

**East of England - Cambridge East Research  
Ethics Committee**

**Annual Report**

**01 April 2015 - 31 March 2016**



## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	East of England - Cambridge East Research Ethics Committee
<b>Type of REC:</b>	RECs recognised to review CTIMPS in healthy volunteers - type i, RECs recognised to review CTIMPS in patients - type iii
<b>Type of Flag:</b>	Establishing Research Databases, Establishing Research Tissue Banks, Medical Device Study, Phase 1 Studies in Healthy Volunteers, Phase 1 Studies in Patients
<b>Chair:</b>	Dr Niki Bannister
<b>Vice-Chair:</b>	Mr Iain Martin
<b>Alternate Vice-Chair:</b>	Dr Rebecca Harmston
<b>REC Manager:</b>	Mrs Carolyn Halliwell
<b>REC Assistant:</b>	Miss Joanne Unsworth
<b>Committee Address:</b>	The Old Chapel Royal Standard Place Nottingham NG1 6FS
<b>Telephone:</b>	0207 104 8098
<b>Email:</b>	NRESCommittee.EastofEngland-CambridgeEast@nhs.net

## Chair's overview of the past year:

2015-16 was another busy year for the Cambridge East Research Ethics Committee, in which I was ably supported by our Vice-Chair Iain Martin and REC Manager Carolyn Halliwell.

Anna Raphael, Simon Russell and Melanie Whittick, three long standing members, moved on due to pressure of work and other commitments. We all thank them for their valued contributions. In their place we welcomed Derek Prater and Ann Colvill.

Rebecca Harmston stepped up to the Alternate Vice-Chair role and took on the Proportionate Review Committee, which we started in January 2016.

Overall, we have had excellent attendance at our full meetings, and our 26 subcommittees have been particularly busy. We look forward to a period of continued stability next year.

## East of England - Cambridge East Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Mrs Carole Alderton	Hospital Volunteer	Lay	01/04/2011	03/06/2015
Dr Niki Bannister	Retired Hospital Doctor	Expert	20/01/2014	
Dr Helen Burns	Retired GP	Expert	05/12/2014	
Dr Alan Calverd	Scientific Consultant	Expert	16/02/2015	
Mrs Ann Colvill	Lay Member, Employment Tribunal Service	Lay	19/01/2016	
Dr Jacqueline Cornelissen	Senior Project Manager - Medical Affairs Research Operations	Lay	01/12/2011	
Dr Rebecca Harmston	Scientific Officer	Lay Plus	01/04/2014	
Mr Iain Martin	Retired RAF Officer	Lay Plus	01/10/2012	
Dr Derek Prater	Pharmacist	Expert	05/05/2015	
Dr Wendi Qian	Statistician	Expert	08/05/2014	
Miss Anna Raphael	Bioethicist	Lay Plus	19/07/2011	18/05/2015
Dr Simon Russell	Consultant Oncologist	Expert	01/04/2011	02/07/2015
Dr Jessica Santos	Global Compliance & Quality Director	Lay Plus	02/04/2014	
Mrs Patricia Westcott	Retired Oncology Specialist Nurse & Co-ordinator for a Cancer Charity	Lay	22/10/2013	
Dr Melanie Whittick	Consultant Pharmacist	Expert	01/04/2011	10/03/16
Dr Joyce Whittington	Psychologist	Expert	02/12/2014	
Miss Suzahn Vermaak	Physiotherapist	Expert	10/02/2016	

## East of England - Cambridge East Research Ethics Committee: Deputy Members

Name	Profession	Status	Meeting date attended
None			

## East of England - Cambridge East Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended
Reverend Keith Lackenby	Reverend	Lay Plus	16/06/2015

**East of England - Cambridge East Research Ethics Committee: Members' Declarations of Interest:**

<b>Name</b>	<b>Declaration of Interest</b>	<b>Date</b>
Dr Niki Bannister	Trustee of national governors association which occasionally undertakes educational related research.	18/12/2015
Dr Helen Burns	Shares in Glaxo Smithkline and Astra Zeneca	18/12/2015
Dr Alan Calverd	Director - United Open MRI Ltd. Director - Radiation Consultancy Services Ltd, Director - Medical Physics Cooperative Ltd, Director - Exhalation Technologies Ltd.Sole Trader - Quality Associates	18/12/2015
Mrs Ann Colvill	Inherited shares in GlaxoSmithKline.	18/02/2016
Dr Jacqueline Cornelissen	None declared	18/12/2015
Dr Rebecca Harmston	Public member of the public and patient involvement group bat City University London, Quality Standards Advisory Committee for GORD in children NICE, Lay member on the Maternal, Neonatal and Child Health Panel with the Health Technology Assessment (HTA), Member of the FARR Institute Public and Patient working group at the FARR Institute in London, Diagnostics Advisory Committee - Therapeutic monitoring of anti-TNF, Drug levels and antibodies in inflammatory bowel disease: the LISA tracker assay at NICE, Steering group for the Early Osteoarthritis research project at the James Lind Alliance in Oxford, Lay member on the Placental Assessment Predicting Pregnancy Outcome (PAPPO) at the Maternal and Fetal Health Research Centre at Manchester University, Member of the Patient Panel at the Norfolk and Norwich University Hospital, Registered with the Cambridge Bioresource (recent), Member of Public and Patient Involvement in Research (PPIRES) hosted by the South Norfolk CCG.Inspire adult panel member with the Norfolk and Suffolk NHS Trust, Lay reviewer for the Health Technology Assessment Programme with the National Institute of Health Research , Lay reviewer for the Policy Research Programme with the Central Commissioning Facility (CCF) at the Department of Health, Lay reviewer for the Research for Patient Benefit Programme NIHR.	05/06/2015
Mr Iain Martin	None declared	18/12/2015
Dr Derek Prater	Previously employed by Mundipharma Research Ltd until April 2014.Previously held a consultancy agreement with Mundipharma Research Ltd, without any committed hours or obligations of availability or exclusivity until 6th March 2015.	18/12/2015
Dr Wendi Qian	Senior Statistician at Cambridge Clinical Trials Unit - Cancer theme	18/12/2015
Dr Jessica Santos	Global Compliance and Quality Director Kenton Health	18/12/2015

	Chair of Ispor Ethics Committeee	
Mrs Patricia Westcott	None declared	18/12/2015
Dr Joyce Whittington	Shares in Astra Zeneca and GlaxoSmithKline	18/12/2015

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

Month	Date	Number of Members Present at Meeting
May	19/05/2015	11
June	16/06/2015	7
July	21/07/2015	11
September	22/09/2015	8
October	20/10/2015	10
November	17/11/2015	8
December	15/12/2015	11
January	19/01/2016	9
February	16/02/2016	9
March	15/03/2016	10

10 full committee meetings were held during the reporting period.

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

Month	Date	Number of Members Present at Meeting
January	19/01/2016	3
February	22/02/2016	3
March	15/03/2016	3

3 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	02/04/2015	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	21/08/2015	2
September	04/09/2015	2
September	18/09/2015	3
October	02/10/2015	2
October	16/10/2015	2
October	30/10/2015	2
November	13/11/2015	3
November	27/11/2015	2

December	11/12/2015	2
December	29/12/2015	2
January	26/01/2016	2
February	09/02/2016	2
February	23/02/2016	2
March	08/03/2016	2
March	22/03/2016	2

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

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

<b>Date</b>	<b>Reason</b>	<b>Action taken</b>

None



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

Name	Number of Meetings Attended
Dr Niki Bannister	8
Dr Helen Burns	10
Dr Alan Calverd	7
Mrs Ann Colvill	2
Dr Jacqueline Cornelissen	7
Dr Rebecca Harmston	6
Mr Iain Martin	8
Dr Derek Prater	9
Dr Wendi Qian	6
Dr Simon Russell	2
Dr Jessica Santos	8
Mrs Patricia Westcott	6
Dr Melanie Whittick	5
Dr Joyce Whittington	9

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

Name	Number of Meetings Attended
Dr Helen Burns	2
Dr Rebecca Harmston	3
Dr Derek Prater	2
Dr Jessica Santos	1
Dr Joyce Whittington	1

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

Name	Number of Meetings Attended
Dr. Niki Bannister	17
Dr Helen Burns	2
Dr Alan Calverd	3
Dr Jacqueline Cornelissen	4
Dr Rebecca Harmston	2
Mr Iain Martin	11
Dr Derek Prater	1
Dr Wendi Qian	3
Dr Jessica Santos	3
Mrs Patricia Westcott	4
Dr Melanie Whittick	1



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

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Dr Niki Bannister	26/05/2015	NREAP Meeting
Dr Niki Bannister	26/06/2015	Equality and Diversity Training
Dr Niki Bannister	25/09/2015	Members Regional Training Day
Dr Helen Burns	11/06/2015	Induction for new Research Ethics Service Committee Members
Dr Helen Burns	01/07/2015	Equality and Diversity Training
Dr Jacqueline Cornelissen	16/06/2015	Web Seminar The New EU Clinical Trial Regulation
Dr Jacqueline Cornelissen	15/12/2015	Equality and Diversity Training
Dr Rebecca Harmston	06/05/2015	Introduction to Phase 1 Research - Trials and Regulations
Dr Rebecca Harmston	11/06/2015	Equality and Diversity
Mr Iain Martin	26/10/2015	Training - Equality and Diversity
Dr Derek Prater	13/06/2015	Induction for new Research Ethics Service Committee members
Dr Derek Prater	15/06/2015	Committee Members Induction
Dr Derek Prater	18/06/2015	Equality and Diversity Training
Dr Derek Prater	25/09/2015	Members Regional Training Day
Dr Derek Prater	07/10/2015	Introduction to Phase I Research - Trials and Regulation
Dr Derek Prater	18/02/2016	National Members Training Day
Dr Wendi Qian	12/06/2015	Training - Equality and Diversity (e-learning module)
Dr Melanie Whittick	25/09/2015	Members Regional Training Day
Dr Joyce Whittington	30/06/2015	Equality and Diversity Training
Dr Joyce Whittington	18/02/2016	Training - National Members Training Day
Dr Joyce Whittington	24/02/2016	Training - Human Tissue Act (Use of Human Samples in Research) - An Introductory Level

## 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	13	29.55
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	2	4.55
Research Database (including renewals)	1	2.27
Others	28	63.64
<b>Total Applications Reviewed</b>	<b>44</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	7
Number of paediatric applications reviewed	2
Number of device applications reviewed	10
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	1

**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	0	0.00
Favourable Opinion with Additional Conditions	3	6.82
Unfavourable Opinion	6	13.64
Provisional Opinion	35	79.55
Provisional Opinion Pending Consultation with Referee	0	0.00
<b>Total</b>	<b>44</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	27	61.36
Further Information Favourable Opinion with Additional Conditions	7	15.91
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	3	6.82
Unfavourable Opinion	6	13.64
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	2.27
<b>Total</b>	<b>44</b>	<b>100</b>

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

<b>Total Applications Reviewed</b>	<b>7</b>
------------------------------------	----------

**Table 6: Breakdown of PRS applications and other activity during reporting period:**

Number of applications made invalid by the REC Manager	0
Number of studies withdrawn prior to the meeting	0
Number of student applications reviewed	5
Number of paediatric applications reviewed	1
Number of device applications reviewed	0
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	0	0.00
Favourable Opinion with Additional Conditions	0	0.00
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	7	100.00
Unfavourable Opinion	0	0.00
<b>Total</b>	<b>7</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>	4.40
<b>Number of completed applications for full ethical review</b>	43
<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>	2.27%
<b>Number of days taken to final decision – average (mean)</b>	30
<b>Number of completed proportionate review applications for ethical review</b>	7
<b>Number of completed proportionate review applications for ethical review over 14 days</b>	3
<b>Number of completed proportionate review applications over 14 days as a % of total</b>	42.86%
<b>Number of SSAs (non-Phase 1) reviewed</b>	3
<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>	85
<b>Number of completed substantial amendments over 35 days</b>	1
<b>Number of completed substantial amendments over 35 days as a % of total substantial amendments</b>	1.18%
<b>Number of completed substantial amendments over 28 days</b>	3
<b>Number of completed substantial amendments over 28 days as a % of total substantial amendments</b>	3.53%
<b>Number of modified amendments reviewed</b>	3
<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>	54
<b>Number of substantial amendments received for information</b>	0
<b>Number of substantial amendments received for new sites/Pis</b>	16
<b>Number of annual progress reports received</b>	85

<b>Number of safety reports received</b>	26
<b>Number of Serious Adverse Events received</b>	1
<b>Number of final reports received</b>	19



**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/EE/0153	PET CT analysis of restenosis after lower limb revascularisation	40
15/EE/0199	Visions of the future in the brain	39
15/EE/0213	Acetate PET to Identify prostate Tumours and Differentiate BPH	26
15/EE/0217	Memory control impairments in Post-traumatic Stress Disorder - Ver1	26
15/EE/0218	SMS - Study of Somatic Mutations using Genome Sequencing	25
15/EE/0226	Oesophageal Squamous cell CARcinoma (OSCAR) study	38
15/EE/0266	18F-FLT as a Biological Marker for HCC following Locoregional Therapy.	37
15/EE/0277	Cambridge CardioResource: Renewal of ethical approval	27
15/EE/0372	A Clinical Investigation to Evaluate the HYPEREMIC catheter v1	28
15/EE/0373	Cognitive and neural effects of methylphenidate in children with ADHD	32
15/EE/0379	Measuring gut permeability in haemodialysis patients	26
15/EE/0385	Medi4736 and Tremelimumab in Non-Small Cell Lung Cancer	27
15/EE/0415	DEtection in Tandem Endocuff Cap Trial (DETECT)	26
15/EE/0418	CA209-451 Nivolumab vs Nivolumab/Ipilimumab or Placebo in ED-SCLC	35
15/EE/0420	Ultrasound Shear Wave Elastography in Liver Disease	24
15/EE/0421	MUKSeven	26
15/EE/0422	Clinical Validation of Non-Contrast Enhanced MR Venography	29
15/EE/0446	Phase 3 extension study in patients with lung infections (INS-312).	27
15/EE/0460	Evaluation of Navina Smart, Version 1.0	45
15/EE/0468	Response Evaluation of Cancer Therapeutics in Metastatic Breast Cancer	36
16/EE/0016	A study to test the safety and efficacy of GSK2269557 in APDS patients	33
16/EE/0017	Cambridge Case:Control Cytosponge II Study	40
16/EE/0030	iQuit in Practice	31
16/EE/0031	Goal Attainment Scaling in Palliative Rehabilitation	40
16/EE/0048	KFL3502 (Version 1 (protocol version 1, 28 Sep 2015))	30
16/EE/0065	Cholecalciferol in Patients on Dialysis - SIMPLIFIED	26
16/EE/0068	Influence of tranexamic acid on blood loss in total joint replacement	27

<b>Further Information Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
15/EE/0151	Barts Gynae Tissue Bank (10/H0304/14 Renewal)	31
15/EE/0324	Home testing of day and night closed loop with pump suspend feature	34

15/EE/0335	COMPARE: a study of haemoglobin testing methods	33
15/EE/0423	COOL-AMI EU PILOT TRIAL	29
16/EE/0015	OAsIs	29
16/EE/0105	ZOL-A trial	34
16/EE/0110	SPECTRE	30

#### 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
15/EE/0419	Integrated Care Research Study	23
16/EE/0054	Sulphate Accumulation in Prostate (SAP)	24
16/EE/0098	A Clinical Investigation to Evaluate the HYPEREMIC catheter v2	27

#### Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
15/EE/0176	Plerixafor kinetics and radiolabelled neutrophils (v1)	27
15/EE/0196	Randomised comparison of modified and conventional iv cannulae (pilot)	27
15/EE/0221	Asthma Research Database	22
15/EE/0262	SPYRAL HTN-OFF MED Study	24
15/EE/0263	SPYRAL HTN-ON MED Study	24
16/EE/0066	Measure of engagement by people with epilepsy on Whatsapp	25

#### Provisional Opinion

REC Reference	Title	Number of Days on Clock
---------------	-------	-------------------------

<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>
15/EE/0214	Eagle: MEDI4736 MT or MEDI4736 + Tremelimumab versus SOC in SCCHN	20

**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>
16/EE/0036	Video Information versus Approved Leaflets for Flexible Cystoscopy	5
16/EE/0088	Dietary survey for hypertensive type 2 diabetes patients.	22
16/EE/0089	Addressing the information needs of lung cancer screening participants	12
16/EE/0108	Psychological impact of an adult ADHD diagnosis	21

<b>Further Information Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
16/EE/0035	The development and field test of MICOT: a pilot study, v1	9
16/EE/0083	Immune cells and muscle regeneration post-kidney transplant	14
16/EE/0114	Evaluating thromboelastography (TEG) and ETP in sickle adults	21

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

**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
---------------	-------	-------------------------

#### **Unfavourable Opinion**

REC Reference	Title	Number of Days on Clock
---------------	-------	-------------------------

#### **Provisional Opinion**

REC Reference	Title	Number of Days on Clock
---------------	-------	-------------------------

#### **Further information response not complete**

REC Reference	Title	Number of Days on Clock
---------------	-------	-------------------------

#### **Withdrawn after the meeting**

REC Reference	Title	Number of Days on Clock
---------------	-------	-------------------------

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

<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>
07/H0304/128/AM12	A 5-Year Registry Study of Humira (Adalimumab) in subjects with CD	SA4	25/06/2015	11
07/Q0104/11/AM02	Forty year follow up of The Cambridge Cohort of open spina bifida	2	22/01/2016	15
07/Q0104/2/AM03	CF Registry	09/04/2015	09/04/2015	24
08/h0304/85+5/AM02	Norwich Biorepository (formerly the Partners in Cancer Research Human	SA2	24/06/2015	18
09/H0304/69/AM09	NeoSun - Final Version 2.0	Substantial Amendment 9	03/09/2015	22
10/H0304/64/AM04	Alemtuzumab for ANCA-Associated Refractory Vasculitis	SA5	17/08/2015	17
10/H0304/66/AM06	Inherited platelet conditions version 1	SA4	10/06/2015	20
11/EE/0379/AM18	Multifaceted podiatry intervention for fall prevention - REFORM study	Substantial Amendment 13	23/03/2015	14
11/EE/0538/AM22	Interval: study of optimum frequency of blood donations in England, V1	Substantial amendment 18	28/04/2015	27
11/EE/0538/AM23	Interval: study of optimum frequency of blood donations in England, V1	SA19	10/06/2015	14
11/EE/0538/AM24	Interval: study of optimum frequency of blood donations in England, V1	Substantial Amendment 20	13/07/2015	20
11/EE/0538/AM25	Interval: study of optimum frequency of blood donations in England, V1	SA21	07/08/2015	18
11/EE/0538/AM27	Interval: study of optimum frequency of blood donations in England, V1	22.0	15/01/2016	14
11/EE/0538/AM28	Interval: study of optimum frequency of blood donations in England, V1	23	27/01/2016	11
11/H0304/3/AM05	The VARSITY Study	SA#03	15/04/2015	20
11/H0304/8/AM08	TIDAL 1 Version 1.0	SA 10.03.15	10/03/2015	22
12/EE/0029/AM06	Fesoterodine and sexual function, Version 1.7	SA4	01/09/2015	21
12/EE/0029/AM07	Fesoterodine and sexual function, Version 1.7	5.0	21/01/2016	16
12/EE/0127/AM03	Single Administration of KBSA301 in Patients with Severe Pneumonia.	Substantial Amendment	06/08/2015	51

		10.08.20		
12/EE/0171/AM29	Belimumab in Idiopathic Membranous Glomerulonephropathy	SA10	22/04/2015	22
12/EE/0178/AM11	BEACON Study: Breast Cancer Outcomes With NKTR-102 (11-PIR-11)	SA#08 - update PIS & ICF	27/04/2015	28
12/EE/0202/AM05	Timing and tissue uptake of MitoQ by cadaveric human kidneys	SA5	02/11/2015	16
12/EE/0220/AM05	Brain function and treatment response	SA#04	08/04/2015	22
12/EE/0363/AM17	Weight Loss Referrals for Adults in Primary Care (WRAP)	Substantial amendment 10	29/04/2015	21
12/EE/0363/AM18	Weight Loss Referrals for Adults in Primary Care (WRAP)	SA 14.08.2015	10/08/2015	11
12/EE/0369/AM11	Genetic influences on the amount of analgesia women need during labour	21/1/2016	21/01/2016	21
12/EE/0543/AM01	PCOSA-1 study	SA1	23/03/2015	14
13/EE/0043/AM04	Oesophageal Cancer Rapid Medical Donation Programme	SA4	28/05/2015	17
13/EE/0069/AM06	Efficacy and Safety of ABP980 Compared to Trastuzumab in Breast Cancer	SA3	23/04/2015	14
13/EE/0069/AM08	Efficacy and Safety of ABP980 Compared to Trastuzumab in Breast Cancer	4	04/09/2015	26
13/EE/0100/AM01	Preliminary Assessment of Advanced Re-biopsy Targeting (PA-ART)	SA1	04/04/2015	28
13/EE/0157/AM01	The Centre for Attention, Learning and Memory (CALM)	SA1	10/07/2015	18
13/EE/0294/AM04	STEFFI	3	28/09/2015	9
13/EE/0335/AM04	COOL-AMI EU case series clinical study	SA3	09/03/2015	13
13/EE/0335/AM06	COOL-AMI EU case series clinical study	SA4	07/07/2015	6
13/EE/0364/AM05	A Phase 2 Study with Denosumab in Non-Small Cell Lung Cancer	Substantial Amendment 3	23/03/2015	12
13/EE/0376/AM03	Norwich DNA Extraction and Sequencing (NODES)	SA2	09/11/2015	28
13/EE/0433/AM04	The Leadless Observational Study	Amendment 3 - Rev F	07/07/2015	20
13/EE/0436/AM05	A safety study of pazopanib and MK-3475 in Renal Cell Carcinoma	SA2	30/04/2015	17
13/EE/0436/AM06	A safety study of pazopanib and MK-3475 in Renal Cell Carcinoma	SA3	11/12/2015	24
13/EE/0438/AM01	PHYSICA KR Clinical Trial	SA1	22/06/2015	18
13/EE/0449/AM09	RCT Evaluating Novel Sensing Technology in Type 2 Diabetes Rev 1.0	SA3	18/03/2015	29
14/EE/0023/AM08	Dose escalating PK study of PH46A	SA4	19/06/2015	10

14/EE/0024/AM02	Real time tissue characterisation using mass spectrometry	SA2	02/10/2015	18
14/EE/0062/AM06	Laminate External Support Protocol, Rev 01	SA 12.05.15	13/05/2015	22
14/EE/0062/AM08	Laminate External Support Protocol, Rev 01	SA4	03/11/2015	26
14/EE/0102/AM08	ENSURE in AF (atrial fibrillation) study	SA#08	21/04/2015	16
14/EE/0102/AM09	ENSURE in AF (atrial fibrillation) study	SA9	06/08/2015	19
14/EE/0122/AM01	The Fenland Study - Phase 2	SA1	18/05/2015	20
14/EE/0122/AM02	The Fenland Study - Phase 2	SA2	14/09/2015	33
14/EE/0122/AM03	The Fenland Study - Phase 2	SA3 - February 2016	03/03/2016	21
14/EE/0146/AM01	PRICKLE	SA#03	21/04/2015	16
14/EE/0178/AM07	Effects of Modafinil on Cognition in Patients with Remitted Depression	SA 30.06.2015	30/06/2015	20
14/EE/1004/AM02	The VBI Trial	Amendment 2	12/10/2015	17
14/EE/1006/AM07	Effect of pH on the PK of sativex	SA2	27/04/2015	25
14/EE/1006/AM08	Effect of pH on the PK of sativex	SA4	20/05/2015	22
14/EE/1006/AM09	Effect of pH on the PK of sativex	SA5	02/07/2015	7
14/EE/1057/AM03	DILfrequency	SA2	01/05/2015	21
14/EE/1057/AM06	DILfrequency	substantial amendment 3	10/03/2016	9
14/EE/1107/AM05	Exploratory study of Respiratory Viral Disease in Healthy Subjects	Substantial Amendment 03	28/04/2016	24
14/EE/1129/AM03	ADDITION - 10 year follow up	substantial amendment 1	11/03/2016	14
14/EE/1134/AM05	Viral Titre Determination in Healthy Subjects challenged with RSV	Substantial Amendment 26.03.15	31/03/2015	21
14/EE/1193/AM02	AIRFLOW-1	SA2	13/11/2015	28
14/EE/1200/AM06	MK3475 vs standard treatment in subjects with head and neck cancer	SA3	19/05/2015	22
14/EE/1200/AM08	MK3475 vs standard treatment in subjects with head and neck cancer	SA5	14/07/2015	21
14/EE/1200/AM09	MK3475 vs standard treatment in subjects with head and neck cancer	SA6	16/08/2015	8
14/EE/1200/AM12	MK3475 vs standard treatment in subjects with head and neck cancer	SA7	16/11/2015	15
14/EE/1245/AM03	A Study to Explore Candidate Biomarkers Relating to RSV Challenge	SA#02	28/04/2015	24

14/EE/1245/AM05	A Study to Explore Candidate Biomarkers Relating to RSV Challenge	SA3	11/08/2015	13
14/EE/1251/AM01	Profiling Mantle cell Lymphoma version 1	SA1	10/04/2015	14
15/EE/0063/AM02	PROTEC1	SA1	05/05/2015	17
15/EE/0063/AM03	PROTEC1	SA2	25/09/2015	8
15/EE/0064/AM01	Community Mental Health Survey 2015	1.0	08/12/2015	15
15/EE/0110/AM01	RSV challenge study to examine JNJ-53718678 in healthy subjects	SA1	11/06/2015	18
15/EE/0110/AM02	RSV challenge study to examine JNJ-53718678 in healthy subjects	Substantial Amendment 2	01/09/2015	27
15/EE/0218/AM01	SMS - Study of Somatic Mutations using Genome Sequencing	SA1	03/11/2015	22
15/EE/0218/AM02	SMS - Study of Somatic Mutations using Genome Sequencing	2.0	27/11/2015	26
15/EE/0335/AM01	COMPARE: a study of haemoglobin testing methods	SA1	22/12/2015	16
15/EE/0379/AM02	Measuring gut permeability in haemodialysis patients	#2	26/01/2016	15
15/EE/0418/AM02	CA209-451 Nivolumab vs Nivolumab/Ipilimumab or Placebo in ED-SCLC	EC01	13/01/2016	28

#### Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
08/H0304/115/AM09	The CHIPS Trial (Control of Hypertension In Pregnancy Study)	SA#09	12/05/2015	28
09/H0304/77/AM07	Generation of Donor Induced Pluripotent Stem (IPS) Cells for Research	SA7	30/03/2015	28
12/EE/0544/AM07	INSPIRE (Isentress Pilot Study in Relapsing MS)	SA4	12/03/2015	28
14/EE/0101/AM04	High and low dose of IgPro20 for the maintenance treatment of CIDP	SA1	15/07/2015	20
15/EE/0151/AM01	Barts Gynae Tissue Bank (10/H0304/14 Renewal)	Substantial Amendment 1	23/09/2015	27

**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
-------------------------	-------	---------	------	-------------------------



08/H0304/115/AM09/1	The CHIPS Trial (Control of Hypertension In Pregnancy Study)	Modified 1 of SA#09	27/08/2015	9
14/EE/0101/AM04/1	High and low dose of IgPro20 for the maintenance treatment of CIDP	Modified 1 of SA1	28/09/2015	8
15/EE/0151/AM01/1	Barts Gynae Tissue Bank (10/H0304/14 Renewal)	MA1SA1	07/01/2016	5

#### Unfavourable opinion timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
-------------------------	-------	---------	------	-------------------------

**Table 11: Items exceeding timelines****Full applications for ethical review over 60 day timeline**

REC Reference	Title	Number of Days on Clock
---------------	-------	-------------------------

**Proportionate review applications for ethical review over 14 day timeline**

REC Reference	Title	Number of Days on Clock
16/EE/0088	Dietary survey for hypertensive type 2 diabetes patients.	22
16/EE/0108	Psychological impact of an adult ADHD diagnosis	21
16/EE/0114	Evaluating thromboelastography (TEG) and ETP in sickle adults	21

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

REC Reference	Title	Number of Days on Clock
---------------	-------	-------------------------

**SSAs (Phase 1) over 14 day timeline**

REC Reference	Title	Number of Days on Clock
---------------	-------	-------------------------

**Substantial Amendments over 35 day timeline**

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
12/EE/0127/AM03	Single Administration of KBSA301 in Patients with Severe Pneumonia.	Substantial Amendment 10.08.20	06/08/2015	51

**Modified Amendments over 14 day timeline**

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
-------------------------	-------	---------	------	-------------------------