

**London - Harrow Research Ethics Committee**

**Annual Report**

**01 April 2015 - 31 March 2016**



## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	London - Harrow Research Ethics Committee
<b>Type of REC:</b>	REC recognised to review CTIMPS in healthy volunteers - type i REC recognised to review CTIMPS in patients - type iii
<b>Type of Flag:</b>	Phase 1 involving healthy volunteers Adults Lacking Capacity
<b>Chair:</b>	Dr Jan Downer
<b>Vice-Chair:</b>	Professor Liz Meerabeau (until 11/11/2015) Miss Shelly Glaister-Young (from 16/11/2015)
<b>Alternate Vice-Chair:</b>	Miss Shelly Glaister-Young (until 16/11/2015) Dr Daryl Bendel (from 02/12/2015)
<b>REC Manager:</b>	Miss Libby Watson (until 07/10/2015) Miss Georgina Castledine (from 07/10/2015)
<b>REC Assistant:</b>	Miss Natasha Bridgeman (until 20/07/2015) Miss Lucy Roberts (from 07/10/2015)
<b>Committee Address:</b>	Level 3, Block B Whitefriars Lewins Mead Bristol BS1 2NT
<b>Telephone:</b>	02071048027
<b>Email:</b>	<a href="mailto:nrescommittee.london-harrow@nhs.net">nrescommittee.london-harrow@nhs.net</a>

**Chair's overview of the past year:**

## London - Harrow Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Mr David Anderson-Ford	Director of Research Ethics and Governance	Lay Plus	01/03/2009	
Ms Jane Batchelor	Centre Administrator, Advanced Cardiovascular Imaging	Lay Plus	24/02/2016	
Dr Daryl Bendel	Consultant in Pharmaceutical and Translational Medicine	Expert	20/10/2014	
Dr Jane Berry	Retired	Lay	01/01/2016	
Dr Tom Bryce	Retired	Lay	01/01/2016	
Mr Andrew Counce	Chief Pharmacist	Expert	01/03/2009	
Mr Kevin Coughlan	Retired	Lay	01/03/2009	10/07/2015
Dr Jan Downer	Consultant Anaesthetist	Expert	01/03/2009	
Dr Annette Gilmore	Research Nurse	Expert	11/11/2011	
Miss Shelly Glaister-Young	Barrister	Lay Plus	01/03/2009	
Dr Mary Leung	Clinical Psychologist	Expert	01/06/2010	
Ms Ann Malkin	Consultant Psychologist	Expert	01/03/2009	
Reverend Catherine McBride	Vicar	Lay	01/02/2014	
Professor Liz Meerabeau	University Professor	Expert	14/05/2013	11/11/2015
Ms Monika Temple	Retired	Lay	01/01/2016	
Mr Jim Wood	Retired IT Consultant	Lay Plus	01/03/2009	

## London - Harrow Research Ethics Committee: Deputy Members

Name	Profession	Status	Meeting date attended
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## London - Harrow Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended
Miss Stephanie Ellis	Civil Servant (Retired)	Lay Plus	09/06/2015
Mr John Richardson	Retired Director of COREC: former Ecumenical Officer for Churches Together in South London	Lay Plus	PRSC 23/03/2016
Dr Michael Schachter	Clinical Pharmacologist	Expert	PRSC 23/03/2016

**London - Harrow Research Ethics Committee: Members' Declarations of Interest:**

<b>Name</b>	<b>Declaration of Interest</b>	<b>Date</b>
Mr David Anderson-Ford	Council member of Association for research ethics Director of Research Ethics and Governance - Brunel University London	10/12/2015
Ms Jane Batchelor	None	25/02/2016
Dr Daryl Bendel	Director (and owner) of Xidea Solutions Limited, which is a consultancy providing support for the BioPharmaceutical industry. Consultant in Pharmaceutical and translational medicine advising clients on matters that includes clinical trials. Two clients currently involved with ongoing clinical trials in the UK. None of other clients are currently intending to conduct trials in the UK. One is a UK company called London Pharma. For the other he is Consultant Medical Director for the Surrey Clinical Research Centre. This clinic is accredited by the MHRA and he is named as the principal investigator for higher risk studies on the accreditation document. Primarily his role is to oversee clinical studies being conducted in the Clinic by other investigators. Oversees the overall clinical governance. Lecturer on the MSc Pharmaceutical Medicine course at the University of Surrey, dealing with the topics of 'Declaration of Helsinki: Ethics and Standards in human pharmacology study' and 'Principles of informed consent'. Faculty of Pharmaceutical Medicine approved educational supervisor.	31/03/2016
Dr Jane Berry	Owner of GSK shares	11/01/2016
Dr Tom Bryce	Volunteer Awareness speaker for Prostate Cancer UK	29/01/2016
Mr Andrew Counce	None	31/03/2016
Dr Jan Downer	None	08/12/2015
Dr Annette Gilmore	None	10/12/2015
Miss Shelly Glaister-Young	None	10/12/2015
Dr Mary Leung	HCPC re-registration period 01/06/15 to 31/05/17 Offers specialist advise on post stroke depression	02/02/2016
Ms Ann Malkin	Chair, Board of Trustees, Communicare Counselling Service	10/12/2015
Reverend Catherine McBride	Ordinary shares in GSK	10/12/2015
Ms Monika Temple	Bank policy advisor at the HRA	08/02/2016
Mr Jim Wood	Shares in Astra Zeneca, GSK, Membership of Brunel University Research Ethics Committee	10/12/2015

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

Month	Date	Number of Members Present at Meeting
May	12/05/2015	8
June	09/06/2015	8
August	11/08/2015	10
September	08/09/2015	8
November	10/11/2015	8
December	08/12/2015	8
January	12/01/2016	9
February	09/02/2016	10
March	08/03/2016	9

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	29/04/2015	3
June	24/06/2015	3
July	29/07/2015	3
August	26/08/2015	3
September	23/09/2015	3
October	28/10/2015	3
November	25/11/2015	3
January	27/01/2016	3
February	24/02/2016	3
March	23/03/2016	3

10 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	10/04/2015	3
April	17/04/2015	2
April	24/04/2015	2
May	01/05/2015	2
May	08/05/2015	2
May	15/05/2015	2
May	22/05/2015	2
June	05/06/2015	2
June	05/06/2015	2
June	08/06/2015	2
June	12/06/2015	2

June	15/06/2015	2
June	19/06/2015	2
June	23/06/2015	2
July	03/07/2015	2
July	10/07/2015	2
July	17/07/2015	2
July	24/07/2015	2
August	07/08/2015	2
August	14/08/2015	2
August	25/08/2015	2
August	28/08/2015	2
September	04/09/2015	2
September	11/09/2015	2
September	18/09/2015	2
September	23/09/2015	2
September	28/09/2015	2
October	07/10/2015	2
October	12/10/2015	2
October	16/10/2015	2
October	23/10/2015	2
October	26/10/2015	2
October	30/10/2015	2
November	06/11/2015	2
November	16/11/2015	2
November	27/11/2015	2
December	04/12/2015	2
December	14/12/2015	2
December	18/12/2015	2
January	04/01/2016	2
January	15/01/2016	2
January	29/01/2016	2
February	05/02/2016	2
February	15/02/2016	2
February	24/02/2016	2
March	11/03/2016	2
March	30/03/2016	2

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

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

None

### Attendance of Members at Full Committee meetings: 01 April 2015 - 31 March 2016

Name	Number of Meetings Attended
Mr David Anderson-Ford	7
Ms Jane Batchelor	1
Dr Daryl Bendel	6
Dr Jane Berry	3
Dr Tom Bryce	3
Mr Andrew Counce	7
Dr Jan Downer	9
Dr Annette Gilmore	6
Miss Shelly Glaister-Young	6
Dr Mary Leung	5
Ms Ann Malkin	6
Reverend Catherine McBride	6
Professor Liz Meerabeau	4
Ms Monika Temple	3
Mr Jim Wood	5

### Attendance of Members at Proportionate Review Sub-Committee meetings: 01 April 2015 - 31 March 2016

Name	Number of Meetings Attended
Dr Daryl Bendel	5
Dr Jan Downer	4
Dr Annette Gilmore	2
Miss Shelly Glaister-Young	7
Ms Ann Malkin	3
Reverend Catherine McBride	3
Professor Liz Meerabeau	2
Mr Jim Wood	2

### Attendance of Members at Sub-Committee meetings: 01 April 2015 - 31 March 2016

Name	Number of Meetings Attended
Dr Daryl Bendel	15
Mr Andrew Counce	6
Dr Jan Downer	21
Dr Annette Gilmore	4
Miss Shelly Glaister-Young	18
Dr Mary Leung	13
Ms Ann Malkin	7
Reverend Catherine McBride	4





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

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Ms Jane Batchelor	26/11/2015	Local Training Day for London RECs
Dr Daryl Bendel	26/01/2016	Equality and Diversity Awareness
Dr Jane Berry	08/02/2016	Equality and Diversity
Dr Tom Bryce	27/01/2016	Equality and Diversity Awareness
Dr Tom Bryce	10/03/2016	Committee Members Induction
Mr Andrew Counce	12/10/2015	Complex Cases
Dr Jan Downer	09/04/2015	Equality and Diversity Awareness
Dr Jan Downer	14/04/2015	Local Training Day
Dr Jan Downer	17/03/2016	Bromley REC Local training day
Dr Annette Gilmore	14/04/2015	Local training day
Miss Shelly Glaister-Young	14/04/2015	Local training day
Miss Shelly Glaister-Young	29/01/2016	Equality and Diversity Awareness
Dr Mary Leung	14/04/2015	Local training day
Dr Mary Leung	29/09/2015	Genetics and Genomics Research
Dr Mary Leung	18/02/2016	Equality and Diversity Awareness
Ms Ann Malkin	14/04/2015	Local training day
Ms Ann Malkin	05/02/2016	Local Training Day - Social Care
Reverend Catherine McBride	14/04/2015	Local training day
Professor Liz Meerabeau	23/07/2015	Research in Disadvantaged and Vulnerable
Ms Monika Temple	28/01/2016	Equality and Diversity Awareness
Mr Jim Wood	18/02/2016	National Members 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	11	23.91
Phase 1	7	15.22
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	0	0.00
Others	28	60.87
<b>Total Applications Reviewed</b>	<b>46</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	2
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	13
Number of paediatric applications reviewed	6
Number of device applications reviewed	3
Number of prisoner applications reviewed	1
Number of applications involving adults unable consent reviewed	6
Number of applications reviewed that are funded by the US DHHS	0
Number of qualitative applications reviewed	2

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

<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	4	8.70
Unfavourable Opinion	0	0.00
Provisional Opinion	42	91.30
Provisional Opinion Pending Consultation with Referee	0	0.00
<b>Total</b>	<b>46</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	24	52.17
Further Information Favourable Opinion with Additional Conditions	17	36.96
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	4	8.70
Unfavourable Opinion	0	0.00
Provisional Opinion	1	2.17
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>46</b>	<b>100</b>

**Table 5: Applications assigned to a Proportionate Review Sub-Committee within the reporting period**

<b>Total Applications Reviewed</b>	<b>24</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	19
Number of studies withdrawn prior to the meeting	0
Number of student applications reviewed	12
Number of paediatric applications reviewed	3
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	4	16.67
Favourable Opinion with Additional Conditions	3	12.50
No Opinion transfer to full committee for review	2	8.33
Provisional Opinion	15	62.50
Unfavourable Opinion	0	0.00
<b>Total</b>	<b>24</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>	5.11
<b>Number of completed applications for full ethical review</b>	46
<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>	6
<b>Number of completed applications over 40 days as a % of total</b>	13.04%
<b>Number of days taken to final decision – average (mean)</b>	34
<b>Number of completed proportionate review applications for ethical review</b>	21
<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>	4.76%
<b>Number of SSAs (non-Phase 1) reviewed</b>	4
<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>	8
<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>	117
<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>	15
<b>Number of completed substantial amendments over 28 days as a % of total substantial amendments</b>	12.82%
<b>Number of modified amendments reviewed</b>	7
<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>	100
<b>Number of substantial amendments received for information</b>	0
<b>Number of substantial amendments received for new sites/PIs</b>	17

<b>Number of annual progress reports received</b>	98
<b>Number of safety reports received</b>	20
<b>Number of Serious Adverse Events received</b>	0
<b>Number of final reports received</b>	1

**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/LO/0778	Home Oral Glucose Tolerance Test	43
15/LO/0781	Evaluation of the safety and efficacy of PAD ciclosporin in dry eye patients	26
15/LO/0801	Metabolic and metagenomic profiling in the characterisation of IBD	31
15/LO/1015	AQUA	29
15/LO/1025	Age-appropriate augmented CBT for late life depression case series	34
15/LO/1027	The Abatacept Systemic SclErosis Trial (ASSET)	33
15/LO/1229	Safety and Blood levels of DS1971, version1	20
15/LO/1260	The impact of welfare advice in General Practice	36
15/LO/1263	A drug utilisation study in patients treated with EXELONÂ® patch	30
15/LO/1369	Design and pilot of a PREM for people with moderate-advanced dementia	36
15/LO/1402	HOPE - HF	35
15/LO/1441	Phase III with ALX0681 in Acquired Thrombotic Thrombocytopenic Purpura	36
15/LO/1454	Autonomic modulation on visceral pain hypersensitivity in NERD	43
15/LO/1830	202007 - FTIH of GSK3389404 in HV	40
15/LO/1867	A PET scan study to assess brain uptake of SK-1405, v1	36
15/LO/1952	Phase II ALNPCSSC placebocontrolled, doubleblind, cardiology trial	28
16/LO/0004	iTACTIC v1.0	48
16/LO/0027	Investigating an infectious aetiology of prostate cancer	29
16/LO/0037	Symprove for treatment of acute diverticulitis	36
16/LO/0038	An observational study to develop ICF oral health core sets (England)	31
16/LO/0153	MS-DOUBT	31
16/LO/0229	Ethnic differences between HCM and athlete's heart (v1)	32
16/LO/0231	Trial of Psychological Workshops for Adolescents in Clinics V1	58
16/LO/0411	Assertive outreach treatment for alcohol related admissions	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/LO/0769	Left Atrial Appendage Occlusion Study III (LAAOS III)	40
15/LO/0799	Monitoring Air Pollution Exposure in Children	30
15/LO/1244	IVA337 SSc POC	40
15/LO/1265	The PIEB Study	29



15/LO/1401	LAIV PROTECT	28
15/LO/1451	QGE031B2204: QGE031 vs placebo in asthma	40
15/LO/1966	Gut liver axis in Biliary Atresia, version 1	36
15/LO/2047	Medivation - D5170C00002	35
15/LO/2069	The PReSUTINeB Study (v1.0).	29
15/LO/2089	Investigation of ACRYSOFA® IQ PanOptix Presbyopia Correcting IOL	30
16/LO/0014	BR1-142 Lumason/SonoVue in Stress Echocardiography	43
16/LO/0085	Enriching relational knowing in stroke care	38
16/LO/0211	Bioavailability & tolerability of Bimekizumab in healthy subjects	33
16/LO/0227	A Feasibility Study of DBT-SE for PD	42
16/LO/0406	RELAX-OAB 105-0010	32
16/LO/0415	Thermography in assessing treatment response to Golimumab in PsA	31
16/LO/0446	Child and Family Views Project	25

#### 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
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#### Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/LO/1012	Acupuncture for cancer patients undergoing Radiotherapy Treatment	23
15/LO/1903	A drug interaction study of MT-8554 v1	16
15/LO/2035	Effect of F901318 on blood levels of midazolam, v1	23
16/LO/0050	Safety, blood levels and effects of Coversin, v1	40

#### Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
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#### Provisional Opinion

REC Reference	Title	Number of Days on Clock
16/LO/0370	Quadriceps muscle size and composition in intensive care patients	n/a

#### 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
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**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
15/LO/1190	Choosing therapy for vitreomacular interface abnormality	9
15/LO/1196	Assessing the optimal follow-up regimen in metal-on-metal hip patients	14
15/LO/1540	Research to evaluate the Active for Health Pathway	10
15/LO/1545	Effect of sterilisation & storage on extracted teeth (in vitro study)	12
15/LO/1946	Mobile DXA Services in the UK: an implementation & outcome evaluation	10
15/LO/1948	A Patient Information Leaflet and Non specific Abdominal Pain	15
15/LO/2115	Smokefree mentalhealth:a qualitative exploration of relapse prevention	11
15/LO/2126	Thrombin generation in patients with myeloproliferative neoplasms	12
15/LO/2128	IBS microbiome	8

#### Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/LO/0840	Predictors of Perinatal Anxiety and Depression	8

15/LO/0847	Exploring the effects of planning on smoking cessation.	13
15/LO/0856	Muscle responses to stretching in children with cerebral palsy	11
15/LO/2132	V1Action research of pharmacist's contribution to integrated care	5
16/LO/0430	Inflammatory synovitis in major joint replacement.	8

#### 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
15/LO/1371	Expression of immune checkpoints in oral cavity squamous cell carcinoma and dysplasia	8
16/LO/0434	Donor-recipient KIR/HLA mismatches and organ transplant outcomes	8
16/LO/0568	Granulomatous prostatitis after BCG therapy for urothelial carcinoma	8
16/LO/0636	THE PATIENT EXPERIENCE OF TOTAL HIP REPLACEMENT: A QUALITATIVE STUDY	7

#### Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/LO/1394	Using health record data for quality improvement	7
15/LO/1705	Generating a tissue engineered oesophagus	13
15/LO/1740	Investigation of the CEJ of unerupted human teeth	13

#### 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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<b>Withdrawn after the meeting</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
15/LO/1366	PRECISE Pilot Study	7

**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>
01/0095/AM15	New Methods of Detecting Problems in Pregnancy	14	17/08/2015	27
04/Q0502/89/AM13	MR Imaging of Brain Generators in Human Epilepsy	7	01/01/2016	17
05/Q0405/71/AM09	Immune Regulation by Dendritic Cells	7	03/09/2015	7
05/Q0502/102/AM21	Remote postconditioning in the clinical setting	Version 17	01/04/2015	25
05/Q0505/58/AM12	Risk Factors for Ovarian Cancer Version 1, 23/05/2005	13	13/02/2015	29
06/Q0505/102/AM07	Risk Factors and Novel Biomarkers in Breast Cancer	9	26/06/2015	22
06/Q0505/22/AM17	CT/PET in patients with interstitial lung disease	12	15/02/2016	31
07/H0715/101/AM19	Quantifying Diffuse Myocarcordial fibrosis using Cardiac MRI	Substantial Amendment 18	18/03/2015	15
08/H0714/8/AM05	Predictive utility of DASIMAR as prognostic Biomarker in ACLF.	6	01/07/2015	6
08/H0715/91/AM17	BOSS (Barrett's Oesophagus Surveillance Study)	9 (no.13)	01/01/2016	22
09/H0715/58/AM05	ALchemy version 1.0	4.0	14/07/2015	16
09/H0715/65/AM04	The impact of genotype on the outcome of obesity treatment	6.1	01/06/2015	29
10/H0714/8/AM17	BREATHER(PENTA 16) Trial: Short-Cycle Therapy(SCT)	Protocol 1.10	29/05/2015	17
10/H0715/39/AM02	Immunological predictors of disease outcome in viral hepatitis	2	13/04/2015	21
10/H0715/57/AM16	MDV3100 for chemotherapy-naïve patients with prostate cancer	ICF v7.0	23/07/2015	6
11/LO/0458/AM07	BP treatment in SVD	SA 7	10/06/2015	6
11/LO/1628/AM01	Development of new therapeutic agents for multiple myeloma	1	19/01/2016	28
11/LO/1636/AM03	Fibre specific signalling in the locomotor myopathy of COPD	SA 3	08/05/2015	22
11/LO/2029/AM02	Recording retinal responses in health and disease	SA1	20/04/2015	6
12/LO/0279/AM03	Developing a decision making aid for orthodontic treatment	4	06/01/2015	21
12/LO/0279/AM04	Developing a decision making aid for orthodontic treatment	5	14/07/2015	19
12/LO/0528/AM04	SNP variants, neuroimaging and neuropsychology in Schizophrenia	11	18/06/2015	22
12/LO/0877/AM08	A randomised trial of antibiotics in laparoscopic donor nephrectomy.v1	5	19/05/2015	30
12/LO/1257/AM15	Oral UT-15C for treatment of Pulmonary Arterial Hypertension	SA9	03/06/2015	21

	(PAH)			
12/LO/1307/AM03	Platelet trafficking through the lungs in pulmonary fibrosis	SA2	23/03/2015	28
12/LO/1325/AM11	Open Label Extension Study - Oral UT-15C for PAH	SA6	03/06/2015	21
12/LO/1378/AM14	Evaluation of PBS: a cluster RCT	SA7	18/03/2015	21
12/LO/1554/AM09	ASSertID - A Study of Sertraline In Dialysis - Version 1	2	23/04/2015	34
12/LO/1771/AM11	Study of Dexamethasone in Patients with AL Amyloidosis	4	09/07/2015	18
12/LO/1903/AM12	A Trial of Nilvadipine in Mild to Moderate Alzheimer's disease	7	21/09/2015	5
12/LO/2009/AM01	Quality and Effectiveness of Supported Tenancies (QEST)	SA1	23/04/2015	35
12/LO/2009/AM02	Quality and Effectiveness of Supported Tenancies (QEST)	2	17/12/2015	27
13/LO/0021/AM11	PRESENT	8	08/10/2015	3
13/LO/0100/AM09	A study of ISIS 420915 in patients with Amyloid Polyneuropathy	Protocol Amendment 6	02/06/2015	22
13/LO/0100/AM10	A study of ISIS 420915 in patients with Amyloid Polyneuropathy	Patient Materials	10/09/2015	15
13/LO/0100/AM11	A study of ISIS 420915 in patients with Amyloid Polyneuropathy	7	16/11/2015	11
13/LO/0332/AM04	Roll-over study for patients on a previous nilotinib Novartis study	3	04/02/2016	20
13/LO/0365/AM11	LeoPARDS	AM08	06/05/2015	27
13/LO/0503/AM07	Asfotase Alfa in infants and children (< 5 Years of Age) with HPP	10	20/10/2015	27
13/LO/0503/AM09	Asfotase Alfa in infants and children (< 5 Years of Age) with HPP	Brochure v1.0	29/01/2016	10
13/LO/0821/AM09	0112 -Phase 3 open-label study in HIV-1 patients with renal impairment	Substantial Amendment [UK Prot	24/04/2015	25
13/LO/0821/AM11	0112 -Phase 3 open-label study in HIV-1 patients with renal impairment	GS-US-292-0112 Notification of	17/11/2015	15
13/LO/1020/AM08	309: XL184 vs placebo in subjects with hepatocellular carcinoma	IB Ed 11	22/12/2015	33
13/LO/1541/AM02	Inflammation resolution in inflammatory bowel disease	SA 2	12/05/2015	8
13/LO/1670/AM03	Autologous Stem Cells in Achilles Tendinopathy	4	10/12/2015	3
13/LO/1758/AM12	A Safety and Efficacy Study of MK8931 for Prodromal AD v.019-00	07	04/06/2015	14
13/LO/1758/AM14	A Safety and Efficacy Study of MK8931 for Prodromal AD v.019-00	9	11/08/2015	14

13/LO/1758/AM16	A Safety and Efficacy Study of MK8931 for Prodromal AD v.019-00	10	03/09/2015	31
13/LO/1758/AM19	A Safety and Efficacy Study of MK8931 for Prodromal AD v.019-00	13	06/01/2016	21
13/LO/1861/AM06	Cariprazine: comparison of slow- and immediate-release forms, ver A	Generic information and consen	31/07/2015	12
13/LO/1891/AM02	MORE-CRT MPP	SA2	02/06/2015	27
13/LO/1891/AM03	MORE-CRT MPP	3	06/02/2016	10
13/LO/1899/AM04	Nasal Challenge with Microbial Constituents and Allergen	sa4	15/06/2015	26
13/LO/1899/AM06	Nasal Challenge with Microbial Constituents and Allergen	5	02/10/2015	23
13/LO/1899/AM07	Nasal Challenge with Microbial Constituents and Allergen	6	20/01/2016	17
14/LO/0034/AM02	Agitation and quality of life in care homes version 1	3	20/07/2015	23
14/LO/0185/AM03	PROXIMUS - PRotective role of OXcabazepine In MULTiple Sclerosis	1	20/07/2015	5
14/LO/0314/AM04	Risk of Seizure Among Subjects with mCRPC	Investigator Brochure 8.0	09/07/2015	15
14/LO/0314/AM06	Risk of Seizure Among Subjects with mCRPC	4	21/03/2016	14
14/LO/0392/AM06	Randomised study of ABT-494 in subjects with Rheumatoid Arthritis	M13-550, Protocol amendment 2.01	18/03/2015	27
14/LO/0788/AM02	The current impact of personal health budgets	2	22/06/2015	33
14/LO/0788/AM03	The current impact of personal health budgets	3	02/09/2015	10
14/LO/0788/AM04	The current impact of personal health budgets	4	09/11/2015	15
14/LO/0882/AM09	GO28915 - MPDL3280A or Docetaxel in Patients with NSCLC	4	15/04/2015	13
14/LO/0882/AM10	GO28915 - MPDL3280A or Docetaxel in Patients with NSCLC	5	06/10/2015	35
14/LO/0882/AM13	GO28915 - MPDL3280A or Docetaxel in Patients with NSCLC	6	02/02/2016	22
14/LO/1249/AM02	CATS29 Crohns Phase IIb, Multicentre, Randomized, Double-blind Study	2	04/08/2015	7
14/LO/1355/AM01	COPE COPD Programme	SA 1	03/06/2015	18
14/LO/1597/AM05	Phase 2a/2b study of alkaline phosphatase in patients with SA-AKI	2	09/03/2016	20
14/LO/1604/AM01	Open-Label Extension Study in Rheumatoid Arthritis.	Update to Patient Material	26/02/2015	27
14/LO/1604/AM03	Open-Label Extension Study in Rheumatoid Arthritis.	2	11/09/2015	10
14/LO/1604/AM06	Open-Label Extension Study in Rheumatoid Arthritis.	3	25/02/2016	22
14/LO/1785/AM01	MUSCLE MRI sequence study	1	16/07/2015	9

14/LO/1834/AM08	SAD and MAD study of GBT440 in healthy volunteers and SCD Patients	SA 04 Amendment	08/04/2015	17
14/LO/1834/AM09	SAD and MAD study of GBT440 in healthy volunteers and SCD Patients	5	08/05/2015	26
14/LO/1834/AM15	SAD and MAD study of GBT440 in healthy volunteers and SCD Patients	6	07/09/2015	7
14/LO/1834/AM16	SAD and MAD study of GBT440 in healthy volunteers and SCD Patients	7	12/10/2015	28
14/LO/1834/AM21	SAD and MAD study of GBT440 in healthy volunteers and SCD Patients	8	28/01/2016	31
14/LO/1863/AM01	Safety, tolerability & PK of LML134 as SAD in healthy Subjects	1	28/05/2015	31
14/LO/2039/AM02	First in-human, SAD, MAD and FE Study of ASP6858 in Healthy Subjects	SA2	06/07/2015	6
14/LO/2039/AM06	First in-human, SAD, MAD and FE Study of ASP6858 in Healthy Subjects	3	28/08/2015	13
14/LO/2039/AM07	First in-human, SAD, MAD and FE Study of ASP6858 in Healthy Subjects	4	09/09/2015	5
14/LO/2039/AM08	First in-human, SAD, MAD and FE Study of ASP6858 in Healthy Subjects	5	21/09/2015	24
14/LO/2218/AM01	ENZAMET Trial	SA1	12/05/2015	20
14/LO/2218/AM04	ENZAMET Trial	3	03/09/2015	12
14/LO/2218/AM06	ENZAMET Trial	4	09/12/2015	12
15/LO/0040/AM01	Evaluate effect of GS6615 on Exercise capacity in subjects with HCM	SA1	27/03/2015	22
15/LO/0217/AM01	ERIC-PPCI	1	08/03/2016	28
15/LO/0236/AM01	A Phase II Trial of MK-3475 in Subjects with Bladder Cancer	1	13/04/2015	22
15/LO/0236/AM02	A Phase II Trial of MK-3475 in Subjects with Bladder Cancer	03	15/06/2015	7
15/LO/0236/AM03	A Phase II Trial of MK-3475 in Subjects with Bladder Cancer	02	07/07/2015	13
15/LO/0236/AM05	A Phase II Trial of MK-3475 in Subjects with Bladder Cancer	4	18/01/2016	20
15/LO/0413/AM02	Safety and Efficacy of Brimonidine-DDS in patients with GA-AMD	1	13/05/2015	8
15/LO/0438/AM01	Harvoni for Acute GT 1 or 4 HCV and Chronic HIV-1 Co-Infection	Subs. Amend 1	12/06/2015	21
15/LO/0781/AM01	Evaluation of the safety and efficacy of PAD ciclosporin in dry eye patients	1	31/08/2015	12
15/LO/0799/AM01	Monitoring Air Pollution Exposure in Children	1	27/05/2015	12



15/LO/0801/AM01	Metabolic and metagenomic profiling in the characterisation of IBD	1	27/10/2015	33
15/LO/1012/AM01	Acupuncture for cancer patients undergoing Radiotherapy Treatment	1	02/09/2015	9
15/LO/1015/AM01	AQUA	1	07/09/2015	10
15/LO/1027/AM01	The Abatacept Systemic SclErosis Trial (ASSET)	1	01/09/2015	25
15/LO/1190/AM01	Choosing therapy for vitreomacular interface abnormality	1	08/10/2015	19
15/LO/1229/AM01	Safety and Blood levels of DS1971, version1	2	29/09/2015	9
15/LO/1229/AM03	Safety and Blood levels of DS1971, version1	4.0	23/10/2015	27
15/LO/1244/AM01	IVA337 SSc POC	1	10/12/2015	14
15/LO/1401/AM01	LAIV PROTECT	1	23/10/2015	14
15/LO/1401/AM02	LAIV PROTECT	2	25/01/2016	20
15/LO/1402/AM01	HOPE - HF	1	04/11/2015	24
15/LO/1740/AM01	Investigation of the CEJ of unerupted human teeth	1	23/11/2015	7
15/LO/1740/AM02	Investigation of the CEJ of unerupted human teeth	2	09/02/2016	7
15/LO/1903/AM01	A drug interaction study of MT-8554 v1	1	14/12/2015	20
15/LO/1952/AM01	Phase II ALNPCSSC placebocontrolled, doubleblind, cardiology trial	1	16/12/2015	17

#### Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
04/Q0505/21/AM03	EUROSCA, Spinocerebellar ataxia, SCA, polyglutamine, ADCA	Amendment-extending 1 the stud	24/03/2015	21
06/Q0505/22/AM16	CT/PET in patients with interstitial lung disease	11	23/09/2015	13
12/LO/1257/AM17	Oral UT-15C for treatment of Pulmonary Arterial Hypertension (PAH)	10	20/11/2015	34
13/LO/0503/AM06	Asfotase Alfa in infants and children (<5 Years of Age) with HPP	SA10	10/04/2015	31
13/LO/1420/AM03	Sexual and Reproductive Health in psychiatric patients	2	08/02/2016	13
13/LO/1758/AM11	A Safety and Efficacy Study of MK8931 for Prodromal AD v.019-00	SA 6	05/06/2015	27

**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>
04/Q0505/21/AM03/2	EUROSCA, Spinocerebellar ataxia, SCA, polyglutamine, ADCA	3	10/07/2015	9
06/Q0505/22/AM16/1	CT/PET in patients with interstitial lung disease	11	28/10/2015	2
12/LO/1257/AM17/1	Oral UT-15C for treatment of Pulmonary Arterial Hypertension (PAH)	11	27/01/2016	5
13/LO/0503/AM06/1	Asfotase Alfa in infants and children (< 5 Years of Age) with HPP	Amendment 10 (re-submission)	15/07/2015	4
13/LO/1758/AM06/1	A Safety and Efficacy Study of MK8931 for Prodromal AD v.019-00	SA5	01/04/2015	7
13/LO/1758/AM11/1	A Safety and Efficacy Study of MK8931 for Prodromal AD v.019-00	Modified SA 6	10/08/2015	4

<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>
04/Q0505/21/AM03/1	EUROSCA, Spinocerebellar ataxia, SCA, polyglutamine, ADCA	Modified Amendment 2	03/06/2015	1

**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
15/LO/1948	A Patient Information Leaflet and Non specific Abdominal Pain	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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