

**North West - Liverpool Central Research Ethics  
Committee**

**Annual Report**

**01 April 2017 - 31 March 2018**



## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	North West - Liverpool Central Research Ethics Committee
<b>Type of REC:</b>	Type III
<b>Type of Flag:</b>	Paediatric
<b>Chair:</b>	Mrs Julie Brake
<b>Vice-Chair:</b>	Mrs Ann Williams
<b>Alternate Vice-Chair:</b>	Mr Frank Killen
<b>REC Manager:</b>	Mrs Carol Ebenezer until 31/01/2018. Vacant 01/02/2018 to present
<b>REC Assistant:</b>	Ms Zainab Ahmed
<b>Committee Address:</b>	3rd Floor Barlow House 4 Minshull Street Manchester M1 3DZ
<b>Telephone:</b>	0207 104 8006
<b>Email:</b>	nrescommittee.northwest-liverpoolcentral@nhs.net

## Chair's overview of the past year:

As this is my final year as Chair of Central Liverpool research Ethics committee I have been reflecting on the changes that have taken place over the 11 years I have been a member of the research ethics community – as I believe it is a community, and the 5 or more years I have been the Chair of this wonderful committee.

We now have PR sub committees well established and HRA reviews supporting the REC committee reviews. The HARP member portal is another major change that is hopefully going to replace or at least vastly reduce the paper used at committees.

On our committee we have also have a number of members leave this year some who are relatively new members due to relocation and new jobs and some who have been members, like myself, for many years.

Lyvonne Tume the Vice Chair left at the end of April 2017 and Ann Williams was successful in becoming the new Vice Chair for our committee.

We continue to work well as a team and have a consistent amount of favourable opinions (both standard and additional conditions) at committee, 25%, and provisional opinions, 75%.

Recruiting new members is always difficult and I would like to thank the committee members for their commitment to attend as many meetings as possible over this past year to ensure we are quorate. I would also like to thank those members “drafted in” from other committees when we have been lower on members for some meetings. The reduced numbers have also meant that for meetings the numbers of proposals members have had to be lead and second reviewer on have increased and the support from committee members has been outstanding as always. There is planned work on recruitment onto committees so hopefully the number of people applying to be REC committee members will increase after this piece of work by the HRA

## North West - Liverpool Central Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Mr Moamen Abdelhakim	Pharmacist	Expert	01/10/2016	05/09/2017
Mr Simon Alford	Research Manager	Lay	03/12/2013	06/07/2018
Miss Fiona Brailsford	Research Coordinator	Lay	16/10/2017	
Mrs Julie Brake	Specialist Diabetes Nurse / Chair	Expert	01/06/2007	
Professor Murthy Burra	Consultant Anaesthetist	Expert	23/09/2011	
Mrs Hannah Chambers	Retired Nurse	Lay	27/09/2012	
Miss Holly Evans	Physiotherapist	Expert	01/07/2017	
Mr Frank Killen	Retired Engineer	Lay Plus	13/09/2007	
Miss Karen Knowles	Transfusion Laboratory Manager	Expert	15/07/2010	
Mr Paul Mooney	Senior Clinical Pharmacist	Expert	13/09/2016	
Mr Fotios Polydoros	Statistician	Expert	02/06/2014	31/08/2017
Ms Jennifer Preston	Patient and Public Involvement Manager	Lay Plus	14/09/2007	14/09/2017
Mrs Joanne Skellern	Lecturer in learning disabilities	Expert	01/09/2016	
Dr Lyvonne Tume	Senior Nursing Research Fellow Paediatric ICU	Expert	15/07/2010	30/04/2017
Mrs Ann Williams	Commissioning and Contract Manager	Lay Plus	01/05/2013	

## North West - Liverpool Central Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended
Mr James Burns	Retired Lay member	Lay	03/05/2017, 06/12/2017, 07/03/2018
Mr Peter Owen	Retired Mathematics Lecturer	Lay Plus	07/06/2017, 06/09/2017 & 06/12/2017 & 07/03/2018
Mr Stephen Edgar	Designer	Lay Plus	07/06/2017

**North West - Liverpool Central Research Ethics Committee: Members' Declarations of Interest:**

<b>Name</b>	<b>Declaration of Interest</b>	<b>Date</b>
Professor Murthy Burra	Council member of Preoperative Association, President, Preoperative Association (Jan 2017 till Dec 2018). Reviewer for British Journal of Anaesthesia. Member of Data Monitoring committee for NIHR Health Technology Assessment Project 15/130/95.	30/11/2017
Mrs Hannah Chambers	Member of CAG	28/11/2017
Miss Holly Evans	currently completing a Masters in clinical and health research and will be submitting an application to HRA	28/06/2017
Mr Frank Killen	None	21/03/2018
Mr Paul Mooney	None	14/03/2018
Mrs Joanne Skellern	None	04/12/2017

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

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

8 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
April	19/04/2017	5
May	24/05/2017	3
June	21/06/2017	3
July	19/07/2017	4
September	20/09/2017	3
October	18/10/2017	3
November	15/11/2017	3
December	20/12/2017	3
January	17/01/2018	3
February	21/02/2018	3
March	21/03/2018	3

11 proportionate 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	3
April	14/04/2017	3
April	28/04/2017	2
May	05/05/2017	2
May	19/05/2017	2
June	02/06/2017	2
June	23/06/2017	2
June	30/06/2017	2
July	14/07/2017	2
July	28/07/2017	2
August	11/08/2017	2
September	01/09/2017	2

September	15/09/2017	2
September	29/09/2017	2
October	13/10/2017	2
October	27/10/2017	2
November	10/11/2017	2
December	01/12/2017	2
December	22/12/2017	2
January	12/01/2018	2
January	26/01/2018	2
February	16/02/2018	2
March	19/03/2018	2
March	30/03/2018	2

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

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

0

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Mr Moamen Abdelhakim	1
Mr Simon Alford	3
Miss Fiona Brailsford	3
Mrs Julie Brake	7
Professor Murthy Burra	6
Mrs Hannah Chambers	4
Miss Holly Evans	2
Mr Frank Killen	6
Miss Karen Knowles	6
Mr Paul Mooney	8
Mr Fotios Polydoros	3
Ms Jennifer Preston	1
Mrs Joanne Skellern	6
Dr Lyvonne Tume	1
Mrs Ann Williams	6

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Mr Simon Alford	1
Mrs Julie Brake	11
Mrs Hannah Chambers	6
Mr Frank Killen	3
Mr Paul Mooney	6
Mrs Joanne Skellern	2
Dr Lyvonne Tume	1
Mrs Ann Williams	6

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Mrs Julie Brake	24
Mr Paul Mooney	23
Dr Lyvonne Tume	2
Mrs Ann Williams	1



**Training 01 April 2017 - 31 March 2018**

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Miss Fiona Brailsford	01/11/2017	on line induction
Professor Murthy Burra	04/07/2017	Adults Lacking Capacity
Mrs Hannah Chambers	26/09/2017	Assessing the risks and benefits of research
Miss Holly Evans	11/07/2017	Member Induction Training on line
Miss Karen Knowles	08/11/2017	Ethical issues of research involving children
Mr Paul Mooney	08/11/2017	The ethical issues of research involving children
Mrs Joanne Skellern	23/05/2017	Medical Devices

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

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

<b>Applications for full ethical review – Study Type</b>	<b>Number</b>	<b>%</b>
Clinical Trial of Investigational Medicinal Product	11	25.00
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	1	2.27
Research Database (including renewals)	1	2.27
Others	31	70.45
<b>Total Applications Reviewed</b>	<b>44</b>	<b>100</b>

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

Number of applications made invalid by the REC Manager	5
Number of applications withdrawn prior to the meeting	2
Number of student applications reviewed	15
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	2

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

<b>Decisions taken at meetings following review of applications</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	2	4.55
Favourable Opinion with Additional Conditions	9	20.45
Unfavourable Opinion	0	0.00
Provisional Opinion	33	75.00
Provisional Opinion Pending Consultation with Referee	0	0.00
<b>Total</b>	<b>44</b>	<b>100</b>
Number of studies sent back to full committee meeting for final opinion	0	

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

<b>Status of applications at date of generation of report</b>	<b>Number</b>	<b>%</b>
Further Information Favourable Opinion with Standard Conditions	29	65.91
Further Information Favourable Opinion with Additional Conditions	2	4.55
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	2	4.55
Favourable Opinion with Additional Conditions	9	20.45
Unfavourable Opinion	0	0.00
Provisional Opinion	1	2.27
Provisional Opinion Pending Consultation with Referee	0	0.00
Further Information response not complete	0	0.00
No decision entered on system	0	0.00
Number of studies withdrawn after the meeting	1	2.27
<b>Total</b>	<b>44</b>	<b>100</b>

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

<b>Total Applications Reviewed</b>	<b>30</b>
------------------------------------	-----------

**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	3
Number of student applications reviewed	11
Number of paediatric applications reviewed	0
Number of device applications reviewed	3
Number of qualitative applications reviewed	4

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

<b>Decisions taken at proportionate review sub-committee meetings</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	10	33.33
Favourable Opinion with Additional Conditions	7	23.33
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	13	43.33
Unfavourable Opinion	0	0.00
<b>Total</b>	<b>30</b>	<b>100</b>

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

<b>Average number of applications reviewed per full meeting</b>	5.50
<b>Number of completed applications for full ethical review</b>	43
<b>Number of completed applications for full ethical review over 60 days</b>	0
<b>Number of completed applications over 60 days as a % of total</b>	0.00%
<b>Number of days taken to final decision – average (mean)</b>	27
<b>Number of completed proportionate review applications for ethical review</b>	29
<b>Number of completed proportionate review applications for ethical review over 21 days</b>	2
<b>Number of completed proportionate review applications over 21 days as a % of total</b>	6.90%
<b>Number of SSAs (non-Phase 1) reviewed</b>	5
<b>Number of completed applications for SSA review over 25 days</b>	0
<b>Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs</b>	0.00%
<b>Number of SSAs (Phase 1) reviewed</b>	0
<b>Number of completed applications for SSA review over 14 days</b>	0
<b>Number of completed applications for SSA review over 14 days as % of all Phase 1 SSAs</b>	0.00%
<b>Number of substantial amendments reviewed</b>	152
<b>Number of completed substantial amendments over 35 days</b>	4
<b>Number of completed substantial amendments over 35 days as a % of total substantial amendments</b>	2.63%
<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>	109
<b>Number of substantial amendments received for information</b>	2
<b>Number of substantial amendments received for new sites/PIs</b>	32
<b>Number of annual progress reports received</b>	112
<b>Number of safety reports received</b>	60
<b>Number of Serious Adverse Events received</b>	0
<b>Number of final reports received</b>	15

**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>
17/NW/0184	A web management system for patients who live with Sickle Cell disorder	25
17/NW/0202	Prevalence of visual impairment V1.0	22
17/NW/0291	An evaluation of bone microarchitecture in type 1 diabetes v1.0	26
17/NW/0327	A compassionate cognitive behavioural psychotherapy group for people w	23
17/NW/0342	MRI of inflammation in epilepsy	22
17/NW/0347	Cold As Ice	21
17/NW/0370	Success Rate of Pregnancy in IUI cycles following endometrial scratch	20
17/NW/0373	PPH Butterfly Study (II): Clinical Testing and Commercialisation	24
17/NW/0376	Study RPL554-CO-203. RPL554 in Patients with Moderate to Severe COPD	25
17/NW/0387	Identifying novel solutions to BRAF inhibitor resistance in melanomaV7	48
17/NW/0456	Fasting vs Non-fasting Prior To coronary catheterization 1.6	26
17/NW/0466	Fanconi anaemia registry	25
17/NW/0487	CQVM149B2209 - compare morning vs evening doses of QVM149 o.d.	23
17/NW/0509	The neuropsychological needs of individuals experiencing homelessness	34
17/NW/0512	PETReA	29
17/NW/0517	STRIVE Study	29
17/NW/0534	Dietary alteration with fixed appliances and advertisement influence	51
17/NW/0602	ESPAC-T plus	38
17/NW/0623	CEBOC	26
17/NW/0626	Long-term outcome of patients with traumatic injury of the pancreas.	26
17/NW/0629	Diagnosing Head and Neck Cancer in Merseyside	24
17/NW/0646	ExPeDITe: Ectopic Pregnancy Diagnosis sTudy	22
17/NW/0674	Treatment of migraine in patients	49
17/NW/0678	The Willow Study	43
17/NW/0700	Lived experience of Person Centred Care: Giving those involved a voice	18
18/NW/0166	Efficacy and Safety of Bimekizumab in Chronic Plaque Psoriasis	28
18/NW/0171	Phase 2 study of INCB050465 in Relapsed or Refractory FL	29
18/NW/0172	STEP 1 - Semaglutide Treatment Effect in People with obesity	53
18/NW/0173	STEP 2 - Semaglutide Treatment Effect in People with obesity and T2DM	49

<b>Further Information Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
17/NW/0220	Loaded Bones: relationships between body mass and bone morphology	21
17/NW/0676	Neurophysiological predictors for successful SCS 1.0	28

<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>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
17/NW/0206	Predicting Alcohol Related Healthcare Utilisation: Validation	21
17/NW/0339	Perspectives (version 1)	20

<b>Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
17/NW/0217	Quality of life, sleep and rheumatoid arthritis (QUASAR): Version 1	21
17/NW/0223	PKU Explore	21
17/NW/0284	Patient Preference in Epilepsy Monotherapy: A Non-interventional Study	15
17/NW/0289	Risk factors for influenza-related complications in children	14
17/NW/0290	Feasibility of a Group Intervention for Post-Traumatic Stress Version1	14
17/NW/0324	Understanding homicide against family carers: Expanding the focus	20
17/NW/0399	USE OF VOLATILE AGENTS TO DIAGNOSE UROLOGICAL DISEASE	30
17/NW/0410	CAT: Creating Acceptable Tablets	22
17/NW/0647	The Kidney and The Brain Study	21

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

<b>Provisional Opinion</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
18/NW/0170	Human rights on adult acute mental health wards	n/a

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
17/NW/0621	Exploring oral health in early psychosis.	20

**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/NW/0241	Abreast of Health: Phase 1 – v1.0	14
17/NW/0244	Assessment of OriColâ„¢ for analysis of gut immune cells and microbiota	20
17/NW/0383	Contributions of physical activity, diet in development of macrosomia	8
17/NW/0555	biochemical changes in atrial fibrillation 2	11
17/NW/0561	Measuring the effects of eye alignment surgery-version 1.0	7
17/NW/0656	ODYSSEY LEGACY; Long-Term effects of LDL-C lowering with Alirocumab.	20
17/NW/0657	The NHOR MacTel Study	20
17/NW/0659	Effect of Sodium Hyaluronate Eyedrop on Contact Lens Wettability	14
18/NW/0045	Walking in Indoor and Outdoor Environments: Effects on Type 2 Diabetes	18
18/NW/0048	Can safety-netting be improved in ambulance services?	19
18/NW/0206	Understanding the Outcomes of Patients with Hepatocellular Carcinoma	26
18/NW/0218	Assessment of Botulinum Toxin A in the treatment of Raynaud’s Disease	19



<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>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
17/NW/0243	Multimodal hallucinations in psychosis and other disorders	13
17/NW/0252	GI CANCER TRANSLATIONAL	7
17/NW/0329	Benzodiazepines and Opioids in Blood and Oral Fluid	6
17/NW/0382	Quality of life and psychosocial wellbeing following VT ablation	6
17/NW/0435	CPEX prior to oesophagectomy to predict post-operative complications	3
17/NW/0655	EVALUATION OF THE NHS CERVICAL SCREENING PROGRAMME IN ENGLAND	13
17/NW/0721	TTF1 as a potential prognostic marker for pulmonary adenocarcinoma	12
18/NW/0047	Primary HPT bone marker changes after parathyroidectomy	16
18/NW/0134	Pilot feasibility study of multispectral imaging in Barrett's	20
18/NW/0207	Point of Care C Reactive Protein Testing	22

<b>Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
17/NW/0437	Investigating the impact of Heart Failure on Patient Reported Outcomes	8
17/NW/0558	Engaged communication to improve obesity management	8
17/NW/0562	Dual focus NBI for the diagnosis of Non-Erosive Reflux Disease	7
17/NW/0608	Feasibility of volatile detection for NG-tube placement (Phase II)	14
17/NW/0720	Non-medical prescribers, medicines optimisation and SDM - v9	13
17/NW/0722	Enhanced NHS Health Check to improve CVD risk estimation	13
18/NW/0046	The effects of numeracy in Type 1 Diabetes mellitus	16

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

<b>Provisional Opinion</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>
18/NW/0210	Diet and deprivation in pregnant women in Dundee	18

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

<b>Favourable opinion</b>				
<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>
07/Q1505/29/AM05	Pathophysiological studies in Alkaptonuria	2	11/10/2017	35
08/H1005/1/AM44	ESPAC-4: European Study Group for Pancreatic Cancer - Trial 4	37	25/05/2017	1
09/H1005/10/AM06	Cell archive of healthy volunteers, Version 1, 14/01/09	5	02/05/2017	11
09/H1005/10/AM07	Cell archive of healthy volunteers, Version 1, 14/01/09	6	08/09/2017	20
09/H1005/55/AM04	Endometrial stem cells in endometriosis	2	21/12/2016	21
09/H1005/55/AM05	Endometrial stem cells in endometriosis	3.0	08/02/2018	6
10/H1005/3/AM13	PASIC study	14	10/04/2017	5
10/H1005/77/AM04	An investigation of the immunogenetics of psoriasis	3	12/12/2017	19
10/H1005/81/AM17	Ocrelizumab in adults with Primary Progressive Multiple Sclerosis	G	24/09/2017	29
10/H1005/81/AM18	Ocrelizumab in adults with Primary Progressive Multiple Sclerosis	16	01/11/2017	33
11/H1005/10/AM19	CLL210 (CamDexRev)	15	05/05/2017	7
11/NW/0143/AM05	Representing Action in Parkinson's disease	4	10/07/2017	13
11/NW/0246/AM39	STAR: Standard vs Modified Drug Therapy in Renal Cancer	MO109353/P/10.0/ 170522	22/05/2017	13
11/NW/0568/AM02	Proteomic analyses in uveal melanoma	2	04/04/2017	7
11/NW/0720/AM06	The development of novel biomarkers for predicting pre-term labour	5	14/09/2017	11
12/NW/0045/AM27	MAJIC	21	20/02/2018	24
12/NW/0258/AM06	PD-CRAFT	6	15/05/2017	10
12/NW/0258/AM08	PD-CRAFT	8	14/09/2017	22
12/NW/0263/AM14	MEK115306 A study of dabrafeniib, trametinib & combination in melanoma	9	14/07/2017	16
12/NW/0263/AM17	MEK115306 A study of dabrafeniib, trametinib & combination in melanoma	10	27/11/2017	7
12/NW/0751/AM14	DAHANCA 21 (version 1)	11	12/04/2017	2
12/NW/0751/AM15	DAHANCA 21 (version 1)	12	07/09/2017	9
13/NW/0153/AM12	CIPHER	9	08/03/2017	20

13/NW/0153/AM15	CIPHER	10	04/10/2017	20
13/NW/0283/AM21	Global Leaders Study V1.0	15	26/06/2017	9
13/NW/0392/AM07	Mr Bubbles	5	11/04/2017	14
13/NW/0567/AM07	Suitability of Nitisinone in Alkaptonuria(SONIA2)	SONIA2 - IB 4.1 - IB 4.2 – ICF data sharing 24Mar17	24/03/2017	14
13/NW/0692/AM14	CARMELINA DM CV outcome study 1218.22	10	25/05/2017	19
13/NW/0699/AM06	Phase 2 efficacy study of CC-4047+dexamethasone in renal impairment	23	19/05/2017	1
13/NW/0699/AM07	Phase 2 efficacy study of CC-4047+dexamethasone in renal impairment	24	03/11/2017	13
14/NW/0020/AM14	Standard dose versus higher and extended dose of Radium 223 in CRPC.	9	12/04/2017	13
14/NW/0020/AM15	Standard dose versus higher and extended dose of Radium 223 in CRPC.	10	16/06/2017	1
14/NW/0028/AM03	Identifying best composite prognosticators in fibrosing lung diseases	3	20/09/2017	7
14/NW/0196/AM06	PAZOFOS	4	23/02/2017	13
14/NW/0196/AM08	PAZOFOS	5	12/06/2017	2
14/NW/0332/AM05	Advanced MRI in epilepsy	5	03/01/2018	2
14/NW/0340/AM07	Dapagliflozin energy balance in T2D	7	08/09/2017	23
14/NW/1019/AM07	CPAP with or without liraglutide in sleep apnoea and diabetes	7	21/08/2017	30
14/NW/1029/AM01	Exploring mutational signatures in iPSCs_v1	1	06/02/2018	9
14/NW/1036/AM06	Study Protocol: 1408P1921	6	21/02/2017	14
14/NW/1147/AM03	Physical activity in those with a family history of type 2 diabetes	4	06/04/2017	15
14/NW/1147/AM04	Physical activity in those with a family history of type 2 diabetes	5	07/07/2017	22
14/NW/1147/AM05	Physical activity in those with a family history of type 2 diabetes	6	18/07/2017	3
14/NW/1208/AM05	Ischaemic preconditioning training in Type 2 Diabetes	5	25/04/2017	9
14/NW/1219/AM24	Nerve Root Block Versus Surgery (NERVES)	13	15/03/2017	17
14/NW/1219/AM26	Nerve Root Block Versus Surgery (NERVES)	14	16/11/2017	13
14/NW/1248/AM20	Tralokinumab in severe asthma	12 CSP-4	17/07/2017	7
14/NW/1488/AM11	AD-4833/TOMM40_303 Extension Alzheimer's Disease study	9	30/03/2017	12
14/NW/1488/AM14	AD-4833/TOMM40_303 Extension Alzheimer's Disease study	11	25/08/2017	19
14/NW/1488/AM16	AD-4833/TOMM40_303 Extension Alzheimer's Disease study	13	06/10/2017	34
14/NW/1488/AM17	AD-4833/TOMM40_303 Extension Alzheimer's Disease study	14	08/02/2018	1
15/NW/0008/AM06	BIO BEHAVIORS	4	06/06/2017	6

15/NW/0008/AM07	BIO BEHÄTETS	5	23/10/2017	21
15/NW/0032/AM08	Imaging cerebral neuroinflammation in CVD (IN-CVD)	5	27/06/2017	25
15/NW/0032/AM09	Imaging cerebral neuroinflammation in CVD (IN-CVD)	6	19/12/2017	16
15/NW/0090/AM07	EcLiPSE Version 1.0	6	12/04/2017	19
15/NW/0090/AM10	EcLiPSE Version 1.0	10	15/11/2017	43
15/NW/0160/AM07	ABC08: Ph Ib Acelarin + cisplatin in advanced biliary tract cancer	6	06/06/2017	4
15/NW/0178/AM02	Reliability and validity of the Hempel Neurological Examination	3	24/01/2018	13
15/NW/0406/AM07	TIP	6	09/03/2017	18
15/NW/0543/AM08	Tulip Study: Anifrolumab in Adults with Active SLE	4	26/07/2017	6
15/NW/0545/AM07	DexEnceph 1.0	5	08/06/2017	2
15/NW/0545/AM10	DexEnceph 1.0	7	27/09/2017	10
15/NW/0551/AM10	ITSMMyAsthma RCT	8	24/11/2017	12
15/NW/0661/AM01	Liverpool Musculoskeletal Biobank	1	02/03/2018	12
15/NW/0747/AM08	BI1302.5 Study-BI695502 safety and efficacy in NS Cell Lung Cancer	2	18/12/2017	22
15/NW/0747/AM10	BI1302.5 Study-BI695502 safety and efficacy in NS Cell Lung Cancer	3	07/02/2018	20
15/NW/0868/AM06	DIUR-005	5	29/06/2017	2
15/NW/0868/AM07	DIUR-005	6	12/07/2017	6
15/NW/0917/AM07	EMR100070-005: Avelumab vs platinum-based doublet in first line NSCLC	6	04/07/2017	8
15/NW/0934/AM02	Biomarkers in pregnant inflammatory bowel disease patients	2	10/04/2017	6
15/NW/0934/AM06	Biomarkers in pregnant inflammatory bowel disease patients	6	25/01/2018	6
16/NW/0010/AM01	EVIE :Slow Release Insemination Vs Standard Intrauterine Insemination	1	11/04/2017	9
16/NW/0022/AM13	Phase III study of Pembrolizumab in metastatic non-squamous NSCLC	6	27/03/2017	28
16/NW/0022/AM14	Phase III study of Pembrolizumab in metastatic non-squamous NSCLC	7	11/05/2017	6
16/NW/0022/AM16	Phase III study of Pembrolizumab in metastatic non-squamous NSCLC	8	03/08/2017	4
16/NW/0022/AM17	Phase III study of Pembrolizumab in metastatic non-squamous NSCLC	09	24/11/2017	13
16/NW/0022/AM19	Phase III study of Pembrolizumab in metastatic non-squamous NSCLC	11	27/02/2018	15

16/NW/0170/AM02	Human immune responses to flaviviruses	1	25/04/2017	12
16/NW/0200/AM03	TALENT (GETNE1509) V.3.0 05/nov/2015	3	29/06/2017	20
16/NW/0218/AM04	QVA149 lung function study	2	26/04/2017	6
16/NW/0232/AM06	12709A Ph3 study of vortioxetine in paed patients(7-11yrs) with MDD	v3.0	01/12/2017	7
16/NW/0233/AM07	12710A Ph 3 study of vortioxetine in paed patients(12-17yrs) with MDD	v3	13/12/2017	4
16/NW/0283/AM01	Wireless Handheld 8-lead ECG Device Performance in Heart Patients v1	1	15/05/2017	9
16/NW/0301/AM03	Improving stretching interventions for children with cerebral palsy	3	08/05/2017	7
16/NW/0301/AM04	Improving stretching interventions for children with cerebral palsy	4	03/10/2017	7
16/NW/0396/AM05	Minidex	4	20/04/2017	7
16/NW/0396/AM06	Minidex	5	16/10/2017	7
16/NW/0396/AM07	Minidex	6	14/02/2018	19
16/NW/0404/AM03	Sexual risk behaviour in adults with Severe Mental Illness	1	07/03/2017	14
16/NW/0404/AM05	Sexual risk behaviour in adults with Severe Mental Illness	2	27/04/2017	7
16/NW/0428/AM05	Phase 2 Open Label Study of SNF472 in Calciphylaxis Patients	5	11/04/2017	5
16/NW/0465/AM02	Patient Concerns Inventory in head and neck cancer clinics	2	01/12/2017	18
16/NW/0495/AM04	A8851008 study of Anidulafungin in children with Invasive Candidiasis	9	04/12/2017	14
16/NW/0496/AM01	RESILIENT	1	22/03/2017	12
16/NW/0500/AM07	Speech-language therapy for child social communication disorder	6	28/02/2018	13
16/NW/0628/AM02	A phase 1b/2 study of DS-1040b in patients with acute ischaemic stroke	2	22/03/2017	14
16/NW/0629/AM04	CF START	4	22/03/2017	11
16/NW/0629/AM06	CF START	5	04/07/2017	14
16/NW/0680/AM02	Stress and Wellbeing after Childbirth (STRAWB2)	2	10/04/2017	2
16/NW/0680/AM03	Stress and Wellbeing after Childbirth (STRAWB2)	3	12/07/2017	6
16/NW/0680/AM04	Stress and Wellbeing after Childbirth (STRAWB2)	4	12/01/2018	35
16/NW/0695/AM01	To investigate Q-Scan device as an adjunct to "at-home" oral hygiene 2	1	12/10/2017	17
16/NW/0717/AM01	PIROUETTE	1	24/01/2018	21
16/NW/0726/AM03	SNFCT2015-05	2	07/06/2017	7

16/NW/0726/AM04	SNFCT2015-05	3	31/07/2017	8
16/NW/0789/AM04	Long term prophylaxis against acute attacks of Hereditary Angioedema	4	16/08/2017	13
16/NW/0790/AM01	POPular-TAVI	1	23/05/2017	15
16/NW/0828/AM01	OPERA Study V3.1 - Radiation dose escalation in rectal adenocarcinoma	UKSA1	30/06/2017	5
16/NW/0831/AM01	A study to evaluate CHF1535 100/6 1¼g NEXThaler® in adult asthmatics	1	11/04/2017	12
16/NW/0854/AM02	Behcet's Syndrome in the UK	1	15/03/2017	11
16/NW/0858/AM02	PREPARE	1	20/07/2017	19
16/NW/0898/AM01	Does the novel "Vacuderm" tourniquet improve cannulation success?	1	24/10/2017	14
17/NW/0019/AM01	A3921192 SOAR - A Study of a Once-A-day investigational drug for RA	1	15/03/2017	12
17/NW/0019/AM02	A3921192 SOAR - A Study of a Once-A-day investigational drug for RA	IB December 2016	12/06/2017	1
17/NW/0032/AM01	Tyrosine Degradation Study (TyDeS )	1	25/04/2017	9
17/NW/0032/AM02	Tyrosine Degradation Study (TyDeS )	2	26/10/2017	12
17/NW/0044/AM01	Liverpool study of Respiratory Immunity in Children	1	24/07/2017	1
17/NW/0056/AM01	Physical activity and cardiovascular risk in pregnancy. Version 2	1	23/03/2017	5
17/NW/0056/AM02	Physical activity and cardiovascular risk in pregnancy. Version 2	9	22/05/2017	13
17/NW/0056/AM04	Physical activity and cardiovascular risk in pregnancy. Version 2	V10	27/07/2017	15
17/NW/0056/AM05	Physical activity and cardiovascular risk in pregnancy. Version 2	VII	14/09/2017	31
17/NW/0056/AM07	Physical activity and cardiovascular risk in pregnancy. Version 2	v12	05/12/2017	28
17/NW/0056/AM08	Physical activity and cardiovascular risk in pregnancy. Version 2	8	23/02/2018	15
17/NW/0062/AM01	Immunophenotypic characterisation of normal bone marrow	1	26/06/2017	23
17/NW/0067/AM01	Multi-Feature US in NAFLD and HCC: A Proof of Concept Study	1	15/08/2017	7
17/NW/0067/AM02	Multi-Feature US in NAFLD and HCC: A Proof of Concept Study	2	26/09/2017	3

17/NW/0077/AM01	Retrospective Database Analysis of IMLYGIC™ for Treatment of Melanoma	1	30/10/2017	32
17/NW/0078/AM02	PSR-NV	1	02/03/2018	12
17/NW/0119/AM02	InS:PIRE- Questionnaire Study	2	23/03/2017	14
17/NW/0119/AM03	InS:PIRE- Questionnaire Study	3	08/11/2017	36
17/NW/0148/AM02	The Retrospective Dementia Patient Categorisation Study (RetroDeC)	2	13/12/2017	47
17/NW/0217/AM03	Quality of life, sleep and rheumatoid arthritis (QUASAR): Version 1	1	26/04/2017	8
17/NW/0217/AM05	Quality of life, sleep and rheumatoid arthritis (QUASAR): Version 1	2	28/06/2017	13
17/NW/0241/AM01	Abreast of Health: Phase 1 – v1.0	1	20/09/2017	16
17/NW/0252/AM01	GI CANCER TRANSLATIONAL	1	29/11/2017	26
17/NW/0284/AM01	Patient Preference in Epilepsy Monotherapy: A Non-interventional Study	1	12/05/2017	12
17/NW/0284/AM05	Patient Preference in Epilepsy Monotherapy: A Non-interventional Study	3	07/02/2018	30
17/NW/0291/AM01	An evaluation of bone microarchitecture in type 1 diabetes v1.0	1	26/06/2017	24
17/NW/0339/AM03	Perspectives (version 1)	2	20/12/2017	27
17/NW/0339/AM05	Perspectives (version 1)	5	23/02/2018	13
17/NW/0373/AM02	PPH Butterfly Study (II): Clinical Testing and Commercialisation	1	17/08/2017	3
17/NW/0373/AM03	PPH Butterfly Study (II): Clinical Testing and Commercialisation	2	11/09/2017	21
17/NW/0373/AM04	PPH Butterfly Study (II): Clinical Testing and Commercialisation	3.0	17/10/2017	6
17/NW/0373/AM06	PPH Butterfly Study (II): Clinical Testing and Commercialisation	4	19/01/2018	0
17/NW/0373/AM07	PPH Butterfly Study (II): Clinical Testing and Commercialisation	5.0	22/02/2018	13
17/NW/0376/AM02	Study RPL554-CO-203. RPL554 in Patients with Moderate to Severe COPD	1	07/12/2017	29
17/NW/0410/AM01	CAT: Creating Acceptable Tablets	1	20/11/2017	23
17/NW/0410/AM02	CAT: Creating Acceptable Tablets	2	07/03/2018	14
17/NW/0509/AM01	The neuropsychological needs of individuals experiencing homelessness	1	17/10/2017	10



17/NW/0555/AM01	biochemical changes in atrial fibrillation 2	1	26/09/2017	48
17/NW/0656/AM01	ODYSSEY LEGACY; Long-Term effects of LDL-C lowering with Alirocumab.	1	15/03/2018	21

#### Unfavourable opinion

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

**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
09/H1005/29/AM26/1	PACIFICO	17	21/03/2017	7

#### 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 21 day timeline

REC Reference	Title	Number of Days on Clock
18/NW/0206	Understanding the Outcomes of Patients with Hepatocellular Carcinoma	26
18/NW/0207	Point of Care C Reactive Protein Testing	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
15/NW/0090/AM10	EcLiPSE Version 1.0	10	15/11/2017	43
17/NW/0119/AM03	InS:PIRE- Questionnaire Study	3	08/11/2017	36
17/NW/0148/AM02	The Retrospective Dementia Patient Categorisation Study (RetroDeC)	2	13/12/2017	47
17/NW/0555/AM01	biochemical changes in atrial fibrillation 2	1	26/09/2017	48

**Modified Amendments over 14 day timeline**

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