

**London - Brent Research Ethics Committee**

**Annual Report**

**01 April 2016 - 31 March 2017**



## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	London - Brent Research Ethics Committee
<b>Type of REC:</b>	CTIMPS in healthy volunteers- type I, CTIMPS in patients- type III
<b>Type of Flag:</b>	Phase 1 Studies in Healthy Volunteers, Qualitative Research, Research Involving Children
<b>Chair:</b>	Dr Manish Saxena
<b>Vice-Chair:</b>	Mrs Sunder Chita
<b>Alternate Vice-Chair:</b>	Miss Zainab Yate
<b>REC Manager:</b>	Mrs Julie Kidd (2011 - 25/01/2017) Miss Nicole Curtis (26/01/2017 – present)
<b>REC Assistant:</b>	N/A
<b>Committee Address:</b>	80 London Road Skipton House London SE1 6LH
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## Chair's overview of the past year:

The Brent REC had a productive year with in depth ethical review of all applications. This was well supported by sufficient number of lay and expert committee members with diverse backgrounds. During the annual report period, the Committee was pleased to welcome Nicole Curtis as new REC Manager, Dr Prashanth Nandhabalan, Professor Ramesh Kapadia and Miss Alice Glaser as new members but was sad to lose Dr Parastoo Babakinejad, Mr Babak Babakinejad, Mr Adeyemi Olagbegi and REC Manager Mrs Julie Kidd. The Committee would like to thank these members for their contribution and to wish him every success in their new post.

The committee has adapted to the new HRA review process well.

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	Dermatologist	Expert	01/03/2016	04/07/2016
Mr Babak Babakinejad	Research Postgraduate	Expert	07/10/2011	03/10/2016
Dr Daniel Bradford	Pharmacologist	Expert	01/07/2013	
Mrs Sunder Chita	Manager	Lay Plus	31/07/2005	
Dr Graham Davison	Pharmaceutical Consultant	Lay	08/06/2010	
Dr Anke Furck	Consultant in Paediatric Intensive Care	Expert	10/05/2013	
Miss Alice Glaser	Investigator Initiated Trials Coordinator	Expert	01/05/2017	
Mrs Diana Harvey	Lawyer	Lay Plus	04/01/2016	
Mr Maurice Hoffman	Retired Teacher	Lay Plus	23/07/2008	
Dr Dusko Ilic	Reader in Stem Cell Science	Expert	02/03/2015	
Professor Ramesh Kapadia	Retired Education Consultant	Lay Plus	01/01/2017	
Dr Prashanth Nandhabalan	Specialist Registrar in Intensive Care and Anaesthesia	Expert	01/01/2017	
Mr Adeyemi Olagbegi	Clinical Pharmacology Study Data Manager	Expert	18/05/2007	16/01/2017
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	12/10/2008	
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
Mrs Elayne Nasr	Retired School Matron	Lay Plus	22/08/2017

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

<b>Name</b>	<b>Declaration of Interest</b>	<b>Date</b>
Mr Suresh Akula	Member of the BRC - Patient Public Involvement in Research, Committee at Imperial	31/03/2017
Dr Daniel Bradford	Director of own company Yoshi Poshi Sushi Ltd that may be employed by CROs.	29/03/2017
Mrs Sunder Chita	Committee Member of Sikh Charity	31/03/2017
Dr Graham Davison	Shareholdings in GlaxoSmithKline and Oxford Biomedica	23/03/2017
Dr Anke Furck	Consultant in Paediatric Intensive Care and Cardiology at RBHT, London.	31/03/2017
Mrs Diana Harvey	None	29/03/2017
Mr Maurice Hoffman	Chair, central Middlesex Hospital rheumatology Patient support Group Admin support, R&D, LNWH T Lay reviewer NIHR	06/03/2017
Dr Dusko Ilic	I am occasionally reviewing grants or manuscript; not a member of committees or peer review bodies on a regular basis.	06/03/2017
Professor Ramesh Kapadia	None	06/03/2017
Dr Prashanth Nandhabalan	Member - Intensive Care Society Member - Faculty of Intensive Care Medicine	27/03/2017
Dr Manish Saxena	Consultancy work with Kona Medical, Astra Zeneca and Genentech. Member and Fellow British Hypertension Society Member European Society of Hypertension Advisor BP UKUK Chief Investigator/ Coordinating Investigator and Principle Investigator on many commercial and academic studies going on at Barts Health NHS Trust as part of Clinical job.	06/03/2017
Dr Zdenek Slavik	Member of Medical Board, Chain of Hope Charity, London SW3 6NP Member of Editorial Board of the following scientific journals: Cor et Vasa Czech-Slovak Paediatric Journal	22/03/2017
Dr Zdenek Slavik	Member of the editorial board of Cor et Vasa and Czech-Slovak Paediatric Journal	30/11/2016
Dr Krishna Soondrum	None	13/03/2017
Miss Zainab Yate	Breastfeeding Peer Supporter with the NHS. Do online polls and surveys of the site www.breastfeedingaversion.com Owner and author of this site.	24/03/2017

### Meetings for Full Ethical Review 01 April 2016 - 31 March 2017:

Month	Date	Number of Members Present at Meeting
April	25/04/2016	9
May	23/05/2016	13
July	25/07/2016	8
August	22/08/2016	7
September	26/09/2016	7
October	24/10/2016	10
November	28/11/2016	9
January	30/01/2017	11
February	27/02/2017	11
March	27/03/2017	10

10 full committee meetings were held during the reporting period.

### Proportionate Review Sub-Committee Meetings held during 01 April 2016 - 31 March 2017:

Month	Date	Number of Members Present at Meeting
April	12/04/2016	3
May	18/05/2016	3
June	22/06/2016	3
July	20/07/2016	4
September	16/09/2016	3
October	19/10/2016	3
December	14/12/2016	3
January	18/01/2017	3
February	15/02/2017	3
March	16/03/2017	3

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

### Sub-Committee Meetings held during 01 April 2016 - 31 March 2017:

Month	Date	Number of Members Present at Meeting
April	15/04/2016	2
April	28/04/2016	2
May	05/05/2016	2
May	30/05/2016	2
June	07/06/2016	2
June	30/06/2016	2
July	04/07/2016	2
July	14/07/2016	3
August	01/08/2016	5
August	15/08/2016	2
August	29/08/2016	2

September	14/09/2016	2
September	30/09/2016	2
October	17/10/2016	3
October	31/10/2016	3
November	11/11/2016	2
November	18/11/2016	2
November	30/11/2016	2
December	08/12/2016	2
December	22/12/2016	2
January	12/01/2017	2
January	19/01/2017	2
January	26/01/2017	2
February	14/02/2017	2
February	24/02/2017	2
February	28/02/2017	2
March	03/03/2017	2
March	15/03/2017	2
March	17/03/2017	2
March	20/03/2017	2
March	31/03/2017	2

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

#### Details of inquorate meeting held:01 April 2016 - 31 March 2017

None.

**Attendance of Members at full committee meetings:01 April 2016 - 31 March 2017**

<b>Name</b>	<b>Number of Meetings Attended</b>
Mr Suresh Akula	9
Dr Parastoo Babakinejad	2
Dr Daniel Bradford	8
Mrs Sunder Chita	8
Dr Graham Davison	6
Dr Anke Furck	7
Mrs Diana Harvey	7
Mr Maurice Hoffman	9
Dr Dusko Ilic	8
Professor Ramesh Kapadia	2
Dr Prashanth Nandhabalan	2
Mr Adeyemi Olagbegi	3
Dr Alexander Rakow	1
Dr Manish Saxena	9
Dr Zdenek Slavik	6
Dr Krishna Soondrum	4
Miss Ourania Xeniou	1
Miss Zainab Yate	2

**Attendance of Members at proportionate review sub-committee meetings: 01 April 2016 - 31 March 2017**

<b>Name</b>	<b>Number of Meetings Attended</b>
Mr Babak Babakinejad	2
Mrs Sunder Chita	8
Dr Anke Furck	1
Mrs Diana Harvey	3
Dr Dusko Ilic	6
Mr Adeyemi Olagbegi	1
Dr Manish Saxena	9
Dr Krishna Soondrum	1

**Attendance of Members at sub-committee meetings: 01 April 2016 - 31 March 2017**

<b>Name</b>	<b>Number of Meetings Attended</b>
Dr Daniel Bradford	4
Mrs Sunder Chita	27
Dr Graham Davison	1
Mrs Diana Harvey	1



Dr Dusko Ilic	2
Mr Adeyemi Olagbegi	1
Dr Manish Saxena	31
Dr Krishna Soondrum	1

**Training 01 April 2016 - 31 March 2017**

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Mr Suresh Akula	27/03/2017	Data Protection Training
Dr Daniel Bradford	27/03/2017	Data Protection Training
Mrs Sunder Chita	27/03/2017	Data Protection Training
Dr Graham Davison	16/11/2016	Members Training Day
Dr Graham Davison	29/11/2016	Equality and Diversity
Dr Graham Davison	16/02/2017	National Members Training Day
Dr Graham Davison	27/03/2017	Data Protection Training
Mrs Diana Harvey	16/11/2016	Members Training Day
Mrs Diana Harvey	01/02/2017	Medical Devices
Mrs Diana Harvey	16/02/2017	National Members Training Day
Mrs Diana Harvey	15/03/2017	Equality and Diversity
Mrs Diana Harvey	27/03/2017	Data Protection Training
Mr Maurice Hoffman	16/02/2017	National Members Training Day
Mr Maurice Hoffman	27/03/2017	Data Protection Training
Dr Dusko Ilic	11/04/2016	Ethics & GCP Forum ICR
Dr Dusko Ilic	11/05/2016	Assessing the Consequences (benefits& harms) of research: a health research authority workshop
Dr Dusko Ilic	24/05/2016	Phase 1 research - trials & regulations
Dr Dusko Ilic	20/02/2017	Equality, Diversity and Human Rights
Dr Dusko Ilic	27/03/2017	Data Protection Training
Dr Prashanth Nandhabalan	14/03/2017	Committee Members Induction
Dr Prashanth Nandhabalan	27/03/2017	Data Protection Training
Dr Manish Saxena	04/05/2016	Regional Chairs' Meeting
Dr Manish Saxena	07/11/2016	Regional Chairs' Meeting
Dr Manish Saxena	27/03/2017	Data Protection Training
Miss Zainab Yate	21/03/2017	Online conference (iLactation) - ethical decision making
Miss Zainab Yate	27/03/2017	Data Protection Training

## PART 2: REC WORKLOAD AND ACTIVITY DURING THE REPORTING PERIOD

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

<b>Applications for full ethical review – Study Type</b>	<b>Number</b>	<b>%</b>
Clinical Trial of Investigational Medicinal Product	9	21.43
Phase 1	13	30.95
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	0	0.00
Others	20	47.62
<b>Total Applications Reviewed</b>	<b>42</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	6
Number of device applications reviewed	3
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	2	4.76
Favourable Opinion with Additional Conditions	5	11.90
Unfavourable Opinion	0	0.00
Provisional Opinion	35	83.33
Provisional Opinion Pending Consultation with Referee	0	0.00
<b>Total</b>	<b>42</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	29	69.05
Further Information Favourable Opinion with Additional Conditions	5	11.90
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	2	4.76
Favourable Opinion with Additional Conditions	5	11.90
Unfavourable Opinion	0	0.00
Provisional Opinion	1	2.38
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>42</b>	<b>100</b>

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

<b>Total Applications Reviewed</b>	<b>28</b>
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**Table 6: Breakdown of PRS applications and other activity during reporting period:**

Number of applications made invalid by the REC Manager	3
Number of studies withdrawn prior to the meeting	0
Number of student applications reviewed	10
Number of paediatric applications reviewed	9
Number of device applications reviewed	1
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	18	64.29
Favourable Opinion with Additional Conditions	2	7.14
No Opinion transfer to full committee for review	1	3.57
Provisional Opinion	7	25.00
Unfavourable Opinion	0	0.00
<b>Total</b>	<b>28</b>	<b>100</b>

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

<b>Average number of applications reviewed per full meeting</b>	4.20
<b>Number of completed applications for full ethical review</b>	42
<b>Number of completed applications for full ethical review over 60 days</b>	0
<b>Number of completed applications over 60 days as a % of total</b>	0.00%
<b>Number of completed applications for full ethical review over 40 days</b>	11
<b>Number of completed applications over 40 days as a % of total</b>	26.19%
<b>Number of days taken to final decision – average (mean)</b>	35
<b>Number of completed proportionate review applications for ethical review</b>	27
<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>	11.11%
<b>Number of SSAs (non-Phase 1) reviewed</b>	10
<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>	14
<b>Number of completed applications for SSA review over 14 days</b>	1
<b>Number of completed applications for SSA review over 14 days as % of all Phase 1 SSAs</b>	7.14%
<b>Number of substantial amendments reviewed</b>	128
<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>	0.78%
<b>Number of completed substantial amendments over 28 days</b>	19
<b>Number of completed substantial amendments over 28 days as a % of total substantial amendments</b>	14.84%
<b>Number of modified amendments reviewed</b>	1
<b>Number of completed modified amendments over 14 days</b>	0
<b>Number of completed modified amendments over 14 days as a % of total modified amendments</b>	0.00%
<b>Number of non substantial amendments received</b>	95
<b>Number of substantial amendments received for information</b>	1
<b>Number of substantial amendments received for new sites/Pis</b>	26
<b>Number of annual progress reports received</b>	61

<b>Number of safety reports received</b>	68
<b>Number of Serious Adverse Events received</b>	2
<b>Number of final reports received</b>	33

**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>
16/LO/0590	Safety PK PD 3part SAD MAD FE study with KVD818 in healthy adult males	28
16/LO/0796	LAA-Occluder Trial OCC2012-02, Version 6, 27NOV2016	47
16/LO/0797	VX15-770-124 Cystic Fibrosis	33
16/LO/0809	PAT-1251 SAD/MAD in Healthy Adult Subjects	24
16/LO/0813	Safety, Tolerability, PK and PD of MT-7117 in Healthy Subjects	34
16/LO/0818	Vestibular retraining exercises and the impact on falls prevention	46
16/LO/0897	DMT Imaging	48
16/LO/0913	KERALINK	40
16/LO/0919	MEDI4736 with Tremelimumab in advanced solid tumours	39
16/LO/1273	Point of care lactate measurement	58
16/LO/1286	Potential Impact of Microbiome on Assisted Reproductive Treatment	60
16/LO/1507	RADAR Trial	52
16/LO/1511	Alere HBsAg Rapid Test version 001	34
16/LO/1661	Online Needs for Young People with Cancer	23
16/LO/1699	Investigating the intrahepatic milieu in HBV therapy	27
16/LO/1825	DP13 SAD/MAD in Healthy Volunteers	33
16/LO/1854	F/TAF for pre-exposure HIV-1 prophylaxis in men & transgender women	40
16/LO/1857	Lynch syndrome-the assessment of identification at MDT	41
16/LO/1876	FIH, Safety & PK Trial Assessing PIN201104 in HVs & Asthmatic Patients	36
16/LO/1890	Semaglutide effect on Furosemide & Rosuvastatin PK in healthy subjects	29
16/LO/1911	Safety, Tolerability and PK of TOP1288 in Healthy Volunteers	34
16/LO/2026	Phase 2 - Sofosbuvir/Velpatasvir for Chronic HCV Infection	31
17/LO/0032	CFHealthHub Data Observatory	39
17/LO/0035	ACtiF - RCT and parallel process evaluation (WP 3.2 and 3.3)	31
17/LO/0202	Pain, Mood, Illness Perceptions and Fatigue in Juvenile Arthritis	38
17/LO/0288	Bronchoscopic evaluation of the Eosinophilic Airway Microbiome (BEAM)	43
17/LO/0303	MAPPS: Study of the mediators and predictors of psychosis v.4	40
17/LO/0306	REGN3918 Single and Multiple dose study	33
17/LO/0317	A study to examine LY3002815 in healthy subjects	27

**Further Information Favourable Opinion with Additional Conditions**



REC Reference	Title	Number of Days on Clock
16/LO/1280	Autism and Homelessness	57
16/LO/1328	Distinct Experiences in Epilepsy - Version 1	45
16/LO/1493	A PET scan study of TAK-041; version 1	23
16/LO/2023	An Evaluation of the Coping Through Football Programme	30
17/LO/0156	Safety, Tolerability and PK of ASP7713 in Healthy Volunteers	34

#### 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
16/LO/1687	Aortic Replacement using individualised regenerative Allografts- ARISE	18
16/LO/2067	OPTIMISE II	25

#### Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/LO/0456	Safety, Tolerability, PK and PD of MAD of inhaled AZD8871	18
16/LO/1266	A PSG study in healthy volunteers after single oral dose sep-380262 v1	21
16/LO/1267	A PET study to assess brain uptake of SEP-380255 v1	25
16/LO/1450	M14-031: Venetoclax in Relapsed/Refractory Multiple Myeloma	42
16/LO/1781	LUTONIX Global AV Registry	20

#### Unfavourable Opinion

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

REC Reference	Title	Number of Days on Clock
17/LO/0389	Psilodep-RCT	n/a

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

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

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

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

<b>Further Information Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
16/LO/0713	The Experience of Facial Prosthesis	13
16/LO/0855	The Effect of Total Knee Arthroplasty on Patients' Weight	11
16/LO/1152	Reading, Literature, and Dignity in a Hospice environment (Exeter)	13
16/LO/1376	The INForMeD Study	14
16/LO/1396	Adolescent's experience of Medically Unexplained Symptoms	14
17/LO/0154	TRAITS-HFpEF	17
17/LO/0314	Methods of collecting traumatic brain injury outcomes	13

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

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

<b>Favourable Opinion with Standard Conditions</b>		
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REC Reference	Title	Number of Days on Clock
16/LO/0703	Self-Efficacy and Mood as predictors of Weight Change- Version 1	10
16/LO/0723	Comparing levels of Physical Activity in Children with Type 1 Diabetes	13
16/LO/0947	Comparison of attachment levels in BPE scores 3 between age groups	8
16/LO/0957	Rheumatoid Arthritis Microbiome Study	11
16/LO/0960	Genetic and epigenetic changes underpinning rare childhood tumours	1
16/LO/1203	Interdental Spacing and Perceived Smile aesthetics. Version 1.8	10
16/LO/1212	CARES	13
16/LO/1218	Optimizing Vitamin D Status in Children with Wheeze / Asthma (OPTIVIT)	6
16/LO/1372	FLU08E A-EnhancedA passiveA safetyA surveillanceA ofA VaxigripA andA Intanza15	14
16/LO/1734	Joint Hypermobility Syndrome Focus Groups	5
16/LO/1739	Safety-netting in primary care consultations	7
16/LO/1741	Statin use and malignant progression in non-dysplastic Barrett's	7
16/LO/1930	UVB Treatment in Paediatric Atopic Dermatitis	6
16/LO/1942	FoPAS: Forefoot pressure after first MTPJ silastic replacement	3
16/LO/2224	PEARL	15
16/LO/2225	STRIDER: Phase Two Follow-up	15
16/LO/2248	Biological Determinants of HRQL and pain in myeloma	13
17/LO/0155	p53 in Endometrial Carcinoma	11

#### Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/LO/0945	Does the UKDDQ measure dietary change?	13
16/LO/1935	Short-Term Clinical Evaluation of SEED 1-Day Pure Moisture Lens	7

#### Unfavourable Opinion

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

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

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

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

<b>Favourable opinion</b>				
<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>
09/H0717/25/AM01	Genetics of common age-related eye diseases, Version 1	1	15/06/2016	30
10/H0717/14/AM26	Prognostic Evaluation of Diagnostic IGRA Consortium - UK PREDICT Study	AM26	26/02/2016	26
10/H0717/20/AM06	UKOSS: Near-miss maternal morbidity surveillance	6	11/07/2016	31
11/LO/1853/AM16	Siltuximab in Patients with High-risk Smoldering Multiple Myeloma	INT-6	09/05/2016	12
12/LO/0282/AM01	Novel Cancer Biomarkers in Blood and Urine	Amendment 1	09/08/2016	13
12/LO/0440/AM48	AMG 785/Placebo in Postmenopausal Women with Osteoporosis- 20070337	1	20/06/2016	10
12/LO/0440/AM51	AMG 785/Placebo in Postmenopausal Women with Osteoporosis- 20070337	Amendment 28 - Safety Informat	28/07/2016	11
12/LO/0440/AM52	AMG 785/Placebo in Postmenopausal Women with Osteoporosis- 20070337	AM52	28/08/2016	3
12/LO/0639/AM16	A-PREDICT	7	08/11/2016	4
12/LO/1876/AM14	GO28141 PhIII Vemurafenib Vs Vemurafenib + GDC-0973 in Melanoma	7	05/07/2016	31
12/LO/1876/AM15	GO28141 PhIII Vemurafenib Vs Vemurafenib + GDC-0973 in Melanoma	15	22/12/2016	25
12/LO/1950/AM16	C25003 Ph3 A+AVD vs ABVD Frontline in Patients with Hodgkin Lymphoma	14	21/10/2016	2
13/LO/0386/AM06	Nilotinib treatment-free remission study in CML patients- ENESTFreedom	4	12/05/2016	22
13/LO/0386/AM07	Nilotinib treatment-free remission study in CML patients- ENESTFreedom	7	21/12/2016	11
13/LO/0538/AM02	TREAT Evaluation	2.0	29/02/2016	2
13/LO/0681/AM06	Multiboost - MCC plus pertussis booster in adolescents	7	29/07/2016	15
13/LO/0681/AM07	Multiboost - MCC plus pertussis booster in adolescents	V7	29/07/2016	7
13/LO/0681/AM09	Multiboost - MCC plus pertussis booster in adolescents	V7	29/07/2016	2
13/LO/1022/AM10	308: Phase 3 study of XL184 vs Everolimus in subjects with RCC	12.0	19/07/2016	9
13/LO/1084/AM03	Phenotype/genotype correlation of inherited corneal	V4	05/09/2016	4

	dystrophies v1			
13/LO/1491/AM03	Volatile Organic Compounds as Biomarkers of Malignant Melanoma	AM03	19/02/2016	25
13/LO/1618/AM09	TELEPATH (Expanded Treatment for Carcinoid Syndrome Symptoms)	SA7	25/08/2016	5
13/LO/1682/AM13	Study of Maintenance Rucaparib in Relapsed High-grade Ovarian Cancer	8	10/03/2016	24
13/LO/1682/AM14	Study of Maintenance Rucaparib in Relapsed High-grade Ovarian Cancer	9	24/08/2016	6
14/LO/0088/AM09	Onapristone prostate phase 1-2	10.0	27/05/2016	3
14/LO/0117/AM07	Ablation Versus Anti-arrhythmic Therapy in reducing hospital episodes	3	19/01/2017	32
14/LO/0699/AM05	Phase 2 study with BAY63-2521 in PH associated with IIP	AM05	11/05/2016	11
14/LO/0699/AM07	Phase 2 study with BAY63-2521 in PH associated with IIP	6	02/06/2016	27
14/LO/0699/AM08	Phase 2 study with BAY63-2521 in PH associated with IIP	#7	20/07/2016	20
14/LO/1284/AM04	Circulating tumour cells in primary lung cancer patients	3; Date: 22 Jan 2016	23/02/2016	31
14/LO/1347/AM04	The use of guided self-help in Anorexia Nervosa	3	26/01/2017	7
14/LO/1356/AM04	WO29217 - Neo-adjuvant Pertuzumab in Breast Cancer	3	13/07/2016	41
14/LO/1356/AM05	WO29217 - Neo-adjuvant Pertuzumab in Breast Cancer	4	24/11/2016	6
14/LO/1357/AM13	A Study to Investigate Single and Multiple Doses of TD139	AM13	26/04/2016	35
14/LO/1406/AM04	Open-label study of GDC-0199 in follicular lymphoma patients	Substantial Amendment 4	01/09/2016	20
14/LO/1695/AM07	DiPEP: Diagnosis of Pulmonary Embolism (PE) in Pregnancy	6	07/03/2016	28
14/LO/2103/AM02	PKPD of intravenous salbutamol in paediatric acute severe asthma	Substantial Amendment 1	29/07/2016	28
14/LO/2103/AM03	PKPD of intravenous salbutamol in paediatric acute severe asthma	2	10/02/2017	6
14/LO/2111/AM02	EVOLUTION VERSION 1	2.0	09/06/2016	11
14/LO/2111/AM03	EVOLUTION VERSION 1	Amendment Number 3.0	17/08/2016	13
15/LO/0090/AM10	Safety & efficacy of AMG557/MEDI5872 in Sjogren's syndrome	Sub Am 6 - Updated Recruitment	12/04/2016	27
15/LO/0099/AM04	SAATELLITE - Phase 2 study of MEDI4893 in mechanically ventilated pts	1.0	30/03/2016	15

15/LO/0104/AM08	Albumin To prevent Infection in chronic liver failure (ATTIRE)	1.0	16/06/2016	7
15/LO/0517/AM03	YOSEMITE Ph 2 study in subjects with Pancreatic Ductal Adenocarcinoma	5	21/07/2016	34
15/LO/0970/AM03	Safety, blood levels and effects of AUT00206, version 1	3	14/03/2016	21
15/LO/1029/AM03	Safety, tolerability, PK & PD of low dose LSD in healthy subjects	Substantial Amendment 02	18/08/2016	14
15/LO/1331/AM03	MP-USS versus MP-MRI for prostate cancer diagnosis	001	01/01/2016	7
15/LO/1331/AM05	MP-USS versus MP-MRI for prostate cancer diagnosis	2	04/10/2016	17
15/LO/1333/AM02	PADMMA	Amendment 2, dated 08 February	16/02/2016	9
15/LO/1333/AM03	PADMMA	3	26/05/2016	14
15/LO/1333/AM07	PADMMA	4.0	26/01/2017	3
15/LO/1453/AM01	ARIES: App to support Recovery in Early Intervention Services	1	03/03/2016	34
15/LO/1453/AM02	ARIES: App to support Recovery in Early Intervention Services	2	22/12/2016	24
15/LO/1691/AM01	Air pollution and behaviour change study	1	02/03/2016	32
15/LO/1747/AM03	Riociguat in children with PAH	3	01/03/2016	1
15/LO/1747/AM05	Riociguat in children with PAH	Substantial Amendment 3	29/07/2016	30
15/LO/1761/AM03	SAMSON trial	1.1	11/12/2015	6
15/LO/1761/AM04	SAMSON trial	1.1	12/11/2015	31
15/LO/1779/AM03	POP-ECG-HF-AF	1	28/02/2017	28
15/LO/2173/AM03	Application of 3D facial imaging in the management of orbital disease	2	31/05/2016	13
16/LO/0060/AM01	Comparing tablets containing ambrisentan and tadalafil; v1	1.0	04/05/2016	2
16/LO/0060/AM02	Comparing tablets containing ambrisentan and tadalafil; v1	02	08/02/2017	7
16/LO/0087/AM04	CATALYST	2.0	22/09/2016	4
16/LO/0089/AM01	MLN0002SC-3027 Vedolizumab SC in Ulcerative Colitis	Protocol Amendment 02, 10th Fe	17/03/2016	5
16/LO/0089/AM03	MLN0002SC-3027 Vedolizumab SC in Ulcerative Colitis	2	19/07/2016	28
16/LO/0089/AM04	MLN0002SC-3027 Vedolizumab SC in Ulcerative Colitis	AM04	10/11/2016	7
16/LO/0090/AM01	MLN0002SC-3031 Vedolizumab SC in Crohn's Disease	1	21/03/2016	30
16/LO/0090/AM02	MLN0002SC-3031 Vedolizumab SC in Crohn's Disease	02	19/07/2016	35
16/LO/0090/AM05	MLN0002SC-3031 Vedolizumab SC in Crohn's Disease	AM05	14/11/2016	3
16/LO/0314/AM01	Safety, tolerability, PK & PD of AZD9567 as MAD in volunteers	1.0	07/04/2016	31
16/LO/0314/AM03	Safety, tolerability, PK & PD of AZD9567 as MAD in volunteers	2	04/08/2016	11

16/LO/0334/AM01	GS-US-296-1080, A Study to evaluate the efficacy&safety of GS-5745	Edition 4	21/06/2016	3
16/LO/0334/AM02	GS-US-296-1080, A Study to evaluate the efficacy&safety of GS-5745	Protocol Amendment 4	22/06/2016	10
16/LO/0334/AM03	GS-US-296-1080, A Study to evaluate the efficacy&safety of GS-5745	5.0	04/10/2016	6
16/LO/0334/AM04	GS-US-296-1080, A Study to evaluate the efficacy&safety of GS-5745	AM04	22/11/2016	5
16/LO/0348/AM03	OPAL cohort study	03	27/01/2017	21
16/LO/0349/AM07	The BOOST programme (V1.0)	No. 07	02/02/2017	21
16/LO/0351/AM03	Multiple dose study of LJN452 in patients with PBAD	SA2	25/10/2016	6
16/LO/0356/AM01	ACTiF - Pilot and Feasibility study (WP 3.1)	1	14/04/2016	5
16/LO/0356/AM02	ACTiF - Pilot and Feasibility study (WP 3.1)	2	11/08/2016	7
16/LO/0356/AM03	ACTiF - Pilot and Feasibility study (WP 3.1)	3	17/11/2016	6
16/LO/0456/AM01	Safety, Tolerability, PK and PD of MAD of inhaled AZD8871	2.0	18/05/2016	28
16/LO/0456/AM03	Safety, Tolerability, PK and PD of MAD of inhaled AZD8871	Clinical Study Protocol Versio	05/10/2016	13
16/LO/0472/AM03	INN-005 protocol	Amendment 1	02/09/2016	11
16/LO/0491/AM01	The impact of 12 minute walk test on McArdle patients v.1	1.0	21/06/2016	6
16/LO/0534/AM01	Subclinical TWOS and ECG Predictors (STEP Study)	AM01	20/10/2016	1
16/LO/0590/AM01	Safety PK PD 3part SAD MAD FE study with KVD818 in healthy adult males	1	06/06/2016	14
16/LO/0590/AM03	Safety PK PD 3part SAD MAD FE study with KVD818 in healthy adult males	Substantial Amendment 2, Proto	27/07/2016	12
16/LO/0590/AM04	Safety PK PD 3part SAD MAD FE study with KVD818 in healthy adult males	5.0	04/11/2016	8
16/LO/0590/AM05	Safety PK PD 3part SAD MAD FE study with KVD818 in healthy adult males	4	19/01/2017	17
16/LO/0703/AM01	Self-Efficacy and Mood as predictors of Weight Change-Version 1	1	18/04/2016	31
16/LO/0796/AM02	LAA-Occluder Trial OCC2012-02, Version 6, 27NOV2016	1	14/07/2016	27
16/LO/0796/AM03	LAA-Occluder Trial OCC2012-02, Version 6, 27NOV2016	02	10/08/2016	5
16/LO/0796/AM04	LAA-Occluder Trial OCC2012-02, Version 6, 27NOV2016	3	11/11/2016	4
16/LO/0797/AM01	VX15-770-124 Cystic Fibrosis	1	07/07/2016	32
16/LO/0797/AM02	VX15-770-124 Cystic Fibrosis	SA02	11/08/2016	14



16/LO/0797/AM03	VX15-770-124 Cystic Fibrosis	3	05/01/2017	10
16/LO/0809/AM01	PAT-1251 SAD/MAD in Healthy Adult Subjects	3.0	23/06/2016	2
16/LO/0809/AM02	PAT-1251 SAD/MAD in Healthy Adult Subjects	AM02	30/09/2016	7
16/LO/0813/AM01	Safety, Tolerability, PK and PD of MT-7117 in Healthy Subjects	Substantial Amendment 1	04/08/2016	16
16/LO/0813/AM02	Safety, Tolerability, PK and PD of MT-7117 in Healthy Subjects	Substantial Amendment 2	22/09/2016	8
16/LO/0813/AM04	Safety, Tolerability, PK and PD of MT-7117 in Healthy Subjects	AM04	07/11/2016	8
16/LO/0897/AM01	DMT Imaging	Amendment 1	05/09/2016	13
16/LO/0913/AM01	KERALINK	Substantial Amendment 1	15/08/2016	12
16/LO/0913/AM02	KERALINK	AM02	23/01/2017	14
16/LO/0919/AM01	MEDI4736 with Tremelimumab in advanced solid tumours	SA#1	07/09/2016	14
16/LO/0919/AM04	MEDI4736 with Tremelimumab in advanced solid tumours	SA#3	23/09/2016	7
16/LO/0960/AM01	Genetic and epigenetic changes underpinning rare childhood tumours	1	13/01/2017	35
16/LO/1218/AM02	Optimizing Vitamin D Status in Children with Wheeze / Asthma (OPTIVIT)	AM02	15/09/2016	2
16/LO/1266/AM01	A PSG study in healthy volunteers after single oral dose sep-380262 v1	Substantial Amendment 1	21/10/2016	11
16/LO/1266/AM02	A PSG study in healthy volunteers after single oral dose sep-380262 v1	2	22/12/2016	25
16/LO/1286/AM01	Potential Impact of Microbiome on Assisted Reproductive Treatment	1	12/01/2017	12
16/LO/1372/AM03	FLU08E Enhanced passive safety surveillance of Vaxigrip and Intanza15	1	07/12/2016	6
16/LO/1450/AM02	M14-031: Venetoclax in Relapsed/Refractory Multiple Myeloma	1	09/12/2016	3
16/LO/1493/AM01	A PET scan study of TAK-041; version 1	01	07/10/2016	13
16/LO/1493/AM02	A PET scan study of TAK-041; version 1	2	29/11/2016	20
16/LO/1507/AM01	RADAR Trial	1	23/12/2016	24
16/LO/1661/AM01	Online Needs for Young People with Cancer	1	18/01/2017	10
16/LO/1825/AM03	DP13 SAD/MAD in Healthy Volunteers	3	10/02/2017	10
16/LO/1854/AM01	F/TAF for pre-exposure HIV-1 prophylaxis in men & transgender women	1	16/12/2016	27
16/LO/1854/AM02	F/TAF for pre-exposure HIV-1 prophylaxis in men &	AM02	17/02/2017	13

	transgender women			
16/LO/1876/AM01	FIH, Safety & PK Trial Assessing PIN201104 in HVs & Asthmatic Patients	1	02/12/2016	9
16/LO/1890/AM01	Semaglutide effect on Furosemide & Rosuvastatin PK in healthy subjects	1	30/11/2016	26
16/LO/1911/AM01	Safety, Tolerability and PK of TOP1288 in Healthy Volunteers	1	12/01/2017	25
16/LO/1911/AM02	Safety, Tolerability and PK of TOP1288 in Healthy Volunteers	Substantial Amendment 2	14/02/2017	3
16/LO/2026/AM01	Phase 2 - Sofosbuvir/Velpatasvir for Chronic HCV Infection	SA#01	08/02/2017	27
BEC 657/AM04	Donation of samples of human material for use in assays of potential	Amendment 18	22/07/2016	25

#### Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
15/LO/0099/AM05	SAATELLITE - Phase 2 study of MEDI4893 in mechanically ventilated pts	4	29/11/2016	35

**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
15/LO/0099/AM05/1	SAATELLITE - Phase 2 study of MEDI4893 in mechanically ventilated pts	4	29/11/2016	9

#### Unfavourable opinion timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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**Table 11: Items exceeding timelines****Full applications for ethical review over 60 day timeline**

REC Reference	Title	Number of Days on Clock
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**Proportionate review applications for ethical review over 14 day timeline**

REC Reference	Title	Number of Days on Clock
16/LO/2224	PEARL	15
16/LO/2225	STRIDER: Phase Two Follow-up	15
17/LO/0154	TRAITS-HFpEF	17

**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
16/LO/1487	A Single-blind, Placebo-control	28

**Substantial Amendments over 35 day timeline**

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
14/LO/1356/AM04	WO29217 - Neo-adjuvant Pertuzumab in Breast Cancer	3	13/07/2016	41

**Modified Amendments over 14 day timeline**

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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