Health Research Authority

Research Ethics Service

London - Riverside Research Ethics Committee

Annual Report

01 April 2017 - 31 March 2018

Part 1 – Committee Membership and Training

Name of REC:	London - Riverside Research Ethics Committee
Type of REC:	RECs recognised to review CTIMPS in healthy volunteers - type i, RECs recognised to review CTIMPS in patients - type iii
Type of Flag:	Phase 1 In healthy volunteers Paediatric
Chair:	Dr Margaret Jones
Vice-Chair:	Dr Matthew Hyde
Alternate Vice-Chair:	Mrs Dinah Smith
REC Manager:	Miss Tina Cavaliere
REC Assistant:	Mr Paolo Buscemi 15/03/2018 to present date Rebecca Howling 18/12/2018 to 15/03/2018 Charlotte Ferris from 20/03/2017 to 31/10/2017
Committee Address:	Level 3 Block B Whitefriars Lewins Mead Bristol BS1 2NT
Telephone:	0207104 8204
Email:	nrescommittee.london-riverside@nhs.net

Chair's overview of the past year:

Our committee has once again reviewed interesting and diverse studies. We welcome the variety of applications which we receive, together with the opportunities to meet the researchers who attend our committee meetings.
We are fortunate to have hardworking and supportive committee members who willingly share their extensive expertise and enthusiasm. We are most grateful for all the work which members do both when they attend the meetings and also with the sub-committee work which is undertaken in correspondence. Our members are keen to facilitate high quality research and are all committed to the HRA's core purposes of protecting and promoting the interests of patients and the public.

Our members use the meetings with researchers to emphasise the need for public and patient involvement both in the overall design of research and especially in the design and content of the participant information sheets.
This year, we have welcomed a new member, Ms Maria Rosala. We are grateful for the work of our vice chairman, Dr Matthew Hyde and our alternate vice chairman, Mrs Dinah Smith.

Once again, we are most grateful to our Manager, Ms Tina Cavaliere who provides us with unfailing support. She has extensive experience and expertise which she shares with patience and good humour. We have also been grateful for the help which we have received from the other administrative staff; we thank Mrs Cathy Chesham for assistance in finding suitable venues for our meetings.

We look forward to working and understanding the new process for clinical trials which will apply under the EU CT regulations.

Margaret Jones

London - Riverside Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Dr Marina Cecelja	Centre Career Establishment Fellow	Expert	03/12/2015	
Dr Irina Chis Ster	Senior Lecturer In Biostatistics	Expert	02/12/2015	
Ms Stephanie Ellis BEM	Former Civil Servant	Lay Plus	01/09/2012	
Dr Nuria Gonzalez-Cinca	Clinical Study Manager	Lay	14/03/2016	
Ms Alison Higgs	Lecturer in Social Work	Lay	22/05/2017	
Dr Matthew Hyde	Research Scientist	Expert	01/09/2009	
Dr Margaret Jones	Retired General Practitioner	Expert	26/09/2007	
Ms Alexandra Mancini	Pan London Lead for Neonatal/Palliative Care	Expert	06/04/2009	12/10/2017
Ms Fanny Mitchell	Retired NHS Manager	Lay Plus	01/10/2009	
Dr Lorraine Murphy	Pharmaceutical Consultant	Expert	13/07/2016	
Miss Maria Rosala	Senior User Experience Researcher & Ethics Lead	Lay Plus	11/01/2018	
Mr Kamen Shoylev	Lawyer	Lay Plus	01/12/2011	
Mrs Dinah Smith	Retired Head Teacher	Lay Plus	11/06/2013	
Ms Julia Williams	Senior Producer	Lay Plus	13/06/2013	

London - Riverside Research Ethics Committee: Deputy Members

Name	Profession	Status	Meeting date attended

London - Riverside Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended
Dr John Morton Broughall	Retired (Ex Medical Scientific Liaison)	Lay	02/10/2017
Mrs Diana Harvey	Solicitor	Lay Plus	03/07/2017

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

Name	Declaration of Interest	Date
Dr Marina Cecelja	None	25/01/2018
Dr Irina Chis Ster	Local Ethics Committee at St George's University of London.	23/01/2018
Ms Stephanie Ellis BEM	None	23/01/2018
Dr Nuria Gonzalez-Cinca	European Commission review (expert member).	04/02/2018
Ms Alison Higgs	Lecturer, Open University (Health and Social Care social work).	23/02/2018
Dr Matthew Hyde	Member of Neonatal Society. Employee of Imperial College London.	23/01/2018
Dr Margaret Jones	Hold shares in Smith & Nephew.	23/01/2018
Ms Fanny Mitchell	None	23/01/2018
Dr Lorraine Murphy	Pharmaceutical consultant working with numerous companies on a contractual basis. Shares in Novartis and small biotech. Diagnostic companies e.g. Verona, Angle, Sphere Medical, Maxcyte, MotifBio, Valirx, Vernalis.	23/01/2018
Miss Maria Rosala	Member of an ethics board in the Home Office, peer review of research proposals by fellow colleagues.	17/02/2018
Mrs Dinah Smith	None	23/01/2018
Ms Julia Williams	None	23/01/2018
Mr Kamen Shoylev	None	05/03/2018

Meetings for Full Ethical Review 01 April 2017 - 31 March 2018:

Month	Date	Number of Members Present at Meeting
April	03/04/2017	10
June	05/06/2017	9
July	03/07/2017	8
August	07/08/2017	10
September	04/09/2017	10
October	02/10/2017	11
November	06/11/2017	9
December	04/12/2017	10
January	08/01/2018	8
March	05/03/2018	11

10 full committee meetings were held during the reporting period.

Proportionate Review Sub-Committee Meetings held during 01 April 2017 - 31 March 2018:

Month	Date	Number of Members Present at Meeting
May	04/05/2017	3
May	23/05/2017	3
June	30/06/2017	3
August	02/08/2017	3
September	06/09/2017	3
October	04/10/2017	3
November	01/11/2017	3
January	03/01/2018	3
January	31/01/2018	3
March	29/03/2018	3

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

Sub-Committee Meetings held during 01 April 2017 - 31 March 2018:

Month	Date	Number of Members Present at Meeting
April	07/04/2017	2
April	14/04/2017	2
April	21/04/2017	2
April	28/04/2017	2

May	05/05/2017	2
May	12/05/2017	2
May	12/05/2017	2
May	19/05/2017	2
May	26/05/2017	2
June	02/06/2017	2
June	09/06/2017	2
June	16/06/2017	4
June	23/06/2017	3
June	30/06/2017	2
July	07/07/2017	2
July	14/07/2017	2
July	21/07/2017	2
July	28/07/2017	2
August	04/08/2017	2
August	11/08/2017	2
August	18/08/2017	2
August	25/08/2017	2
September	01/09/2017	2
September	08/09/2017	2
September	15/09/2017	2
September	22/09/2017	2
September	29/09/2017	2
October	06/10/2017	2
October	13/10/2017	2
October	20/10/2017	2
October	27/10/2017	2
November	03/11/2017	2
November	10/11/2017	3
November	17/11/2017	3
November	24/11/2017	4
December	01/12/2017	2
December	08/12/2017	3
December	15/12/2017	2
December	22/12/2017	2
December	29/12/2017	3
January	05/01/2018	2
January	12/01/2018	4
January	19/01/2018	2
January	26/01/2018	2
February	02/02/2018	2
February	09/02/2018	2
February	16/02/2018	2
February	23/02/2018	2
March	02/03/2018	2
March	09/03/2018	2
March	16/03/2018	2
March	23/03/2018	2
March	30/03/2018	2

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

Details of inquorate meeting held: 01 April 2017 - 31 March 2018

None

Attendance of Members at full committee meetings: 01 April 2017 - 31 March 2018

Name	Number of Meetings Attended
Dr Marina Cecelja	5
Dr Irina Chis Ster	8
Ms Stephanie Ellis BEM	10
Dr Nuria Gonzalez-Cinca	7
Ms Alison Higgs	7
Dr Matthew Hyde	8
Dr Margaret Jones	9
Ms Fanny Mitchell	7
Dr Lorraine Murphy	9
Miss Maria Rosala	1
Mr Kamen Shoylev	5
Mrs Dinah Smith	10
Ms Julia Williams	8

Attendance of Members at proportionate review sub-committee meetings: 01 April 2017 - 31 March 2018

Name	Number of Meetings Attended
Dr Marina Cecelja	2
Dr Irina Chis Ster	2
Ms Stephanie Ellis BEM	2
Dr Nuria Gonzalez-Cinca	3
Ms Alison Higgs	2
Dr Matthew Hyde	5
Dr Margaret Jones	6
Dr Lorraine Murphy	2
Mr Kamen Shoylev	1
Mrs Dinah Smith	4

Attendance of Members at sub-committee meetings: 01 April 2017 - 31 March 2018

Name	Number of Meetings Attended
Dr Marina Cecelja	5
Dr Irina Chis Ster	4
Ms Stephanie Ellis BEM	8
Dr Nuria Gonzalez-Cinca	7
Ms Alison Higgs	3
Dr Matthew Hyde	25
Dr Margaret Jones	25
Ms Fanny Mitchell	7

Dr Lorraine Murphy	9
Mr Kamen Shoylev	5
Mrs Dinah Smith	13
Ms Julia Williams	6

Training 01 April 2017 - 31 March 2018

Name of Member	Date	Event(s) attended
Dr Marina Cecelja	08/05/2017	Good Clinical Practice and the Medicines for Human Use (Clinical Trials) Regulations (Refresher)
Dr Marina Cecelja	04/12/2017	HARP Member Portal Training
Dr Irina Chis Ster	04/12/2017	HARP Member Portal Training
Ms Stephanie Ellis BEM	12/04/2017	Attended HRA Patient and Public Involvement Workshop
Ms Stephanie Ellis BEM	12/04/2017	Northwick Park - round table discussions and lessons learned
Ms Stephanie Ellis BEM	12/04/2017	Improving Information Sheets
Ms Stephanie Ellis BEM	10/05/2017	ShED 22- Phase 2 review analysis
Ms Stephanie Ellis BEM	24/11/2017	HRA National Chairs' Day and Policy
Ms Stephanie Ellis BEM	04/12/2017	HARP Member Portal Training
Ms Stephanie Ellis BEM	12/12/2017	National Members Training Day
Dr Nuria Gonzalez-Cinca	13/06/2017	Equality Diversity and Human Rights
Dr Nuria Gonzalez-Cinca	04/12/2017	HARP Member Portal Training
Dr Nuria Gonzalez-Cinca	12/12/2017	National Members Training Day
Dr Nuria Gonzalez-Cinca	07/02/2018	Introduction into Phase 1 Research- Trial and Regulation
Ms Alison Higgs	14/11/2017	Increased understanding of complex cases
Ms Alison Higgs	04/02/2018	Developed understanding of key ethical issues
Dr Matthew Hyde	12/09/2017	Genetic and Genomic Research
Dr Matthew Hyde	04/12/2017	HARP Member Portal training
Dr Margaret Jones	24/11/2017	National Chairs' Day and Policy Event
Dr Margaret Jones	04/12/2017	HARP Member Portal Training
Dr Margaret Jones	12/12/2017	National Members Training Day
Ms Fanny Mitchell	04/12/2017	HARP Member Portal Training
Ms Fanny Mitchell	13/03/2018	Confidentiality Consent/assent Research on children Medical devices Drug development Blinding Role of CAG Law and Ethics Compassionate & Innovative treatment of children Caldecott/ Fraser
Dr Lorraine Murphy	04/12/2017	HARP Member Portal Training
Dr Lorraine Murphy	16/01/2018	Reading UK Policy framework for Health and Social care research
Dr Lorraine Murphy	18/01/2018	Medical Devices
Dr Lorraine Murphy	18/01/2018	Research involving human tissue
Dr Lorraine Murphy	18/01/2018	Use of HRA Schedule of Events
Dr Lorraine Murphy	20/02/2018	EMA guidelines on strategies to identify and mitigate risks in FIH

		clinical trials
Dr Lorraine Murphy	24/03/2018	Approval for research involving ionising radiation
Miss Maria Rosala	25/02/2018	Induction for RES members
Miss Maria Rosala	27/02/2018	Equality Diversity and Human Rights
Mr Kamen Shoylev	04/12/2017	HARP Member Portal Training
Mrs Dinah Smith	23/05/2017	Training - Medical Devices Training Day
Mrs Dinah Smith	04/12/2017	HARP Member Portal Training
Ms Julia Williams	04/12/2017	HARP Member Portal Training
Ms Julia Williams	06/03/2018	Data protection and Cyber security. BBC online training course
Ms Julia Williams	12/03/2018	How to review a phase 1 study
Ms Julia Williams	12/03/2018	Capacity and research. Definition, Assessment and Promotion
Ms Julia Williams	17/03/2018	Consent and assent for Children's research
Ms Julia Williams	19/03/2018	What is fair risk and benefit in research involving children and young people
Ms Julia Williams	19/03/2018	General Data Protection – Rachel Smith video presentation (You tube)

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	17	31.37
Phase 1	4	7.84
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	1	1.96
Others	29	58.82
Total Applications Reviewed	**51**	**100**

Table 2: Breakdown of full applications and other activity during reporting period

Number of applications made invalid by the REC Manager	3
Number of applications withdrawn prior to the meeting	3
Number of student applications reviewed	13
Number of paediatric applications reviewed	12
Number of device applications reviewed	1
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	2

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	10	19.61
Favourable Opinion with Additional Conditions	4	7.84
Unfavourable Opinion	4	7.84
Provisional Opinion	33	64.71
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	**51**	**100**
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**

Status of applications at date of generation of report	Number	%
Further Information Favourable Opinion with Standard Conditions	32	62.75
Further Information Favourable Opinion with Additional Conditions	0	0.00
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	10	19.61
Favourable Opinion with Additional Conditions	4	7.84
Unfavourable Opinion	4	7.84
Provisional Opinion	0	0.00
Provisional Opinion Pending Consultation with Referee	0	0.00
Further Information response not complete	1	1.96
No decision entered on system	0	0.00
Number of studies withdrawn after the meeting	0	0.00
Total	**51**	**100**

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

Total Applications Reviewed	**25**

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	6
Number of student applications reviewed	9
Number of paediatric applications reviewed	2
Number of device applications reviewed	1
Number of qualitative applications reviewed	6

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	12	48.00
Favourable Opinion with Additional Conditions	0	0.00
No Opinion transfer to full committee for review	3	12.00
Provisional Opinion	10	40.00
Unfavourable Opinion	0	0.00
Total	**25**	**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	5.10
Number of completed applications for full ethical review	51
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	9.80%
Number of days taken to final decision – average (mean)	32

Number of completed proportionate review applications for ethical review	22
Number of completed proportionate review applications for ethical review over 21 days	1
Number of completed proportionate review applications over 21 days as a % of total	4.55%

Number of SSAs (non-Phase 1) reviewed	3
Number of completed applications for SSA review over 25 days	0
Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs	0.00%

Number of SSAs (Phase 1) reviewed	3
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	159
Number of completed substantial amendments over 35 days	1
Number of completed substantial amendments over 35 days as a % of total substantial amendments	0.63%
Number of completed substantial amendments over 28 days	10
Number of completed substantial amendments over 28 days as a % of total substantial amendments	6.29%

Number of modified amendments reviewed	16
Number of completed modified amendments over 14 days	1
Number of completed modified amendments over 14 days as a % of total modified amendments	6.25%

Number of non substantial amendments received	109
Number of substantial amendments received for information	1
Number of substantial amendments received for new sites/PIs	28
Number of annual progress reports received	81
Number of safety reports received	75
Number of Serious Adverse Events received	2
Number of final reports received	7

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**
17/LO/0473	Phase 2 study ATR-101 for the Treatment of Cushing's Syndrome	29
17/LO/0474	IMR-SCD-OBS - PK and PD of Hydroxyurea in Sickle Cell Disease	33
17/LO/0504	Study to evaluate a mepolizumab autoinjector in severe asthma	37
17/LO/0927	CITADEL-202: Safety and Efficacy of INCB050465 in B-Cell Lymphoma	38
17/LO/0933	SAPPHIRE - A randomised study for participants with RVO	31
17/LO/0935	Changes in Structure & Blood flow of GBM in response to CRT	30
17/LO/1049	iCareWean	45
17/LO/1083	Life after discharge from Intensive Care: relatives stories	33
17/LO/1089	TB-RISK version 1.1	37
17/LO/1098	The ACPGBI Robotic Registry	31
17/LO/1260	RADIO	35
17/LO/1267	The DEPICT study	27
17/LO/1284	Safety, Tolerability, PK and PD of DDA945 in Healthy Volunteers	34
17/LO/1306	REACH 3	34
17/LO/1395	Study CLEE011G2301 (EarLEE-1) in High Risk Early Breast Cancer	40
17/LO/1398	EUROPOP study	31
17/LO/1438	WIN-HD	27
17/LO/1491	Psychological aspects of egg donation	31
17/LO/1531	INGENIOS	41
17/LO/1635	HMB-ICU (V1 31Aug17)	36
17/LO/1650	Atrial Fibrillation Screening in General Practice by Pharmacists	39
17/LO/1865	Combination therapy with isatuximab in patients with multiple myeloma	38
17/LO/1867	Social information processing in adolescents with eating disorders	39
17/LO/1875	Renal Adjuvant MultiPle Arm Randomised Trial (RAMPART)	48
17/LO/1906	Gender Dysphoria and Autism: The Development of Gender Identity	58
17/LO/1947	RENOIR V1.1	25
18/LO/0038	Ethical issues in mitochondrial disorders	32
18/LO/0325	Vinblastine +/- Bevacizumab for treatment of pediatric LGG	24
18/LO/0355	REFALS	32
18/LO/0380	Phase 1 PK and PD study of BIA 5-1058 in healthy subjects (QCL118167)	28
18/LO/0381	1368-0005 BI 655130 in patients with active ulcerative colitis	47
18/LO/0387	Proof-of-Concept Study of Neflamapimod	37

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**
17/LO/1010	PKGReg	23
17/LO/1301	STILE version 1.0	24
17/LO/1360	What Outcomes do Young People Who Self-harm Expect from Therapy	25
17/LO/1442	Phase 1 PK study of ivermectin (W0035) oral suspensions (QCL118100)	24
17/LO/1504	Investigating the Effects of Kisspeptin on Human Brain Processing	24
17/LO/1627	Pharmacokinetic Study of NER1006 in Healthy Subjects (QCL117983)	29
17/LO/1674	Following up gender diverse young people referred to adult services	24
17/LO/1830	QUEST-PR	27
18/LO/0023	Developing and validating SAM	35
18/LO/0358	Application of wearable neuroimaging to map infant cognitive function	25

Favourable Opinion with Additional Conditions		
REC Reference	**Title**	**Number of Days on Clock**
17/LO/1077	AmBeR UCD: Can we measure ammonia in breath sample? Version 1	24
17/LO/1942	TULIP - SYD985 vs Physician’s Choice for HER2-positive Breast Cancer	24
17/LO/2018	PETRAM study	21
18/LO/0032	Improving adherence in nonadherent kidney transplant patients	30

Unfavourable Opinion		
REC Reference	**Title**	**Number of Days on Clock**
17/LO/0803	EUROPOP study	24
17/LO/1099	Investigating the Effects of Kisspeptin on Human Brain Processing	24

17/LO/1879	Evaluating MEDI0382 vs Placebo in Patients with Type 2 Diabetes	24
17/LO/1992	Does Patient Centred Care improve medication Adherence?	40

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**
18/LO/0016	Individual variability in training response	n/a

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**
17/LO/1340	An acute study investigating the impact of resistant starch on satiety	14
17/LO/1489	QUALITATIVE STUDY ON ACL INJURY DIAGNOSIS DELAY - PATIENT PERSPECTIVE	15
17/LO/1490	Managing malnutrition in later life	20
17/LO/1702	CORE BLOOD - blood samples for generation of cell lines	22
17/LO/1895	Developing a safety-netting intervention V1	20
18/LO/0066	CHILDREN'S PERSPECTIVES OF ALVEOLAR BONE GRAFTING	12
18/LO/0067	Placental Pathophysiology	8
18/LO/0216	Immunological and imaging features of spondyloarthritis	14
18/LO/0219	geko VLU efficacy study	10

18/LO/0535	Genomics and Proteomics in Coronary Artery Disease (Version 1.0)	12

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**
17/LO/0888	Haemopoietic self renewal and differentiation	9
17/LO/0892	Chart review in Cutaneous T-cell lymphoma	14
17/LO/1121	Resilience, well-being and relationships in couples with dementia	7
17/LO/1259	Long term results of trapeziectomy alone vs with FCR suspension v1.6	17
17/LO/1697	COPD in Illicit Drug Users	9
17/LO/1890	Improve Biological Sample Collection	16
17/LO/1897	The role of time perspective in self-care in type 1 diabetes	12
18/LO/0060	National Neonatal Early Respiratory Care Study	4
18/LO/0061	Research Governance of Dementia Studies (RGDS)	6
18/LO/0215	UVEA-Brig	14
18/LO/0531	Reconstructive burden of wider excision margins	14
18/LO/0532	Advanced MRI for vestibular schwannomas	14

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

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

Provisional Opinion

REC Reference	Title	Number of Days on Clock

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

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

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

Favourable opinion				
Amendment REC Reference	**Title**	**Version**	**Date**	**Number of Days on Clock**
07/H0706/81/AM26	Molecular basis of chronic inflammatory and degenerative diseases	Amendment 25	02/11/2017	18
08/H0706/100/AM24	Phase II AZD2281 in platinum sensitive serous ovarian cancer	Patient ID Card v3.0 27 October 2016	27/10/2016	29
08/H0706/100/AM25	Phase II AZD2281 in platinum sensitive serous ovarian cancer	8	19/05/2017	7
09/H0706/20/AM09	Genetic basis of craniofacial malformations	1 January 2018	01/01/2018	7
09/H0706/35/AM10	Immune reconstitution studies in cord blood transplantation. Vn 1.1	5	03/07/2017	4
09/H0706/62/AM05	Aetiopathogenesis of penile in-situ cancer and invasive penis cancer-2	Amendment 5 16/11/2017	16/11/2017	11
10/H0706/65/AM68	ARISTOTLE	SA #47	30/11/2017	12
11/LO/1162/AM04	Non-Hodgkin's Lymphoma in Young Adults	Amendment 3 - February 2017	22/02/2017	8
12/LO/1506/AM14	HGS1006-C1121 Phase 3 study of belimumab plus SoC in Lupus Nephritis	PA06	18/05/2017	8
12/LO/1506/AM15	HGS1006-C1121 Phase 3 study of belimumab plus SoC in Lupus Nephritis	Substantial Amendment 8	23/02/2017	15
12/LO/1506/AM16	HGS1006-C1121 Phase 3 study of belimumab plus SoC in Lupus Nephritis	14	05/07/2017	7
12/LO/2019/AM11	Breast Screening and Monitoring Study	8	12/06/2017	20
12/LO/2019/AM12	Breast Screening and Monitoring Study	9	24/07/2017	10
12/LO/2019/AM13	Breast Screening and Monitoring Study	10	19/12/2017	27
13/LO/0002/AM27	Efficacy & safety of GS-1101 with Ofatumumab in previously treated CLL	SA17	11/10/2017	21
13/LO/0002/AM28	Efficacy & safety of GS-1101 with Ofatumumab in previously treated CLL	2018/01/05 SA#18	05/01/2018	20
13/LO/0242/AM13	GE180 and microglial activation in AD and MCI subjects	Amendment 6 22/06/2016	22/06/2016	29
13/LO/0242/AM14	GE180 and microglial activation in AD and MCI subjects	Amendment 7 10 November 2017	14/11/2017	21
13/LO/0254/AM02	Profiling and culturing of neuroblastoma and soft tissue sarcoma cells	Amendment 2 8th Jan 2018	07/03/2018	9
13/LO/0699/AM24	ELAD study	SA17	01/06/2017	15

13/LO/0699/AM29	ELAD study	SA19 05.01.18	05/01/2018	9
13/LO/0822/AM13	VinCaP	8	13/07/2017	6
13/LO/1152/AM08	An exploratory breast lead interval study (EBLIS)	Amendment 8 19.05.2017	19/05/2017	11
13/LO/1198/AM03	Exacerbations in severe asthma patients: mechanisms and biomarkers	4.0	25/04/2017	13
13/LO/1463/AM25	InterAACT A Multicentre Randomised Phase II Advanced Anal Cancer Trial	Sub Amendment 14- Change PI & update recruitment. 2017/02/08	13/12/2017	21
13/LO/1463/AM26	InterAACT A Multicentre Randomised Phase II Advanced Anal Cancer Trial	7 - Amendment 15- update RSI	08/02/2018	11
13/LO/1787/AM05	PROFILE Study Version 1.1	7	28/08/2017	6
13/LO/1787/AM07	PROFILE Study Version 1.1	Amendment 8 16.01.2018	14/02/2018	17
14/LO/0022/AM11	Randomised Phase II study in untreated advanced renal cell carcinoma	9.0	14/06/2017	19
14/LO/0022/AM12	Randomised Phase II study in untreated advanced renal cell carcinoma	10.0	04/07/2017	9
14/LO/0528/AM25	SAD Safety, PK&PD of IV GSK2831781 in HV & patients with psoriasis	SA12	26/06/2017	8
14/LO/0528/AM28	SAD Safety, PK&PD of IV GSK2831781 in HV & patients with psoriasis	13	26/10/2017	15
14/LO/0813/AM06	CanACT feasibility	4	06/06/2017	10
14/LO/0818/AM20	MK-3475 versus SOC in 1L Subjects with PD-L1 Strong Metastatic NSCLC	SA11	04/08/2017	16
14/LO/0818/AM21	MK-3475 versus SOC in 1L Subjects with PD-L1 Strong Metastatic NSCLC	SA12	29/09/2017	13
14/LO/1102/AM06	Helping Urgent Care Users Cope with Distress about Physical Complaints	amendment 3 27.11.17	27/11/2017	6
14/LO/1169/AM16	dHCP	10.0	04/05/2017	7
14/LO/1169/AM17	dHCP	11.0	22/05/2017	10
14/LO/1169/AM19	dHCP	Amendment 12.0, 31.01.2018	14/02/2018	1
14/LO/1192/AM10	Bosutinib vs Imatinib in Newly Diagnosed CML	1	06/06/2017	7
14/LO/1192/AM12	Bosutinib vs Imatinib in Newly Diagnosed CML	SA08	09/10/2017	12

14/LO/1192/AM13	Bosutinib vs Imatinib in Newly Diagnosed CML	AV001_SA09_Pfizer, Imatinib Patient Emergency Card	07/11/2017	27
14/LO/1194/AM04	Neurophysiology in disorders of glycinergic neurotransmisson	3	01/08/2017	7
14/LO/1293/AM09	Study of Effectiveness and Safety of SD-101 in Subjects with Epidermolysis Bullosa	005	11/05/2017	3
14/LO/1464/AM08	Natural History of Acute Hepatic Porphyria (AHP)	Amendment 3Í¾ 30-JAN-2018	30/01/2018	2
14/LO/1490/AM21	Study of Nivolumab in patients with Melanoma	5	09/05/2017	7
14/LO/1490/AM22	Study of Nivolumab in patients with Melanoma	6	29/09/2017	32
14/LO/1490/AM23	Study of Nivolumab in patients with Melanoma	Rev Protocol 05, Incorporating Amendment 06	29/01/2018	1
14/LO/2071/AM07	Healthy Start, Happy Start: Helping parents with children's behaviour	5	09/05/2017	13
14/LO/2071/AM08	Healthy Start, Happy Start: Helping parents with children's behaviour	6	17/08/2017	7
15/LO/0121/AM12	A Phase I/II trial of MK-3475 (pembrolizumab) in children’s solid tumors and lymphoma	MK-3475-051	12/05/2017	10
15/LO/0121/AM14	A Phase I/II trial of MK-3475 (pembrolizumab) in children’s solid tumors and lymphoma	SA18 - Protocol 07 + IB15 + PI	10/01/2018	14
15/LO/0242/AM01	GENPET: Targeted FCH-PET-CT imaging based on genetic profile	v1.0 11.08.2017	11/08/2017	26
15/LO/0571/AM02	ALERT	SA2	26/06/2017	4
15/LO/1119/AM06	ARTESiA: Apixaban in patients with device-detected sub-clinical AF	6.0	14/09/2017	2
15/LO/1120/AM04	ODYSSEY (Once daily DTG-based ART in young people vs standard therapy)	Protocol V3.0	13/03/2017	10
15/LO/1138/AM04	SVR SOF Cirrhosis Registry Study	4	07/04/2017	14
15/LO/1138/AM05	SVR SOF Cirrhosis Registry Study	7	31/03/2017	22
15/LO/1138/AM09	SVR SOF Cirrhosis Registry Study	SA07	09/10/2017	22
15/LO/1138/AM10	SVR SOF Cirrhosis Registry Study	SA 09: Sofosbuvir/Velpatasvir/	05/12/2017	8
15/LO/1236/AM08	NEOD001 versus placebo in AL Amyloidosis	NEOD001	12/06/2017	14
15/LO/1236/AM09	NEOD001 versus placebo in AL Amyloidosis	Substantial Am #8 -	12/01/2018	13

		Main ICF v6 & Protocol amd #3 06/11/17		
15/LO/1238/AM08	CUTHIVAC002	AM07	10/04/2017	10
15/LO/1246/AM05	MM-141-07-02-02 (CARRIE) Pancreatic Cancer Phase 2	3	26/04/2017	11
15/LO/1419/AM14	PEARLS (pembrolizumab as adjuvant treatment for lung cancer)	MK3475-091	02/08/2017	14
15/LO/1419/AM16	PEARLS (pembrolizumab as adjuvant treatment for lung cancer)	Substantial Amendment #5– Investigator's Brochure Edition 15, dated 18 September 2017Inve	10/11/2017	13
15/LO/1432/AM08	RIM4DMD	2.0	21/07/2017	27
15/LO/1432/AM09	RIM4DMD	5	29/09/2017	3
15/LO/1635/AM05	ABACUS	Amendment 5 (SA004)	07/12/2017	22
15/LO/1665/AM11	Safetxt: a randomised controlled trial of a safer sex intervention	10	28/02/2018	22
15/LO/1729/AM05	VX15-770-123 - Cystic Fibrosis study for 3-5 year olds	SA04 Protocol Amend	25/05/2017	14
15/LO/2008/AM06	MK1439A in treatment naÃ¯ve HIV1 infected subjects with NNRTI transmitt	SA07 MK-1439A-030	27/03/2017	13
15/LO/2008/AM07	MK1439A in treatment naÃ¯ve HIV1 infected subjects with NNRTI transmitt	SA08	23/05/2017	14
15/LO/2008/AM08	MK1439A in treatment naÃ¯ve HIV1 infected subjects with NNRTI transmitt	SA09	14/06/2017	16
15/LO/2008/AM09	MK1439A in treatment naÃ¯ve HIV1 infected subjects with NNRTI transmitt	SA10	24/08/2017	7
15/LO/2008/AM10	MK1439A in treatment naÃ¯ve HIV1 infected subjects with NNRTI transmitt	11	13/10/2017	9
15/LO/2034/AM08	A Phase Ib study of pembrolizumab plus chemotherapy in TNBC	SA05	15/08/2017	13
15/LO/2034/AM10	A Phase Ib study of pembrolizumab plus chemotherapy in TNBC	SA06- IB 15 Update	08/11/2017	23
15/LO/2073/AM08	KEYNOTE-158	SA06 MK-3475-158	28/03/2017	13
15/LO/2073/AM09	KEYNOTE-158	SA07	09/06/2017	21
15/LO/2073/AM13	KEYNOTE-158	SA11 - Change of CI	09/02/2018	14

16/LO/0006/AM10	Safety and Biomarker Study with EPI-589 in Parkinson's Disease	2017/09/29	29/09/2017	13
16/LO/0021/AM11	NEOD001 versus placebo in AL Amyloidosis with cardiac dysfunction	NEOD-001 Protocol Am 3	29/11/2017	8
16/LO/0333/AM10	Phase II Study of Pembrolizumab in Advanced Recurrent Ovarian Cancer	SA04	21/08/2017	14
16/LO/0333/AM11	Phase II Study of Pembrolizumab in Advanced Recurrent Ovarian Cancer	SA06	24/10/2017	20
16/LO/0333/AM12	Phase II Study of Pembrolizumab in Advanced Recurrent Ovarian Cancer	SA07 - Protocol 01 + PIS/ICF A	21/02/2018	18
16/LO/0443/AM11	A multicentre, open-label, randomised ITP study	8.0	19/10/2017	14
16/LO/0542/AM10	CYNAPSUS CTH-301	#SA05	18/10/2017	15
16/LO/0545/AM01	iMYC	Substantial amendment 1- Protocol version 3	13/03/2017	27
16/LO/0545/AM02	iMYC	Substantial Amendment 2 - Halt to Recruitment. 16.01.18	16/01/2018	5
16/LO/0952/AM02	TARGET3D	5.0	29/05/2017	35
16/LO/1106/AM11	A Phase III Study of Pembrolizumab + Chemotherapy in 1L TNBC	SA08 - Updated MK-3475 risk language - PIS/CF V7 and ePROs. la	05/09/2017	33
16/LO/1106/AM12	A Phase III Study of Pembrolizumab + Chemotherapy in 1L TNBC	SA09	19/10/2017	12
16/LO/1161/AM08	COBALT: Coversin in patients with PNH	5	28/06/2017	13
16/LO/1342/AM02	Mephedrone administration study	1.0	30/08/2017	11
16/LO/1342/AM03	Mephedrone administration study	Substantial amendment 2, 06 February 2018	05/02/2018	10
16/LO/1354/AM03	LY2951742 in Patients with Episodic or Chronic Cluster Headache	5	01/08/2017	7
16/LO/1354/AM04	LY2951742 in Patients with Episodic or Chronic Cluster Headache	I5Q-MC-CGAR-IB 2017_ICF V6_Addenda 1.2.2017/05/30	04/12/2017	2

16/LO/1355/AM02	InPACT	2	17/08/2017	14
16/LO/1390/AM01	APAChe	1.1	15/05/2017	6
16/LO/1624/AM02	An Open-Label Extension Trial to Assess the Long-Term Safety of ZX008	Protocol Am2-01NOV2016	15/03/2017	29
16/LO/1624/AM03	An Open-Label Extension Trial to Assess the Long-Term Safety of ZX008	5.0	26/07/2017	15
16/LO/1624/AM04	An Open-Label Extension Trial to Assess the Long-Term Safety of ZX008	AM04 - Protocol Am3.0 + PIS/IC	09/10/2017	8
16/LO/1709/AM04	4296: NASH-Semaglutide in subjects with non-alcoholic steatohepatitis	2	11/05/2017	10
16/LO/1709/AM06	4296: NASH-Semaglutide in subjects with non-alcoholic steatohepatitis	4	08/09/2017	28
16/LO/1718/AM01	Neonatal Resuscitation - Sustained Inflations	Amendment 1 11/1/18	02/02/2018	12
16/LO/1879/AM05	Network dysfunction following paediatric traumatic brain injury	Amendment number 1 (07/12/2017	07/12/2017	19
16/LO/1915/AM02	Mental Health and Psychological Wellbeing Drop-In Centre	2	06/06/2017	18
16/LO/1919/AM05	Sarizotan in Patients with Rett Syndrome with Respiratory Symptoms	Protocol Amend 4, v5.0, ICFs UK v3.0	23/03/2017	20
16/LO/1919/AM06	Sarizotan in Patients with Rett Syndrome with Respiratory Symptoms	4	27/04/2017	13
16/LO/1919/AM07	Sarizotan in Patients with Rett Syndrome with Respiratory Symptoms	5	26/10/2017	8
16/LO/1919/AM08	Sarizotan in Patients with Rett Syndrome with Respiratory Symptoms	Substantial Amendment 6	23/01/2018	10
16/LO/1922/AM01	Can vibration therapy increase bone length?	1	05/04/2017	8
16/LO/2041/AM02	THE BLF EARLY COPD DEVELOPMENT PARTNERSHIP GRANT	1	04/04/2017	14
16/LO/2041/AM03	THE BLF EARLY COPD DEVELOPMENT PARTNERSHIP GRANT	2	05/06/2017	30
16/LO/2041/AM05	THE BLF EARLY COPD DEVELOPMENT PARTNERSHIP GRANT	Substantial Amendment 5, 23 No	23/11/2017	20
16/LO/2041/AM07	THE BLF EARLY COPD DEVELOPMENT PARTNERSHIP GRANT	Substantial Amendment 6 22 Jan 2018 Notice of Amendment IRAS Version 5.6.1 4	23/01/2018	10

16/LO/2041/AM10	THE BLF EARLY COPD DEVELOPMENT PARTNERSHIP GRANT	Substantial Amendment 7, 12th March 2018	13/03/2018	22
16/LO/2093/AM04	mitoPK	3	12/07/2017	8
16/LO/2093/AM05	mitoPK	4	04/10/2017	17
16/LO/2093/AM06	mitoPK	Amendment 5 28th November 2017	28/11/2017	15
16/LO/2227/AM02	Supporting Mental Wellbeing (SMW), v1	Amendment 1, 08/03/17	09/03/2017	11
17/LO/0019/AM01	How service users experience formulations in therapy for psychosis v1	2	06/10/2017	11
17/LO/0019/AM02	How service users experience formulations in therapy for psychosis v1	v3 22/12/17	22/12/2017	11
17/LO/0057/AM01	WELCOME project	1	15/06/2017	15
17/LO/0057/AM02	WELCOME project	Amendment 2, 18/08/2017	25/08/2017	14
17/LO/0057/AM03	WELCOME project	3	06/10/2017	11
17/LO/0401/AM02	M15-942 DAA Re-Treatment for Virologic Failures in AbbVie HCV Studies	M15-942	19/12/2017	18
17/LO/0473/AM02	Phase 2 study ATR-101 for the Treatment of Cushing's Syndrome	IB and ICF Update	07/11/2017	28
17/LO/0504/AM02	Study to evaluate a mepolizumab autoinjector in severe asthma	SA02	25/05/2017	21
17/LO/0512/AM01	Cost of Autism Diagnostic Assessment Study	1	23/05/2017	12
17/LO/0512/AM04	Cost of Autism Diagnostic Assessment Study	2	13/07/2017	20
17/LO/0512/AM10	Cost of Autism Diagnostic Assessment Study	3 05/02/2018	05/02/2018	15
17/LO/0927/AM02	CITADEL-202: Safety and Efficacy of INCB050465 in B-Cell Lymphoma	SA1	27/09/2017	15
17/LO/0933/AM01	SAPPHIRE - A randomised study for participants with RVO	2017/11/27 SA 1 - updated ICF	27/11/2017	17
17/LO/1077/AM01	AmBeR UCD: Can we measure ammonia in breath sample? Version 1	1 30 October 2017	31/10/2017	12
17/LO/1260/AM01	RADIO	1	24/10/2017	6
17/LO/1260/AM02	RADIO	Substantial Amendment 2	28/11/2017	14
17/LO/1267/AM01	The DEPICT study	Amendment 1, 20	20/11/2017	19

		Nov 2017		
17/LO/1301/AM01	STILE version 1.0	1.1	12/09/2017	3
17/LO/1442/AM02	Phase 1 PK study of ivermectin (W0035) oral suspensions (QCL118100)	SA01	08/02/2018	15
17/LO/1490/AM01	Managing malnutrition in later life	1.Protocol v2.1 13/02/2018	13/03/2018	11
17/LO/1635/AM01	HMB-ICU (V1 31Aug17)	SA1 12/01/18	12/01/2018	15
17/LO/1865/AM01	Combination therapy with isatuximab in patients with multiple myeloma	Amendment 1: Substantial amend	02/02/2018	3
17/LO/1867/AM01	Social information processing in adolescents with eating disorders	A1, 26/01/2018	08/02/2018	10
17/LO/1942/AM01	TULIP - SYD985 vs Physician's Choice for HER2-positive Breast Cancer	2017/11/09	15/12/2017	16
18/LO/0023/AM01	Developing and validating SAM	1, 09/02/18	09/02/2018	24

Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
12/LO/0082/AM16	009: Open-label Oral CP-690,550 for Treatment of Ulcerative Colitis	A3921139 Substantial Amendment	01/09/2017	30
14/LO/0022/AM14	Randomised Phase II study in untreated advanced renal cell carcinoma	Substantial Amendment 11	23/11/2017	36
14/LO/0818/AM22	MK-3475 versus SOC in 1L Subjects with PD-L1 Strong Metastatic NSCLC	2018/02/19 SA13 – Protocol 09	19/02/2018	26
15/LO/1138/AM07	SVR SOF Cirrhosis Registry Study	08	24/05/2017	9
15/LO/1419/AM12	PEARLS (pembrolizumab as adjuvant treatment for lung cancer)	13.0	24/04/2017	11
15/LO/1419/AM13	PEARLS (pembrolizumab as adjuvant treatment for lung cancer)	MK3475-091	09/06/2017	17
15/LO/2073/AM12	KEYNOTE-158	SA10 - Protocol 08 + IB 15 + P	08/11/2017	27
16/LO/0021/AM09	NEOD001 versus placebo in AL Amyloidosis with cardiac dysfunction	2	26/06/2017	25
16/LO/0333/AM08	Phase II Study of Pembrolizumab in Advanced Recurrent Ovarian Cancer	SA03 IB13 & PIS update	31/03/2017	20

16/LO/0443/AM09	A multicentre, open-label, randomised ITP study	7.0	30/03/2017	19
16/LO/1161/AM09	COBALT: Coversin in patients with PNH	6	25/08/2017	21
16/LO/2041/AM04	THE BLF EARLY COPD DEVELOPMENT PARTNERSHIP GRANT	3	14/08/2017	31

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**
12/LO/0082/AM16/1	009: Open-label Oral CP-690,550 for Treatment of Ulcerative Colitis	A3921139 Substantial Amendment	06/11/2017	19
14/LO/0022/AM14/1	Randomised Phase II study in untreated advanced renal cell carcinoma	Modified Amendment to Sub Amen	02/01/2018	8
14/LO/0818/AM18/2	MK-3475 versus SOC in 1L Subjects with PD-L1 Strong Metastatic NSCLC	MK-3475-024	28/06/2017	6
14/LO/0818/AM22/1	MK-3475 versus SOC in 1L Subjects with PD-L1 Strong Metastatic NSCLC	SA13 Modified	27/03/2018	6
15/LO/1419/AM13/1	PEARLS (pembrolizumab as adjuvant treatment for lung cancer)	MK3475-091	11/07/2017	8
15/LO/1665/AM08/1	Safetxt: a randomised controlled trial of a safer sex intervention	8	03/05/2017	6
15/LO/2034/AM05/1	A Phase Ib study of pembrolizumab plus chemotherapy in TNBC	Modified Amendment to Amendment	01/06/2017	14
15/LO/2073/AM12/1	KEYNOTE-158	SA10 - Protocol 08 + IB 15 + P	09/02/2018	3
16/LO/0021/AM09/1	NEOD001 versus placebo in AL Amyloidosis with cardiac dysfunction	AM3	01/12/17	10
16/LO/0333/AM08/1	Phase II Study of Pembrolizumab in Advanced Recurrent	SA03	19/07/2017	5

	Ovarian Cancer			
16/LO/0443/AM09/1	A multicentre, open-label, randomised ITP study	7.0 (Modified)	25/07/2017	13
16/LO/1106/AM09/1	A Phase III Study of Pembrolizumab + Chemotherapy in 1L TNBC	SA06	07/06/2017	13
16/LO/1161/AM09/2	COBALT: Coversin in patients with PNH	8	30/10/2017	11
16/LO/2041/AM04/1	THE BLF EARLY COPD DEVELOPMENT PARTNERSHIP GRANT	4.0	29/09/2017	1

Unfavourable opinion timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
14/LO/0818/AM18/1	MK-3475 versus SOC in 1L Subjects with PD-L1 Strong Metastatic NSCLC	SA10 Modification	01/06/2017	13
16/LO/1161/AM09/1	COBALT: Coversin in patients with PNH	Modified Substantial amendment	09/10/2017	12

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 21 day timeline		
REC Reference	**Title**	**Number of Days on Clock**
17/LO/1702	CORE BLOOD - blood samples for generation of cell lines	22

SSAs (non Phase 1) over 25 day timeline		
REC Reference	**Title**	**Number of Days on Clock**

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

Substantial Amendments over 35 day timeline				
Amendment REC Reference	**Title**	**Version**	**Date**	**Number of Days on Clock**
14/LO/0022/AM14	Randomised Phase II study in untreated advanced renal cell carcinoma	Substantial Amendment 11	23/11/2017	36

Modified Amendments over 14 day timeline				
Amendment REC Reference	**Title**	**Version**	**Date**	**Number of Days on Clock**
12/LO/0082/AM16/1	009: Open-label Oral CP-690,550 for Treatment of Ulcerative Colitis	A3921139 Substantial Amendment	06/11/2017	19