NHS
Health Research Authority

Research Ethics Service

London - Brent Research Ethics Committee

Annual Report

01 April 2015 - 31 March 2016

Part 1 – Committee Membership and Training

Name of REC:	London - Brent Research Ethics Committee
Type of REC:	REC recognised to review CTIMPS in healthy volunteers - type i REC recognised to review CTIMPS in patients - type iii
Type of Flag:	Qualitative, Research involving children
Chair:	Dr Manish Saxena
Vice-Chair:	Mrs Sunder Chita
Alternate Vice-Chair:	Miss Zainab Yate
REC Manager:	Ms Julie Kidd
REC Assistant:	Mr Suubi Kawooya – March 2016 – present Ms Sivatharshini Sivakumaran – July 2015 to February 2016
Committee Address:	80 London Road Skipton House London SE1 6LH
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Chair's overview of the past year:

The Brent REC had a challenging year with changes in membership; some existing members going on a leave of absence and some new members joining the Committee. During the annual report period, the Committee was pleased to welcome Diana Harvey and Parastoo Babakinejad as new members but was sad to lose Alexander Rakow. The Committee would like to thank Alexander for his contribution and to wish him every success in his new post.

It was also an interesting year with new HRA initiated changes regarding the HRA approval.

The Committee continues to provide specialised review in paediatric, qualitative and Phase 1 pharmaceutical research. Members of the Committee attended a variety of courses throughout the year and shared their learning with the committee.

The Committee performed well in terms of delivering on time, safeguarding participants' safety and facilitating research in a safe and ethical way. We look forward to challenges ahead.

London - Brent Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Mr Suresh Akula	Retired Civil Servant	Lay Plus	13/02/2009	
Dr Parastoo Babakinejad	GP	Expert	01/03/2016	
Mr Babak Babakinejad	Research Postgraduate	Expert	07/10/2011	
Dr Daniel Bradford	Pharmacologist	Expert	01/07/2013	
Mrs Sunder Chita	Manager	Lay Plus	31/07/2005	
Dr Graham Davison	Pharmaceutical Consultant	Expert	08/06/2010	
Dr Anke Furck	Consultant in Paediatric Intensive Care	Expert	10/05/2013	
Mrs Diana Harvey	Lawyer	Lay Plus	04/01/2016	
Mr Maurice Hoffman	Retired	Lay Plus	23/07/2008	
Dr Dusko Ilic	Reader in Stem Cell Science	Expert	02/03/2015	
Mr Adeyemi Olagbegi	Clinical Pharmacology Study Data Manager	Expert	18/05/2007	
Dr Alexander Rakow	Consultant Neonatologist	Expert	04/06/2014	30/03/2016
Dr Manish Saxena	Clinical Lecturer	Expert	30/03/2011	
Dr Zdenek Slavik	Consultant Paediatric Cardiologist/Intensivist	Expert	20/10/2011	
Dr Krishna Soondrum	Consultant Paediatric Gastroenterologist	Expert	01/09/2014	
Miss Ourania Xeniou	Senior Clinical Research Associate	Lay	30/06/2008	
Miss Zainab Yate	Bioethics Researcher	Lay	10/06/2008	

London - Brent Research Ethics Committee: Deputy Members

Name	Profession	Status	Meeting date attended

London - Brent Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended
Dr Andrew Hilson	Consultant in Nuclear Medicine	Expert	September 2015
Mr Roy Sinclair	Pharmacist	Expert	September 2015

London - Brent Research Ethics Committee: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Mr Suresh Akula	Member of Imperial PPI/E Research Committee	27/01/2016
Dr Parastoo Babakinejad	Member of UK Dermatology Clinical Trials Network and British Association of Dermatologist	31/03/2016
Dr Daniel Bradford	Medical contractor for Astellas Pharmaceuticals	31/03/2016
Mrs Sunder Chita	Health Service Research Manager	22/03/2016
Dr Graham Davison	GSK, Clingen, Oxford Biomedica. 1) First time in Man studies2) Early clinical trials	27/01/2016
Dr Anke Furck	Working as a Paediatric Consultant in PICU and Paediatric Cardiology at the Royal Brompton & Harefield NHS Foundation Trust, London	31/03/2016
Mrs Diana Harvey	None	11/01/2016
Mr Maurice Hoffman	Admin Support LNWHT R+D	27/01/2016
Dr Dusko Ilic	Review panel Horizon 2020 (European Commission) 2013 - present.Stem Cells, Regenerative Medicine.	27/01/2016
Mr Adeyemi Olagbegi	Director of Clinical Data supplies	31/03/2016
Dr Alexander Rakow	Private practice,Operation Smile,Neonatal Medical	27/01/2016
Dr Manish Saxena	Advisory to Kona MedicalPrinciple investigator in many academic studies and member of the British hypertension society	27/01/2016
Dr Zdenek Slavik	Member of Medical Board of Chain of Hope Charity and UK Member of Editorial Board: Cos et Vasal, Czech - Slovak Paediatric Journal	31/03/2016
Miss Zainab Yate	None	31/03/2016

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

Month	Date	Number of Members Present at Meeting
April	27/04/2015	10
May	18/05/2015	12
July	27/07/2015	14
August	24/08/2015	5
September	07/09/2015	7
September	21/09/2015	7
October	26/10/2015	10
November	30/11/2015	11
January	25/01/2016	12
February	29/02/2016	11
March	21/03/2016	7

11 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	20/04/2015	3
May	20/05/2015	3
June	22/06/2015	3
July	20/07/2015	3
August	20/08/2015	3
September	21/09/2015	3
October	20/10/2015	3
October	23/10/2015	3
December	16/12/2015	3
January	21/01/2016	3
February	18/02/2016	3
March	17/03/2016	4

12 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	08/04/2015	2
April	23/04/2015	2
May	12/05/2015	2
May	22/05/2015	2
May	26/05/2015	2
June	09/06/2015	3
June	23/06/2015	2

July	08/07/2015	2
July	22/07/2015	2
July	30/07/2015	2
August	05/08/2015	2
August	11/08/2015	2
August	25/08/2015	2
September	04/09/2015	2
September	07/09/2015	2
September	08/09/2015	2
September	22/09/2015	2
October	07/10/2015	2
October	21/10/2015	2
November	11/11/2015	2
November	25/11/2015	2
December	14/12/2015	2
December	28/12/2015	2
January	01/01/2016	2
January	14/01/2016	2
January	29/01/2016	2
February	15/02/2016	2
March	15/03/2016	2

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

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

Date	Reason	Action taken
24/08/2015	Several members did not attend on the day.	Another meeting was set up on 07/09/2015

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

Name	Number of Meetings Attended
Mr Suresh Akula	7
Dr Daniel Bradford	7
Mrs Sunder Chita	9
Dr Graham Davison	8
Dr Anke Furck	5
Mrs Diana Harvey	3
Mr Maurice Hoffman	9
Dr Dusko Ilic	9
Mr Adeyemi Olagbegi	7
Dr Alexander Rakow	6
Dr Manish Saxena	10
Dr Zdenek Slavik	6
Dr Krishna Soondrum	9
Miss Ourania Xeniou	6
Miss Zainab Yate	3

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

Name	Number of Meetings Attended
Mrs Sunder Chita	11
Dr Graham Davison	2
Dr Anke Furck	1
Mr Maurice Hoffman	1
Dr Dusko Ilic	1
Mr Adeyemi Olagbegi	2
Dr Manish Saxena	11
Dr Zdenek Slavik	1
Dr Krishna Soondrum	1
Miss Ourania Xeniou	1
Miss Zainab Yate	5

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

Name	Number of Meetings Attended
Dr Daniel Bradford	1
Mrs Sunder Chita	26
Dr Graham Davison	2
Dr Manish Saxena	27
Miss Zainab Yate	1

Training 01 April 2015 - 31 March 2016

Name of Member	Date	Event(s) attended
Mr Suresh Akula	30/11/2015	Human Tissue Act Presentation
Dr Daniel Bradford	20/05/2015	Training - Equality and Diversity - 20.05.15
Dr Daniel Bradford	18/08/2015	Equality and Diversity
Dr Daniel Bradford	30/11/2015	Human Tissue Act Presentation
Mrs Sunder Chita	30/11/2015	Human Tissue Act Presentation
Dr Graham Davison	30/11/2015	Human Tissue Act Presentation
Dr Anke Furck	29/05/2015	Mental Capacity Act
Dr Anke Furck	30/11/2015	Human Tissue Act Presentation
Mrs Diana Harvey	30/11/2015	Human Tissue Act Presentation
Mr Maurice Hoffman	08/04/2015	Ethics and GCP training
Mr Maurice Hoffman	30/11/2015	Human Tissue Act Presentation
Dr Dusko Ilic	17/06/2015	Induction
Dr Dusko Ilic	22/07/2015	Qualitative Research and Ethics Review
Dr Dusko Ilic	30/11/2015	Human Tissue Act Presentation
Mr Adeyemi Olagbegi	30/11/2015	Human Tissue Act Presentation
Dr Alexander Rakow	30/11/2015	Human Tissue Act Presentation
Dr Manish Saxena	19/05/2015	Chair's NREAP Meeting
Dr Manish Saxena	02/11/2015	Chair's NREAP Meeting
Dr Manish Saxena	30/11/2015	Human Tissue Act Presentation
Dr Zdenek Slavik	28/04/2015	MCA
Dr Zdenek Slavik	30/11/2015	Human Tissue Act Presentation
Dr Krishna Soondrum	30/11/2015	Human Tissue Act Presentation
Miss Ourania Xeniou	30/11/2015	Human Tissue Act Presentation

PART 2: REC WORKLOAD AND ACTIVITY DURING THE REPORTING PERIOD

Table 1: Applications assigned to a full committee meeting held within the reporting period:

Applications for full ethical review – Study Type	Number	%
Clinical Trial of Investigational Medicinal Product	12	29.27
Phase 1	12	29.27
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	1	2.44
Research Database (including renewals)	0	0.00
Others	16	39.02
Total Applications Reviewed	**41**	**100**

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	3
Number of student applications reviewed	6
Number of paediatric applications reviewed	5
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	0
Number of qualitative applications reviewed	1

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

Decisions taken at meetings following review of applications	Number	%
Favourable Opinion with Standard Conditions	5	12.20
Favourable Opinion with Additional Conditions	13	31.71
Unfavourable Opinion	1	2.44
Provisional Opinion	22	53.66
Provisional Opinion Pending Consultation with Referee	1	2.44
Total	**41**	**100**
Number of studies sent back to full committee meeting for final opinion	6	

Table 4: **Summary of current status of applications reviewed during the reporting period**

Status of applications at date of generation of report	Number	%
Further Information Favourable Opinion with Standard Conditions	22	53.66
Further Information Favourable Opinion with Additional Conditions	0	0.00
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	5	12.20
Favourable Opinion with Additional Conditions	13	31.71
Unfavourable Opinion	1	2.44
Provisional Opinion	0	0.00
Provisional Opinion Pending Consultation with Referee	0	0.00
Further Information response not complete	0	0.00
No decision entered on system	0	0.00
Number of studies withdrawn after the meeting	0	0.00
Total	**41**	**100**

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

Total Applications Reviewed	**21**

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

Number of applications made invalid by the REC Manager	2
Number of studies withdrawn prior to the meeting	0
Number of student applications reviewed	11
Number of paediatric applications reviewed	5
Number of device applications reviewed	2
Number of qualitative applications reviewed	5

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

Decisions taken at proportionate review sub-committee meetings	**Number**	**%**
Favourable Opinion with Standard Conditions	8	38.10
Favourable Opinion with Additional Conditions	4	19.05
No Opinion transfer to full committee for review	1	4.76
Provisional Opinion	8	38.10
Unfavourable Opinion	0	0.00
Total	**21**	**100**

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

Average number of applications reviewed per full meeting	3.73
Number of completed applications for full ethical review	41
Number of completed applications for full ethical review over 60 days	0
Number of completed applications over 60 days as a %of total	0.00%
Number of completed applications for full ethical review over 40 days	5
Number of completed applications over 40 days as a %of total	12.20%
Number of days taken to final decision – average (mean)	32

Number of completed proportionate review applications for ethical review	20
Number of completed proportionate review applications for ethical review over 14 days	2
Number of completed proportionate review applications over 14 days as a %of total	10.00%

Number of SSAs (non-Phase 1) reviewed	7
Number of completed applications for SSA review over 25 days	2
Number of completed applications for SSA review over 25 days as %of all non- Phase 1 SSAs	28.57%

Number of SSAs (Phase 1) reviewed	13
Number of completed applications for SSA review over 14 days	0
Number of completed applications for SSA review over 14 days as %of all Phase 1 SSAs	0.00%

Number of substantial amendments reviewed	125
Number of completed substantial amendments over 35 days	0
Number of completed substantial amendments over 35 days as a %of total substantial amendments	0.00%
Number of completed substantial amendments over 28 days	14
Number of completed substantial amendments over 28 days as a %of total substantial amendments	11.20%

Number of modified amendments reviewed	2
Number of completed modified amendments over 14 days	0
Number of completed modified amendments over 14 days as a %of total modified amendments	0.00%

Number of minor amendments received	73
Number of substantial amendments received for	0

information	
Number of substantial amendments received for new sites/PIs	23
Number of annual progress reports received	65
Number of safety reports received	34
Number of Serious Adverse Events received	2
Number of final reports received	28

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

Further Information Favourable Opinion with Standard Conditions		
REC Reference	**Title**	**Number of Days on Clock**
15/LO/0612	A study to assess the effects of AZD9977 single dose on healthy males	25
15/LO/0707	The mediating role of ACT processes in psychological distress	30
15/LO/0970	Safety, blood levels and effects of AUT00206, version 1	26
15/LO/1029	Safety, tolerability, PK & PD of low dose LSD in healthy subjects	24
15/LO/1030	Phase I study to assess the PD of AZD9977 in healthy male subjects	38
15/LO/1301	Safety, blood levels & effects of DS1040 alone or with clopidogrel, v1	27
15/LO/1316	A Study in Healthy Elderly People of a Drug that May Improve Memory.V1	32
15/LO/1331	MP-USS versus MP-MRI for prostate cancer diagnosis	55
15/LO/1415	PK of MMV390048 in healthy volunteers	30
15/LO/1416	Comparing the PK of AZD9977 formulations in healthy male subjects	19
15/LO/1548	GLOOCOSE	60
15/LO/1747	Riociguat in children with PAH	24
15/LO/1780	Microbiomes in Pregnancy	25
15/LO/1798	Phase 1 SAD study to assess Safety, Tolerability, PK & PD of ASP6294	36
16/LO/0087	CATALYST	55
16/LO/0089	MLN0002SC-3027 Vedolizumab SC in Ulcerative Colitis	58
16/LO/0090	MLN0002SC-3031 Vedolizumab SC in Crohn's Disease	40
16/LO/0314	Safety, tolerability, PK & PD of AZD9567 as MAD in volunteers	18
16/LO/0334	GS-US-296-1080, A Study to evaluate the efficacy & safety of GS-5745	34
16/LO/0472	INN-005 protocol	36
16/LO/0489	Experiencing the enhanced recovery pathway for caesarean section.	34
16/LO/0495	Inherited Cardiovascular Diseases Biobank	30

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

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

Favourable Opinion with Standard Conditions		
REC Reference	**Title**	**Number of Days on Clock**
15/LO/0664	Safety, tolerability, PK & PD of LSD in elderly healthy subjects	16
16/LO/0060	Comparing tablets containing ambrisentan and tadalafil; v1	14
16/LO/0348	OPAL cohort study	31
16/LO/0349	The BOOST programme (V1.0)	31
16/LO/0356	ACtiF - Pilot and Feasibility study (WP 3.1)	32

Favourable Opinion with Additional Conditions		
REC Reference	**Title**	**Number of Days on Clock**
15/LO/0714	PASTIS	34
15/LO/0853	Switch Study of Dolutegravir + Rilpivirine in HIV infected adults-636	24
15/LO/0854	Switch Study of Dolutegravir + Rilpivirine in HIV infected adults -637	24
15/LO/1094	Subcutaneous medications for palliative care patients at home	23
15/LO/1333	PADMMA	30
15/LO/1453	ARIES: App to support Recovery in Early Intervention Services	25
15/LO/1556	Entonox as an alternative method of pain relief for IUCD insertion.	24
15/LO/1761	SAMSON trial	23
15/LO/1773	Niemann Pick Type C patient finder	24
15/LO/1779	POP-ECG-HF-AF	24
16/LO/0057	BIOBLOOD	28
16/LO/0351	Multiple dose study of LJN452 in patients with PBAD	32
16/LO/0491	The impact of 12 minute walk test on McArdle patients v.1	27

Unfavourable Opinion		
REC Reference	**Title**	**Number of Days on Clock**
15/LO/0763	MARINAC Study	57

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

Provisional Opinion Pending Consultation with Referee		
REC Reference	**Title**	**Number of Days on Clock**

Further information response not complete		
REC Reference	**Title**	**Number of Days on Clock**

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

Table 9.2: **Breakdown of current status of all PRS applications reviewed within the reporting period**

Further Information Favourable Opinion with Standard Conditions		
REC Reference	**Title**	**Number of Days on Clock**
15/LO/0762	Social behaviour in borderline PD	12
15/LO/0765	Dynamite v1.0	15
15/LO/0963	Assessing the validity and reliability of ultrasound scanning	3
15/LO/1495	Study of T2DM patients using the NAPC patient engagement tool	12
15/LO/1519	Axial Spondyloarthritis Registry	9
15/LO/1893	Fetal MRI in CDH at 3T	13
16/LO/0221	Evaluation of Oxygen-Enhanced MRI in Pulmonary Hypertension	12
16/LO/0399	Diabetic Food Survey (V1)	13

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

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

Favourable Opinion with Standard Conditions		
REC Reference	**Title**	**Number of Days on Clock**
15/LO/0959	Perspectives and ideas surrounding patient education in severe asthma	14
15/LO/0961	Characterisation of Paediatric Myelodysplasic Syndromes	14
15/LO/1177	Genotype-phenotype correlation of oral manifestations of FAP	9
15/LO/1312	SPECTROSCOPIC DIAGNOSIS OF MELANOMA	5
15/LO/1315	Why the urgency?	2
15/LO/2181	ProMOTE Sub Study	4
16/LO/0530	Self-compassion and coping in young people diagnosed with IBD	10
16/LO/0534	Subclinical TWOS and ECG Predictors (STEP Study)	14

Favourable Opinion with Additional Conditions		
REC Reference	**Title**	**Number of Days on Clock**
15/LO/1691	Air pollution and behaviour change study	11
15/LO/1883	Sleep disordered breathing in children with neuromuscular disease	7
15/LO/1890	Music Therapy with Children and Parents: The Dynamics of Expertise v1	13
15/LO/2173	Application of 3D facial imaging in the management of orbital disease	18

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**

Favourable opinion				
Amendment REC Reference	**Title**	**Version**	**Date**	**Number of Days on Clock**
10/H0717/14/AM19	Prognostic Evaluation of Diagnostic IGRA Consortium - UK PREDICT Study	19 (as per HARP)	20/04/2015	6
10/H0717/14/AM22	Prognostic Evaluation of Diagnostic IGRA Consortium - UK PREDICT Study	PREDICT protocol version 10 da	13/07/2015	9
10/H0717/20/AM03	UKOSS: Near-miss maternal morbidity surveillance	3	27/01/2015	4
10/H0717/20/AM04	UKOSS: Near-miss maternal morbidity surveillance	4	19/08/2015	7
10/H0717/20/AM05	UKOSS: Near-miss maternal morbidity surveillance	Amendment 5Í¾ Date: 01/03/2016	02/03/2016	30
10/H0717/3/AM01	Development of a 3-D Model of AML	1	02/11/2014	35
11/H0717/6/AM08	Magnetic Resonance Biomarkers in Neonatal Encephalopathy	8	11/09/2015	19
11/LO/1261/AM07	INOVATYON SECOND LINE CHEMOTHERAPY OVARIAN CANCER	3	03/07/2015	5
11/LO/1261/AM09	INOVATYON SECOND LINE CHEMOTHERAPY OVARIAN CANCER	4	28/09/2015	8
11/LO/1853/AM13	Siltuximab in Patients with High-risk Smoldering Multiple Myeloma	5	12/03/2015	6
11/LO/1869/AM17	A7471009 EFFICACY & SAFETY STUDY OF PF-00299804 VS ERLOTINIB IN NSCLC	3	18/02/2015	26
12/LO/0440/AM37	AMG 785/Placebo in Postmenopausal Women with Osteoporosis- 20070337	AM20	16/11/2015	26
12/LO/0440/AM40	AMG 785/Placebo in Postmenopausal Women with Osteoporosis- 20070337	AM 21	09/02/2016	17
12/LO/0440/AM41	AMG 785/Placebo in Postmenopausal Women with Osteoporosis- 20070337	22	09/02/2016	17
12/LO/0639/AM08	A-PREDICT	5	23/06/2015	7
12/LO/0639/AM14	A-PREDICT	6	27/11/2015	20
12/LO/0781/AM03	SIGNIFY Version 1.6	Amendment 5 (3rd Substantial A	07/09/2015	4
12/LO/1193/AM01	Biological and Functional Characterisation of Bone Marrow Diseases	1; 27/04/15	29/04/2015	2

12/LO/1434/AM07	RENEW study	Amendment 3 15th April 2015	17/04/2015	22
12/LO/1434/AM08	RENEW study	Revision E to F 23/06/2015	28/07/2015	8
12/LO/1472/AM04	EBGen	4.0	24/06/2015	25
12/LO/1876/AM11	GO28141 PhIII Vemurafenib Vs Vemurafenib + GDC-0973 in Melanoma	11	17/03/2015	21
12/LO/1876/AM12	GO28141 PhIII Vemurafenib Vs Vemurafenib + GDC-0973 in Melanoma	Amendment 12; Protocol V5, IB	13/05/2015	23
12/LO/1876/AM13	GO28141 PhIII Vemurafenib Vs Vemurafenib + GDC-0973 in Melanoma	6	15/12/2015	14
12/LO/1950/AM07	C25003 Ph3 A+AVD vs ABVD Frontline in Patients with Hodgkin Lymphoma	Investigator Brochure Ed 12 an	15/04/2015	21
12/LO/1950/AM09	C25003 Ph3 A+AVD vs ABVD Frontline in Patients with Hodgkin Lymphoma	7	22/07/2015	8
12/LO/1950/AM11	C25003 Ph3 A+AVD vs ABVD Frontline in Patients with Hodgkin Lymphoma	AM11 Edition 13	28/11/2015	21
12/LO/1966/AM10	TELESTAR (Telotristat Etiprate for SSA Refractory Carcinoid Syndrome)	5	14/12/2015	6
13/LO/0077/AM08	The HALT Hepatitis Study	Substantial amendment 3; 01.05	12/05/2015	22
13/LO/0386/AM05	Nilotinib treatment-free remission study in CML patients-ENESTFreedom	CAMN107I2201; version 03; date	09/09/2015	27
13/LO/0681/AM04	Multiboost - MCC plus pertussis booster in adolescents	Multiboost; version 5; dt 11/0	21/05/2015	14
13/LO/0681/AM05	Multiboost - MCC plus pertussis booster in adolescents	AM06	08/01/2016	30
13/LO/0855/AM17	Idelalisib in Combination with Rituximab for Previously Treated iNHL	SA #11; Date: 2015/09/24	24/09/2015	12
13/LO/0855/AM20	Idelalisib in Combination with Rituximab for Previously Treated iNHL	6.0	31/07/2015	26
13/LO/1022/AM09	308: Phase 3 study of XL184 vs Everolimus in subjects with RCC	AM09	16/12/2015	10
13/LO/1084/AM02	Phenotype/genotype correlation of inherited corneal dystrophies v1	V3	17/04/2015	10
13/LO/1498/AM01	Developing a smartphone App for HIV care	1	05/08/2015	2

13/LO/1536/AM05	Exenatide-PD	Amendment 5; 25/03/2015	28/04/2015	28
13/LO/1536/AM06	Exenatide-PD	6	16/07/2015	7
13/LO/1618/AM07	TELEPATH (Expanded Treatment for Carcinoid Syndrome Symptoms)	3	12/06/2015	11
13/LO/1618/AM08	TELEPATH (Expanded Treatment for Carcinoid Syndrome Symptoms)	Substantial Amendment 5	12/02/2016	13
13/LO/1666/AM03	The HALT-LTBI Study	Amendment 6 V 5; 01/05/2015	19/05/2015	15
13/LO/1682/AM07	Study of Maintenance Rucaparib in Relapsed High-grade Ovarian Cancer	5	20/03/2015	4
13/LO/1682/AM10	Study of Maintenance Rucaparib in Relapsed High-grade Ovarian Cancer	6	22/07/2015	20
13/LO/1682/AM12	Study of Maintenance Rucaparib in Relapsed High-grade Ovarian Cancer	7	11/09/2015	7
13/LO/1792/AM04	A PET scan study of [18F]-FBA-A20FMDV2; version 1	Protocol amendment 04, dated 1	24/04/2015	28
14/LO/0088/AM03	Onapristone prostate phase 1-2	3	18/02/2015	4
14/LO/0088/AM04	Onapristone prostate phase 1-2	4.0	15/04/2015	12
14/LO/0088/AM05	Onapristone prostate phase 1-2	6.0; 01/07/2015	02/07/2015	32
14/LO/0088/AM07	Onapristone prostate phase 1-2	8.0; Date: 2015/10/07	08/10/2015	13
14/LO/0088/AM08	Onapristone prostate phase 1-2	AM09	12/01/2016	3
14/LO/0117/AM05	Ablation Versus Anti-arrhythmic Therapy in reducing hospital episodes	Substantial Amendment 2 (20th	24/07/2015	14
14/LO/0645/AM02	Colonic Propionate, Appetite and Glucose Homeostasis	3	19/06/2015	9
14/LO/0645/AM03	Colonic Propionate, Appetite and Glucose Homeostasis	Amendment 4, 07/09/2015 (Our R	09/09/2015	2
14/LO/0699/AM03	Phase 2 study with BAY63-2521 in PH associated with IIP	5	23/06/2015	22
14/LO/0699/AM04	Phase 2 study with BAY63-2521 in PH associated with IIP	Substantial Amendment #4, 02 J	24/09/2015	14
14/LO/1070/AM03	Phase 1 TAK-079 Single Dose Escalation Study in Healthy Subjects	Substantial Amendment 3	03/06/2015	7

		Protoc		
14/LO/1070/AM06	Phase 1 TAK-079 Single Dose Escalation Study in Healthy Subjects	Substantial Amendment 4 ICD v6	09/10/2015	4
14/LO/1070/AM07	Phase 1 TAK-079 Single Dose Escalation Study in Healthy Subjects	Substantial Amendment 5 - Prot	21/10/2015	22
14/LO/1284/AM02	Circulating tumour cells in primary lung cancer patients	Substantial Amendment 2; Date:	29/10/2015	10
14/LO/1331/AM02	Chronic viral gastroenteritis in post-transplant patients	2.0	19/06/2015	26
14/LO/1331/AM03	Chronic viral gastroenteritis in post-transplant patients	3	03/08/2015	6
14/LO/1347/AM03	The use of guided self-help in Anorexia Nervosa	Amendment n.2, Date: 10//09/20	16/09/2015	8
14/LO/1356/AM01	WO29217 - Neo-adjuvant Pertuzumab in Breast Cancer	01	14/04/2015	6
14/LO/1356/AM02	WO29217 - Neo-adjuvant Pertuzumab in Breast Cancer	2	17/08/2015	29
14/LO/1392/AM01	Phase 3 study of CT P13 vs Remicade in patients with Crohn's disease	changes to inclusion/exclusion	30/03/2015	7
14/LO/1406/AM03	Open-label study of GDC-0199 in follicular lymphoma patients	3	13/04/2015	14
14/LO/1580/AM01	VX14-770-116: Ph IV - Observational Study for CF Patients	Substantial Amendment 1 Protoc	16/07/2015	21
14/LO/1649/AM01	SAD & MAD study to assess safety tolerability PK PD and FE of AZD7986	AMD 1	12/03/2015	19
14/LO/1649/AM02	SAD & MAD study to assess safety tolerability PK PD and FE of AZD7986	Amendment 1, Final 1.0	21/07/2015	28
14/LO/1691/AM03	Safety, Tolerability & PK of SAD, MAD & FE ASP2205 in Healthy Subjects	2.2	06/07/2015	7
14/LO/1691/AM05	Safety, Tolerability & PK of SAD, MAD & FE ASP2205 in Healthy Subjects	Restart of a Trial	01/09/2015	13
14/LO/1691/AM08	Safety, Tolerability & PK of SAD, MAD & FE ASP2205 in Healthy Subjects	v2.2 dated 10th April 2015	03/11/2015	30
14/LO/1695/AM04	DiPEP: Diagnosis of Pulmonary Embolism (PE) in Pregnancy	new email and letter templates	24/03/2015	23
14/LO/1695/AM05	DiPEP: Diagnosis of Pulmonary Embolism (PE) in Pregnancy	4	17/07/2015	4

14/LO/1695/AM06	DiPEP: Diagnosis of Pulmonary Embolism (PE) in Pregnancy	5	17/12/2015	31
14/LO/1715/AM01	The use of Next Generation sequencing in newborn screening	1; 22.04.2015	06/05/2015	19
14/LO/1715/AM06	The use of Next Generation sequencing in newborn screening	2, Date: 08/10/2015	14/10/2015	2
14/LO/1715/AM07	The use of Next Generation sequencing in newborn screening	AM03	27/01/2016	28
14/LO/1790/AM04	Safety, Tolerability, PK and PD of ALN PCSSC in Elevated LDL-C	3	07/08/2015	9
14/LO/1828/AM02	Single Ascending Intravenous Infusion Study in Healthy Subjects	3	02/04/2015	5
14/LO/1828/AM04	Single Ascending Intravenous Infusion Study in Healthy Subjects	BP29462; version C; 2015/05/18	20/05/2015	11
14/LO/1828/AM05	Single Ascending Intravenous Infusion Study in Healthy Subjects	BP29462:D:2015/07/30	05/08/2015	9
14/LO/1857/AM02	RCT in children with ESES syndrome	AM02	08/05/2015	21
14/LO/1857/AM03	RCT in children with ESES syndrome	AM03	16/06/2015	8
14/LO/2105/AM01	ToSCA: Trial of Sertraline versus CBT for generalised Anxiety	1	09/03/2015	8
14/LO/2105/AM09	ToSCA: Trial of Sertraline versus CBT for generalised Anxiety	8, Date: 16th September 2015	17/09/2015	25
14/LO/2111/AM01	EVOLUTION VERSION 1	1.0	08/04/2015	14
15/LO/0087/AM02	A Phase I Clinical Trial of DARC	4; Version 3.0; 2015/07/17	28/07/2015	13
15/LO/0087/AM03	A Phase I Clinical Trial of DARC	3.0	10/08/2015	7
15/LO/0090/AM01	Safety & efficacy of AMG557/MEDI5872 in Sjogren's syndrome	IRAS resubmission including io	01/04/2015	34
15/LO/0090/AM04	Safety & efficacy of AMG557/MEDI5872 in Sjogren's syndrome	2	20/07/2015	16
15/LO/0090/AM05	Safety & efficacy of AMG557/MEDI5872 in Sjogren's syndrome	Protocol amendment UK 7; Date:	28/09/2015	8
15/LO/0090/AM09	Safety & efficacy of AMG557/MEDI5872 in Sjogren's syndrome	Protocol amendment UK	03/03/2016	29

		17Feb16		
15/LO/0095/AM01	The therapeutic relationship in using the Mental Health Recovery Star	1 13/07/2015	24/07/2015	5
15/LO/0099/AM03	SAATELLITE - Phase 2 study of MEDI4893 in mechanically ventilated pts	Amendment 3, Date: 14 Aug 2015	02/09/2015	16
15/LO/0104/AM03	Albumin To prevenT Infection in chronic liveR failurE (ATTIRE)	Amendment 2; Version 1; Date:	27/07/2015	30
15/LO/0104/AM04	Albumin To prevenT Infection in chronic liveR failurE (ATTIRE)	Substantial Amendment 03, Vers	28/08/2015	6
15/LO/0212/AM01	A study to see if GS-6615 shortens QT interval in patients with LQT3	2	01/07/2015	7
15/LO/0212/AM02	A study to see if GS-6615 shortens QT interval in patients with LQT3	AM02	20/11/2015	32
15/LO/0395/AM03	Single & multiple dose, food effect, gender and age study	Amendment 1, Version: 1, Date:	08/09/2015	2
15/LO/0517/AM01	YOSEMITE Ph 2 study in subjects with Pancreatic Ductal Adenocarcinoma	3	16/04/2015	21
15/LO/0517/AM02	YOSEMITE Ph 2 study in subjects with Pancreatic Ductal Adenocarcinoma	4	11/06/2015	10
15/LO/0612/AM01	A study to assess the effects of AZD9977 single dose on healthy males	1	10/07/2015	6
15/LO/0612/AM02	A study to assess the effects of AZD9977 single dose on healthy males	1	27/08/2015	4
15/LO/0612/AM03	A study to assess the effects of AZD9977 single dose on healthy males	Amendment 3; Date: 2015/10/09	09/10/2015	6
15/LO/0664/AM01	Safety, tolerability, PK & PD of LSD in elderly healthy subjects	1.1	02/07/2015	6
15/LO/0664/AM02	Safety, tolerability, PK & PD of LSD in elderly healthy subjects	1.2	28/07/2015	6
15/LO/0714/AM01	PASTIS	2.0	02/09/2015	6
15/LO/0714/AM02	PASTIS	Substantial Amendment 02; Date	30/10/2015	10
15/LO/0714/AM03	PASTIS	v4	27/01/2016	3
15/LO/0853/AM01	Switch Study of Dolutegravir + Rilpivirine in HIV infected	AM 02	15/06/2015	8

	adults-636			
15/LO/0854/AM01	Switch Study of Dolutegravir + Rilpivirine in HIV infected adults -637	AM 02	15/06/2015	9
15/LO/0970/AM02	Safety, blood levels and effects of AUT00206, version 1	1	11/12/2015	3
15/LO/1029/AM01	Safety, tolerability, PK & PD of low dose LSD in healthy subjects	Amendment 01, Date: 28/10/201	29/10/2015	35
15/LO/1333/AM01	PADMMA	Am1	08/12/2015	14
15/LO/1495/AM01	Study of T2DM patients using the NAPC patient engagement tool	AM01	20/01/2016	15
15/LO/1747/AM02	Riociguat in children with PAH	AM02	24/11/2015	15
15/LO/1761/AM01	SAMSON trial	1.1	04/01/2016	6
15/LO/1761/AM02	SAMSON trial	AM02	06/09/2015	3
15/LO/1780/AM01	Microbiomes in Pregnancy	1	14/01/2016	2
15/LO/2173/AM02	Application of 3D facial imaging in the management of orbital disease	AM01	13/01/2016	16
BEC1050/AM08	Recruiting & screening Healthy Male & Female volunteers	4.0	28/07/2015	15

Unfavourable opinion				
Amendment REC Reference	**Title**	**Version**	**Date**	**Number of Days on Clock**
13/LO/1536/AM07	Exenatide-PD	Amendment 7; Date: 2015/09/21	01/10/2015	35
14/LO/1649/AM04	SAD & MAD study to assess safety tolerability PK PD and FE of AZD7986	1	17/12/2015	34

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**
13/LO/1536/AM07/1	Exenatide-PD	7	22/12/2015	7

14/LO/1649/AM04/2	SAD & MAD study to assess safety tolerability PK PD and FE of AZD7986	Modified SA03	10/12/2015	6

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**
15/LO/0765	Dynamite v1.0	15
15/LO/2173	Application of 3D facial imaging in the management of orbital disease	18

SSAs (non Phase 1) over 25 day timeline		
REC Reference	**Title**	**Number of Days on Clock**
15/LO/1293	A Multicenter, International,	28
15/LO/2118	A Multicenter, International,	32

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**

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