</b>	90

<b>Number of safety reports received</b>	43
<b>Number of Serious Adverse Events received</b>	1
<b>Number of final reports received</b>	17

**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>
15/SC/0269	Retrospective Perspectives of a Child Bereavement Intervention.	40
15/SC/0313	Cross-Over and Long Term Follow Up Study Following the PLACE Trial	26
15/SC/0324	Oxford UKR: Second decade outcome study	33
15/SC/0348	NeoMero: 2 year follow up of neonatal meningitis and late onset sepsis	21
15/SC/0372	Investigating Pain Mechanisms in Endometriosis - Version 1	20
15/SC/0381	FPA008-002_ Study of FPA008 in joint disease (PVNS/dt-TGCT)	30
15/SC/0406	Evaluation of avelumab* combined with axitinib in advanced RCC	20
15/SC/0413	UCPCR Study V1.0	20
15/SC/0414	PLUMMB: Pembrolizumab in Muscle Invasive/Metastatic Bladder Cancer	22
15/SC/0468	Validation of a stress device for the knee	31
15/SC/0476	Optimum radiographic assessment of the knee	31
15/SC/0508	Psychological support for fears about other people	24
15/SC/0509	ICARIS Trial	26
15/SC/0580	Phase 2/3 study of GS-5745 in patients with Ulcerative Colitis	26
15/SC/0583	Phase 2 study of GS-5745 in Subjects with Crohn`s Disease	26
15/SC/0587	Sensory and neural correlates of pain in irritable bowel syndrome	29
15/SC/0602	A study of GSK3050002 in subjects with psoriatic arthritis (PsA).	36
15/SC/0636	Imaging the contributions of the hippocampus to memory	28
15/SC/0647	Exploration of the optimal exercises for early hip osteoarthritis.	26
15/SC/0660	A Phase 2a study of oral ZPL-3893787 in adults with plaque psoriasis	28
15/SC/0666	MOXIe	23
15/SC/0699	M13-549 Phase 3 JAK study csDMARD subjects with Moderate to Severe RA	31
15/SC/0700	M13-545 Phase 3 JAKstudy MTX Naive subjects with Moderate to Severe RA	31
15/SC/0701	M14-465 Phase 3 study in joint structure in Mod/Severe RA with MTX-IR	31
15/SC/0708	Assessing anxiety following stroke	33
16/SC/0006	IMCgp100-201 Phase 1b/2 IMCgp100 in combination or alone	26
16/SC/0010	A Phase II Study of PNT2258 in Patients with Richter's Transformation	49
16/SC/0016	TEPHRA Version 1	15
16/SC/0137	CA209-511 Nivolumab with Ipilimumab in Subjects with Melanoma	25
16/SC/0139	Phase 1B/2 study of avelumab in patients with advanced malignancies	33
16/SC/0146	Imaging heart repair following a heart attack	31



<b>Further Information Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
15/SC/0260	How do patients use multiple ways to access mental health care?	36
15/SC/0338	Quantifying the effects of brain injury fatigue - version 1	25
15/SC/0483	Characterisation of and intervention in visual cortical damage	32
15/SC/0510	Brown Adipose Tissue Activation Study	23
15/SC/0697	Scaffold Evaluation for Rotator Cuff Repair (SECuRe)	33
15/SC/0731	ALERT	26
15/SC/0769	COMBO	26
16/SC/0007	Phase I Study of Oral PQR309 in Patients with Advanced Solid Tumors	37

<b>Further Information Unfavourable Opinion</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>

<b>Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
15/SC/0287	Provision Of Psychological support to People in Intensive care (v1.0)	17
15/SC/0772	A study of patient support after radiotherapy for prostate cancer.	27

<b>Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
15/SC/0259	Repurposing anti-TNF for treating Dupuytren's disease	16
15/SC/0268	The in vivo migration and micromotion of the TriFit TS femoral stem	28
15/SC/0337	Doctor Referral of Overweight People to Low Energy Treatment - DROPLET	21
15/SC/0401	How Can Compassionate Resilience Help People with Complex PTSD?	17
15/SC/0551	Meniscal Tear and Osteoarthritis Risk (MenTOR)	22
15/SC/0658	Fat and Protein Study	19
16/SC/0109	UK STAR	24

<b>Unfavourable Opinion</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
15/SC/0230	Prebiotic intervention for ASD, version 3	17

<b>Provisional Opinion</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
16/SC/0130	Feasibility study of Group CBT for Dissociative/Non-epileptic Seizures	n/a

<b>Provisional Opinion Pending Consultation with Referee</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>

<b>Further information response not complete</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>

<b>Withdrawn after the meeting</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>

**Table 9.2: Breakdown of current status of all PRS 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>
15/SC/0340	Mobile Technology Use in the Clinical Environment: Patient Viewpoints	9
15/SC/0491	ctDNA v6.0	7
15/SC/0598	HEALS Cohort Study	7
16/SC/0133	Impact of Tai Chi on quality of life in palliative care.	15

<b>Further Information Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>

<b>Further Information Unfavourable Opinion</b>		
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REC Reference	Title	Number of Days on Clock
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#### Favourable Opinion with Standard Conditions

REC Reference	Title	Number of Days on Clock
15/SC/0273	(5-HT) receptor expression in malignant and non-malignant tissue	10
15/SC/0274	Positive deviance in healthcare study	14
15/SC/0493	Ethnic variations in infant mortality	5
15/SC/0494	Record linkage for analysis of housing energy efficiency and health	6
15/SC/0668	Pregnancy and Childbirth Questionnaire Study	8
16/SC/0073	HEALTH OF CIVIL SERVANTS 2	11

#### Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/SC/0673	Dementia Carers Instrument Development: DECIDE	13
15/SC/0783	Validation of the activPAL activity monitor in MS	13

#### Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
15/SC/0283	RIVER Registry – RIVaroxaban Evaluation in Real life setting	10

#### 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/Q1605/95/AM07	STUDIES OF THE VASCULAR PROPERTIES OF ARTERIAL BYPASS GRAFTS	05	18/12/2015	7
06/Q1605/55/AM06	Genetic diversity and gene expression in white blood cells (version I)	Substantial Amendment 4	19/05/2015	26
07/H0605/76/AM40	ICON6 GCIG Trial (International Collaborative Ovarian Neoplasm 6)	40	09/11/2015	7
08/H0605/6/AM19	EXCITE	Substantial Amendment Number 1	21/08/2015	12
09/H0605/114/AM23	BUMPES Trial	12	27/04/2015	12
09/H0605/62/AM15	Midbrain micturition pathways	AM15 Substantial Amendment Num	25/04/2015	10
10/H0605/31/AM13	CREW (ColoREctal Wellbeing) cohort	12	29/04/2015	12
10/H0605/58/AM08	PET SubStudy to WN25203; Amyloid Load in Prodromal Alzheimers Disease	7	25/11/2015	23
10/H0605/59/AM30	WN25203 - Proof of Efficacy of RO4909832 in prodromal alzheimer's	Substantial Amendment 18	01/10/2015	16
10/H0605/59/AM31	WN25203 - Proof of Efficacy of RO4909832 in prodromal alzheimer's	19	19/11/2015	18
10/H0605/83/AM24	REVEAL Version 1.0	Amendment AM23: REVEAL Amendme	05/05/2015	4
10/H0605/83/AM26	REVEAL Version 1.0	REVEAL Amendment 24	01/07/2015	10
10/H0605/83/AM28	REVEAL Version 1.0	27	18/12/2015	15
10/H0605/83/AM30	REVEAL Version 1.0	28	12/02/2016	28
11/H0605/12/AM10	Motor consolidation during sleep	7	07/12/2015	15
11/SC/0528/AM17	INTERLACE	013	21/09/2015	15
12/SC/0118/AM07	Antidepressants, emotions and personality	AM07 Substantial Amendment: 6	28/05/2015	12
12/SC/0118/AM08	Antidepressants, emotions and personality	7	04/12/2015	16

12/SC/0383/AM07	Phase I of AZD0424 alone and in combination in advanced solid tumours	12 SC 0383 Sub Amen - CTA 11 2	24/03/2015	13
12/SC/0383/AM09	Phase I of AZD0424 alone and in combination in advanced solid tumours	12	09/06/2015	6
12/SC/0383/AM10	Phase I of AZD0424 alone and in combination in advanced solid tumours	14	17/12/2015	18
13/SC/0020/AM11	OxRen	Amendment 9 21/08/15	21/08/2015	17
13/SC/0114/AM22	BARACK D	Substantial Amendment- SA12 27	27/03/2015	8
13/SC/0114/AM24	BARACK D	Substantial Amendment 13 [SA13	27/01/2015	14
13/SC/0114/AM27	BARACK D	27	28/10/2015	13
13/SC/0114/AM28	BARACK D	16	03/12/2015	15
13/SC/0152/AM01	Use of an in vitro model to study novel influenza vaccines	2.0	27/07/2015	13
13/SC/0204/AM06	The Pleural Infection Longitudinal Outcome Study (PILOT)	AM06- Substantial Amendment 04	08/07/2015	6
13/SC/0328/AM03	Depression and proton MRS at 7T	3	22/07/2015	12
13/SC/0420/AM01	Development of a 3D lung model to investigate fibrotic lung disease	1	08/03/2016	10
13/SC/0437/AM01	Connectivity in memory disorders	1	01/09/2015	11
13/SC/0502/AM01	Neural Mechanisms underlying tactile perceptual learning	AM01 Substantial Amendment 1.0	15/04/2015	18
13/SC/0503/AM08	B2151002: Phase 1b of PF-05212384 in combination.	UK EIU Pregnant Partner Releas	06/08/2015	15
13/SC/0503/AM09	B2151002: Phase 1b of PF-05212384 in combination.	B2151002 Substantial Amendment	18/08/2015	14
13/SC/0503/AM10	B2151002: Phase 1b of PF-05212384 in combination.	8	29/10/2015	26
13/SC/0517/AM03	FORM -2C v0.1	1	09/02/2016	28
13/SC/0523/AM04	The impact of AZD4017 on bone turnover in post-menopausal osteopaenia	7.0	17/04/2015	25
13/SC/0581/AM02	VIOLA (Version 1.0 15-Oct-2013)	Viola Substantial Amendment 2	23/10/2014	13

13/SC/0581/AM03	VIOLA (Version 1.0 15-Oct-2013)	3.0	12/11/2015	15
13/SC/0629/AM01	EORTC 90091-10093	01	22/12/2015	14
13/SC/0638/AM18	HIPvac Trial	19	21/10/2015	8
13/SC/0638/AM21	HIPvac Trial	21	29/01/2016	33
14/SC/0030/AM02	Circadian Rhythms and Personality Disorders	3	10/02/2016	28
14/SC/0032/AM11	Pfizer B1481022 - Phase 3 PF-04950615 in Reducing Major CV Events	B1481022 <sup>1</sup> Halt to Screening/Re	23/02/2015	18
14/SC/0032/AM14	Pfizer B1481022 - Phase 3 PF-04950615 in Reducing Major CV Events	B1481022 <sup>1</sup> Screening/Recruitment	30/03/2015	12
14/SC/0032/AM16	Pfizer B1481022 - Phase 3 PF-04950615 in Reducing Major CV Events	Substantial Amendment 16	24/07/2015	20
14/SC/0032/AM19	Pfizer B1481022 - Phase 3 PF-04950615 in Reducing Major CV Events	AM19 - Substantial Amendment:	02/07/2015	20
14/SC/0032/AM25	Pfizer B1481022 - Phase 3 PF-04950615 in Reducing Major CV Events	AM25 Substantial Amendment: NH	07/08/2015	14
14/SC/0032/AM29	Pfizer B1481022 - Phase 3 PF-04950615 in Reducing Major CV Events	AM29	29/09/2015	24
14/SC/0032/AM31	Pfizer B1481022 - Phase 3 PF-04950615 in Reducing Major CV Events	30	03/11/2015	28
14/SC/0032/AM35	Pfizer B1481022 - Phase 3 PF-04950615 in Reducing Major CV Events	Substantial Amendment AM35	08/12/2015	17
14/SC/0032/AM36	Pfizer B1481022 - Phase 3 PF-04950615 in Reducing Major CV Events	34	21/01/2016	25
14/SC/0033/AM10	Pfizer B1481038 - Phase 3 PF-04950615 in Reducing Major CV Events	B1481038 <sup>1</sup> Halt to Screening/Re	23/02/2015	18
14/SC/0033/AM15	Pfizer B1481038 - Phase 3 PF-04950615 in Reducing Major CV Events	B1481038 <sup>1</sup> Screening/Recruitment	30/03/2015	12
14/SC/0033/AM18	Pfizer B1481038 - Phase 3 PF-04950615 in Reducing Major CV Events	Substantial Amendment 18	27/04/2015	21
14/SC/0033/AM20	Pfizer B1481038 - Phase 3 PF-04950615 in Reducing Major CV Events	Patient recruitment, retention	02/07/2015	22
14/SC/0033/AM26	Pfizer B1481038 - Phase 3 PF-04950615 in Reducing Major CV Events	AM26 Substantial Amendment: NH	07/08/2015	14

14/SC/0033/AM29	Pfizer B1481038 - Phase 3 PF-04950615 in Reducing Major CV Events	AM29	29/09/2015	24
14/SC/0033/AM31	Pfizer B1481038 - Phase 3 PF-04950615 in Reducing Major CV Events	5	03/11/2015	28
14/SC/0033/AM34	Pfizer B1481038 - Phase 3 PF-04950615 in Reducing Major CV Events	31	08/12/2015	17
14/SC/0033/AM37	Pfizer B1481038 - Phase 3 PF-04950615 in Reducing Major CV Events	32	16/02/2016	3
14/SC/0075/AM07	Pfizer B3461028 Study for patients with TTR-CM	B3461028 Substantial Amendment	01/10/2015	8
14/SC/0147/AM02	Red cell membrane cholesterol: a marker of unstable carotid plaque?	1	13/11/2015	16
14/SC/0218/AM02	Telemonitoring and/or self monitoring in Hypertension (TASMINH4)	AM02 Substantial Amendment: 2	05/06/2015	23
14/SC/0237/AM03	Urodynamic assessment methods before Prostate Surgery	2, 07 May 2015	07/05/2015	29
14/SC/0247/AM01	The STAT-ROC Feasibility Study (v1.0)	Substantial Amendment: AM01 15	15/05/2015	20
14/SC/1008/AM04	Safety and tolerability study of MP0250	2	12/01/2016	13
14/SC/1014/AM10	The JANUS 1 Study Incyte INCB 18424-362	6 08/06/2015	08/06/2015	13
14/SC/1018/AM02	"Walk30X5" Physiotherapy Walking Programme	Substantial Amendment 2	14/05/2015	4
14/SC/1018/AM03	"Walk30X5" Physiotherapy Walking Programme	3	21/09/2015	5
14/SC/1092/AM02	REACT2	AM02: Substantial Amendment 2	10/06/2015	13
14/SC/1092/AM04	REACT2	Protocol Amendment Version 4	22/05/2015	17
14/SC/1097/AM02	BRRIDE 2 Breast Risk Reduction Intermittent Diet Evaluation	14 SC 1097 Subl Amen 2.0 23.03	23/03/2015	21
14/SC/1097/AM03	BRRIDE 2 Breast Risk Reduction Intermittent Diet Evaluation	BRRIDE2_Protocol_V4.0_24 06 1	24/06/2015	13
14/SC/1243/AM01	Gait Analysis of Lower Limb Surgical Patients	1	10/07/2015	11
14/SC/1254/AM01	Studying Mitochondrial DNA quality control in human oocytes	Amendment 1.0	23/03/2015	9

		dated 6/March/20		
14/SC/1284/AM05	SIRRT (Selinexor in Relapsed/Refractory Richters Transformation)	IB v4.0, addition of new site	03/04/2015	25
14/SC/1284/AM07	SIRRT (Selinexor in Relapsed/Refractory Richters Transformation)	AM7 Substantial Amendment ICF	30/04/2015	13
14/SC/1284/AM08	SIRRT (Selinexor in Relapsed/Refractory Richters Transformation)	4, 2015/06/22	22/06/2015	14
14/SC/1284/AM10	SIRRT (Selinexor in Relapsed/Refractory Richters Transformation)	10	26/10/2015	11
14/SC/1312/AM01	IMox study	1.0	18/03/2015	29
14/SC/1312/AM02	IMox study	2	01/04/2015	31
14/SC/1312/AM04	IMox study	3: 28/07/2015	28/07/2015	15
14/SC/1312/AM06	IMox study	AM06	19/10/2015	14
14/SC/1315/AM04	MPD-RC 114	AM04 Substantial Amendment 2	01/04/2015	15
14/SC/1321/AM08	ASSESS Measuring economic burden of heart failure patients in UK	Protocol v02 20 March 2015	20/03/2015	4
14/SC/1356/AM01	Disrupted sleep in a UK heart failure population	Substantial Amendment 1	20/04/2015	7
14/SC/1369/AM01	ASCOT: Lifestyle study for cancer survivors	Substantial Amendment: AM1 25.	25/03/2015	24
14/SC/1369/AM02	ASCOT: Lifestyle study for cancer survivors	Substantial Amendment 2	13/05/2015	6
14/SC/1369/AM05	ASCOT: Lifestyle study for cancer survivors	03	17/12/2015	12
14/SC/1371/AM01	Designing a community based service model for the East of England	1	21/12/2015	14
14/SC/1374/AM02	AZD9496 First Time in Patients Ascending Dose Study	2	17/09/2015	20
14/SC/1406/AM02	Validation of HOMAtx	1	31/08/2015	12
14/SC/1424/AM01	Efficacy of an online mindfulness intervention for spinal cord injured patients	1	14/01/2016	6
14/SC/1430/AM01	Neuroimaging study of borderline personality disorder	1 09/04/2015	14/04/2015	3
14/SC/1430/AM02	Neuroimaging study of borderline personality disorder	2	09/03/2016	17
15/SC/0004/AM02	The Effect of Obesity and Weight Loss in Heart Failure	1.0, 10/6/2015	10/06/2015	18
15/SC/0019/AM01	CORKA Community Based Rehabilitation after Knee Arthroplasty	1, August 2015	20/08/2015	8



15/SC/0019/AM02	CORKA Community Based Rehabilitation after Knee Arthroplasty	2	30/11/2015	20
15/SC/0022/AM02	TB038 Heterologous effects of BCG	SA02 29.04.2015	29/04/2015	13
15/SC/0022/AM03	TB038 Heterologous effects of BCG	SA03 21.08.2015	21/08/2015	19
15/SC/0028/AM01	Study to assess the effect of AZD3241 in Multiple System Atrophy	D0490C00023, V2.0	29/01/2015	33
15/SC/0028/AM02	Study to assess the effect of AZD3241 in Multiple System Atrophy	D0490C00023, Version 3	28/05/2015	7
15/SC/0059/AM01	SPARC:SBRT pre-operatively for borderline resectable pancreatic cancer	4	27/01/2016	6
15/SC/0075/AM03	The LOGIC 2 study in BRAF melanoma	1	29/10/2015	25
15/SC/0138/AM01	Antivirals for influenza like illness? Clinical and Cost-effectiveness	1	01/10/2015	14
15/SC/0144/AM01	High-resolution imaging of inherited retinal degenerations	1	17/12/2015	20
15/SC/0179/AM03	Is monomeric C-reactive Protein located within human serum?	Amendment 3.0	25/01/2016	19
15/SC/0259/AM01	Repurposing anti-TNF for treating Dupuytren's disease	1, Protocol Version 3.4	15/07/2015	10
15/SC/0259/AM02	Repurposing anti-TNF for treating Dupuytren's disease	AM02 Substantial Amendment 2: 1	13/08/2015	20
15/SC/0259/AM03	Repurposing anti-TNF for treating Dupuytren's disease	3	16/12/2015	22
15/SC/0259/AM05	Repurposing anti-TNF for treating Dupuytren's disease	4	09/02/2016	19
15/SC/0268/AM01	The in vivo migration and micromotion of the TriFit TS femoral stem	Amendment 1 06/10/2105	12/10/2015	28
15/SC/0287/AM01	Provision Of Psychological support to People in Intensive care (v1.0)	1	10/02/2016	25
15/SC/0313/AM01	Cross-Over and Long Term Follow Up Study Following the PLACE Trial	1	13/01/2016	12
15/SC/0337/AM01	Doctor Referral of Overweight People to Low Energy Treatment - DROPLET	1.0 24/08/2015	24/08/2015	27
15/SC/0337/AM04	Doctor Referral of Overweight People to Low Energy Treatment - DROPLET	SA2	19/02/2016	20
15/SC/0406/AM02	Evaluation of avelumab* combined with axitinib in advanced RCC	1	02/09/2015	13
15/SC/0406/AM03	Evaluation of avelumab* combined with axitinib in advanced RCC	2	10/09/2015	20
15/SC/0406/AM05	Evaluation of avelumab* combined with axitinib in advanced	Protocol	10/11/2015	21

	RCC	Amendment 2		
15/SC/0414/AM01	PLUMMB: Pembrolizumab in Muscle Invasive/Metastatic Bladder Cancer	1	07/09/2015	18
15/SC/0414/AM02	PLUMMB: Pembrolizumab in Muscle Invasive/Metastatic Bladder Cancer	02	13/01/2016	11
15/SC/0508/AM01	Psychological support for fears about other people	1	18/12/2015	21
15/SC/0509/AM02	ICARIS Trial	1	07/03/2016	11
15/SC/0510/AM01	Brown Adipose Tissue Activation Study	1	10/03/2016	20
15/SC/0580/AM01	Phase 2/3 study of GS-5745 in patients with Ulcerative Colitis	1.2	14/12/2015	21
15/SC/0583/AM01	Phase 2 study of GS-5745 in Subjects with Crohn`s Disease	01	08/01/2016	11
15/SC/0587/AM01	Sensory and neural correlates of pain in irritable bowel syndrome	1	17/12/2015	19
15/SC/0598/AM01	HEALS Cohort Study	1	08/12/2015	21
15/SC/0602/AM05	A study of GSK3050002 in subjects with psoriatic arthritis (PsA).	3	03/03/2016	15

<b>Unfavourable opinion</b>				
<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>
11/H0605/12/AM09	Motor consolidation during sleep	AM09: Substantial Amendment Nu	14/05/2015	7
13/SC/0016/AM10	Oral vs Intravenous Antibiotics (OVIVA) for Bone and Joint Infection	AM10 Substantial Amendment 7,	07/05/2015	13
13/SC/0467/AM05	Phase I,dose escalation of LTX-315 in transdermally accessible tumours	SA UK07	02/09/2015	7
14/SC/0032/AM12	Pfizer B1481022 - Phase 3 PF-04950615 in Reducing Major CV Events	Substantial Amendment: AM012 P	02/04/2015	20
14/SC/0033/AM12	Pfizer B1481038 - Phase 3 PF-04950615 in Reducing Major CV Events	Substantial Amendment: AM12	02/04/2015	25
14/SC/1099/AM02	Rectal mucus sampling to assess for biomarkers of GI disease.	2	14/03/2016	14
15/SC/0009/AM03	Phase I study of PQR309 in Patients with Relapsed/Refractory Lymphoma	3	14/10/2015	15
15/SC/0028/AM03	Study to assess the effect of AZD3241 in Multiple System Atrophy	3	27/11/2015	25

15/SC/0138/AM02	Antivirals for influenza like illness? Clinical and Cost-effectiveness	1	12/02/2016	34
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**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>
11/H0605/12/AM09/1	Motor consolidation during sleep	Modified Substantial Amendment	14/05/2015	5
13/SC/0016/AM10/1	Oral vs Intravenous Antibiotics (OVIVA) for Bone and Joint Infection	Modified Amendment 8	19/06/2015	5
13/SC/0467/AM05/1	Phase I, dose escalation of LTX-315 in transdermally accessible tumours	SA UK08	18/09/2015	13
15/SC/0009/AM03/1	Phase I study of PQR309 in Patients with Relapsed/Refractory Lymphoma	3	16/11/2015	10
15/SC/0028/AM03/1	Study to assess the effect of AZD3241 in Multiple System Atrophy	03	07/01/2016	4
15/SC/0138/AM02/1	Antivirals for influenza like illness? Clinical and Cost-effectiveness	2	21/03/2016	3

<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 14 day timeline**

REC Reference	Title	Number of Days on Clock
16/SC/0133	Impact of Tai Chi on quality of life in palliative care.	15

**SSAs (non Phase 1) over 25 day timeline**

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

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

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

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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