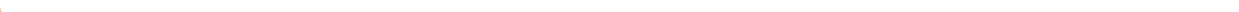


**North West - Liverpool Central Research Ethics
Committee**

Annual Report

01 April 2016 - 31 March 2017



Part 1 – Committee Membership and Training

Name of REC:	North West - Liverpool Central Research Ethics Committee
Type of REC:	Type III
Type of Flag:	Paediatrics
Chair:	Mrs Julie Brake
Vice-Chair:	Dr Lyvonne Tume
Alternate Vice-Chair:	Mr Frank Killen
REC Manager:	Mrs Carol Ebenezer
REC Assistant:	Ms Zainab Ahmed
Committee Address:	3rd Floor Barlow House 4 Minshull Street Manchester M1 3DZ
Telephone:	020 71048008
Email:	nrescommittee.northwest-liverpoolcentral@nhs.net

Chair's overview of the past year:

This has been another very busy and successful year for our committee. Once again the commitment shown by the Liverpool Central Ethics committee members is evident.

Membership to the REC is voluntary on top of members' full and busy lives, and the time taken to review the proposals and produce reports for the meetings is appreciated not only by me and the HRA but also by the researchers themselves who will often come back to our committee due how we conduct our meetings.

We are a busy committee with over 40% of the reviewed proposals at the monthly REC meetings being CTIMPS, a considerable increase from last year, and these proposals do tend to be more complex and time consuming for the lead reviewers and generate more discussion on the day.

We continue to receive emails from researchers telling us how grateful they are for the feedback they receive, the reception they receive and the speed in which we give our opinions.

I would like to thank Derek Hollinsbee for his time on our committee and the considerable time and effort he has put into the committee work especially as he has been the only Pharmacist on our committee for many years.

We have been very fortunate in having 3 new members, Joanne Skellern, Moamen Abdelhakim and Paul Mooney who have fitted into the committee extremely well.

The HRA is a changing entity and a number of changes in policy and procedure happen regularly that effect the functioning of the committee and the members of Liverpool Central REC adapt to these changes very well. For example the introduction of "Applying a proportionate approach of seeking consent" and the new HRA Approval process which was introduced at the end of March 2016.

Once again the committee has run smoothly this year due to the work and co-ordination of the REC manager Carol Ebenezer and REC assistant Zainab Tauqeer

North West - Liverpool Central Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Mr Moamen Abdelhakim	Pharmacist	Expert	01/10/2016	
Mr Simon Alford	Research Manager	Lay	03/12/2013	
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	
Mr Derek Hollingsbee	Pharmacist	Expert	23/11/2006	31/12/2016
Mr Frank Killen	Retired Engineer	Lay Plus	13/09/2007	
Miss Karen Knowles	Biomedical Scientist	Expert	15/07/2010	
Mr Paul Mooney	Senior Clinical Pharmacist	Expert	13/09/2016	
Mr Fotios Polydoros	Statistician	Expert	02/06/2014	
Ms Jennifer Preston	Patient and Public Involvement Manager	Lay Plus	14/09/2007	
Mrs Joanne Skellern	Lecturer in learning disabilities	Expert	01/09/2016	
Dr Lyvonne Tume	Senior Nursing Research Fellow Paediatric ICU	Expert	15/07/2010	
Mrs Ann Williams	Senior Improvement Officer	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	04/05/2016, 06/07/2016
Mrs Sue Fitzpatrick	Director	Lay	06/07/2016
Mr Richard Hovey	Business Analyst	Lay Plus	01/02/2017
Mrs Gillian Rimington	Paralegal	Lay	PRSC 24/05/2016, 22/09/2016, 19/10/2016, 19/01/2017

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

Name	Declaration of Interest	Date
Mr Moamen Abdelhakim	None	30/09/2016
Mr Simon Alford	None	08/12/2016
Mrs Julie Brake	Consultancy work for Boehringer Ingelheim and Lilly pharmaceuticals.	08/12/2016
Professor Murthy Burra	Council Member and Honorary Treasurer Preoperative Association. Reviewer for British Journal of Anaesthesia.	08/12/2016
Mrs Hannah Chambers	Member of CAG	08/12/2016
Mr Frank Killen	None	08/12/2016
Miss Karen Knowles	none	08/12/2016
Mr Paul Mooney	None	30/09/2016
Mr Fotios Polydoros	Statistician at Liverpool University CR-UK Cancer Trials Unit	08/12/2016
Ms Jennifer Preston	None	08/12/2016
Mrs Joanne Skellern	none	08/12/2016
Dr Lyvonne Tume	Nursing president elect (ESPNIC- European Society of Paediatric and Neonatal Intensive Care	08/12/2016
Mrs Ann Williams	Member of a NICE public health care committee. I am member of food standards agency social science research committee	08/12/2016

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

Month	Date	Number of Members Present at Meeting
April	06/04/2016	9
May	04/05/2016	9
June	01/06/2016	8
July	06/07/2016	9
September	07/09/2016	11
October	05/10/2016	11
November	02/11/2016	11
December	07/12/2016	11
February	01/02/2017	8

9 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	20/04/2016	4
May	24/05/2016	3
June	24/06/2016	3
July	25/07/2016	4
September	22/09/2016	3
October	19/10/2016	3
November	22/11/2016	4
December	19/12/2016	3
January	19/01/2017	4
February	23/02/2017	3
March	23/03/2017	4

11 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	01/04/2016	2
April	08/04/2016	2
April	15/04/2016	3
April	22/04/2016	3
April	29/04/2016	2
May	13/05/2016	2
May	27/05/2016	3
June	03/06/2016	2
June	10/06/2016	2
June	24/06/2016	3
July	01/07/2016	3

July	08/07/2016	3
July	22/07/2016	3
July	29/07/2016	3
August	05/08/2016	2
August	12/08/2016	3
August	19/08/2016	3
August	26/08/2016	3
September	02/09/2016	2
September	09/09/2016	2
September	16/09/2016	2
September	23/09/2016	2
September	30/09/2016	2
October	07/10/2016	3
October	21/10/2016	3
October	28/10/2016	3
November	11/11/2016	3
November	25/11/2016	3
December	02/12/2016	3
December	09/12/2016	2
December	16/12/2016	2
December	23/12/2016	2
January	27/01/2017	2
February	10/02/2017	2
February	24/02/2017	3
March	03/03/2017	3
March	10/03/2017	3
March	17/03/2017	3
March	31/03/2017	3

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

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

0

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

Name	Number of Meetings Attended
Mr Moamen Abdelhakim	3
Mr Simon Alford	7
Mrs Julie Brake	9
Professor Murthy Burra	7
Mrs Hannah Chambers	6
Mr Derek Hollingsbee	5
Mr Frank Killen	6
Miss Karen Knowles	7
Mr Paul Mooney	4
Mr Fotios Polydoros	7
Ms Jennifer Preston	6
Mrs Joanne Skellern	3
Dr Lyvonne Tume	6
Mrs Ann Williams	7

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

Name	Number of Meetings Attended
Mr Simon Alford	3
Mrs Julie Brake	10
Professor Murthy Burra	4
Mrs Hannah Chambers	3
Mr Fotios Polydoros	2
Ms Jennifer Preston	1
Dr Lyvonne Tume	4
Mrs Ann Williams	7

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

Name	Number of Meetings Attended
Mrs Julie Brake	37
Mr Derek Hollingsbee	22
Mr Paul Mooney	5
Mr Fotios Polydoros	1
Dr Lyvonne Tume	35

Training 01 April 2016 - 31 March 2017

Name of Member	Date	Event(s) attended
Mr Moamen Abdelhakim	10/01/2017	Member Induction
Mrs Julie Brake	01/12/2016	National Training Day for Committee Chairs
Professor Murthy Burra	27/09/2016	Human Tissue Act Introductory Level
Professor Murthy Burra	14/10/2016	Genetic and genomic research
Mr Frank Killen	27/09/2016	Human Tissue Act
Miss Karen Knowles	22/03/2017	Members National Training Day
Mr Paul Mooney	15/11/2016	on line induction
Mr Paul Mooney	10/01/2017	Member Induction
Mr Fotios Polydoros	22/03/2017	Members national training day
Mrs Joanne Skellern	22/03/2017	National Members Training Day
Mrs Ann Williams	13/03/2017	e Consent

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	22	43.14
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	1	1.96
Others	28	54.90
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	0
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	12
Number of paediatric applications reviewed	14
Number of device applications reviewed	4
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	0
Number of applications reviewed that are funded by the US DHHS	0
Number of qualitative applications reviewed	1

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

Decisions taken at meetings following review of applications	Number	%
Favourable Opinion with Standard Conditions	2	3.92
Favourable Opinion with Additional Conditions	7	13.73
Unfavourable Opinion	0	0.00
Provisional Opinion	42	82.35
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	42	82.35
Further Information Favourable Opinion with Additional Conditions	0	0.00
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	2	3.92
Favourable Opinion with Additional Conditions	7	13.73
Unfavourable Opinion	0	0.00
Provisional Opinion	0	0.00
Provisional Opinion Pending Consultation with Referee	0	0.00
Further Information response not complete	0	0.00
No decision entered on system	0	0.00
Number of studies withdrawn after the meeting	0	0.00
Total	51	100

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

Total Applications Reviewed	27
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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	6
Number of studies withdrawn prior to the meeting	1
Number of student applications reviewed	12
Number of paediatric applications reviewed	3
Number of device applications reviewed	2
Number of qualitative applications reviewed	3

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

Decisions taken at proportionate review sub-committee meetings	Number	%
Favourable Opinion with Standard Conditions	8	29.63
Favourable Opinion with Additional Conditions	10	37.04
No Opinion transfer to full committee for review	1	3.70
Provisional Opinion	8	29.63
Unfavourable Opinion	0	0.00
Total	27	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	5.67
Number of completed applications for full ethical review	51
Number of completed applications for full ethical review over 60 days	1
Number of completed applications over 60 days as a % of total	1.96%
Number of completed applications for full ethical review over 40 days	6
Number of completed applications over 40 days as a % of total	11.76%
Number of days taken to final decision – average (mean)	29
Number of completed proportionate review applications for ethical review	26
Number of completed proportionate review applications for ethical review over 14 days (please note, the timeline for proportionate review applications was extended from 14 to 21 calendar days from December 2016)	0
Number of proportionate review applications for ethical review over 21 days	0
Number of completed proportionate review applications over 14 days as a % of total	0.00%
Number of SSAs (non-Phase 1) reviewed	18
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	0
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	152
Number of completed substantial amendments over 35 days	2
Number of completed substantial amendments over 35 days as a % of total substantial amendments	1.32%
Number of completed substantial amendments over 28 days	4
Number of completed substantial amendments over 28 days as a % of total substantial amendments	2.63%
Number of modified amendments reviewed	5
Number of completed modified amendments over 14 days	0
Number of completed modified amendments over 14 days as a % of total modified amendments	0.00%
Number of non substantial amendments received	85

Number of substantial amendments received for information	2
Number of substantial amendments received for new sites/PIs	54
Number of annual progress reports received	160
Number of safety reports received	53
Number of Serious Adverse Events received	0
Number of final reports received	39

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
16/NW/0200	TALENT (GETNE1509) V.3.0 05/nov/2015	32
16/NW/0218	QVA149 lung function study	29
16/NW/0232	12709A Ph3 study of vortioxetine in paed patients(7-11yrs) with MDD	23
16/NW/0233	12710A Ph 3 study of vortioxetine in paed patients(12-17yrs) with MDD	29
16/NW/0254	12712A Extension study of vortioxetine in patients (7-18yrs) with MDD	31
16/NW/0283	Wireless Handheld 8-lead ECG Device Performance in Heart Patients v1	24
16/NW/0301	Improving stretching interventions for children with cerebral palsy	18
16/NW/0331	AMPLIFY	24
16/NW/0332	CBT for internalised stigma in inpatients with psychosis	22
16/NW/0396	Minidex	23
16/NW/0402	TOPNEGSURG	30
16/NW/0404	Sexual risk behaviour in adults with Severe Mental Illness	34
16/NW/0418	Volatile metabolome analysis in Inflammatory Bowel Disease	20
16/NW/0428	Phase 2 Open Label Study of SNF472 in Calciphylaxis Patients	27
16/NW/0466	Use of Electromyograph (EMG) to detect spinal nerve root proximity Vs2	24
16/NW/0495	A8851008 study of Anidulafungin in children with Invasive Candidiasis	27
16/NW/0496	RESILIENT - Version 3.0	34
16/NW/0500	Speech-language therapy for child social communication disorder	34
16/NW/0588	3D / 4D Ultrasound Guided Embryo Transfer vs.Clinical Touch Technique	26
16/NW/0626	PROBIT	28
16/NW/0628	A phase 1b/2 study of DS-1040b in patients with acute ischaemic stroke	37
16/NW/0629	CF START	21
16/NW/0655	Performance Evaluation of a Coagulation Monitoring System	20
16/NW/0680	Stress and Wellbeing after Childbirth (STRAWB2)	44
16/NW/0695	To investigate Q-Scan device as an adjunct to "at-home" oral hygiene 2	27
16/NW/0717	PIROUETTE	48
16/NW/0725	G1T28-02_Phase 1b/2a Safety and PK Study of G1T28 (3652_0004)	55
16/NW/0726	SNFCT2015-05	45
16/NW/0764	Investigating the effect of IMT in children and adults with CF	36
16/NW/0787	GLPG2222-CL-201 in subjects with CF with F508del CFTR mutation	30
16/NW/0789	Long term prophylaxis against acute attacks of Hereditary Angioedema	37
16/NW/0790	POPular-TAVI	35

16/NW/0791	MODIFY Fatigue: pilot intervention in inflammatory bowel disease v1	45
16/NW/0828	OPERA Study V3.1 - Radiation dose escalation in rectal adenocarcinoma	24
16/NW/0831	A study to evaluate CHF1535 100/6 1¼g NEXThaler® in adult asthmatics	20
16/NW/0858	PREPARE	21
16/NW/0860	Low cost devices for measuring intravenous fluid delivery and response	23
17/NW/0019	A3921192 SOAR - A Study of a Once-A-day investigational drug for RA	38
17/NW/0032	Tyrosine Degradation Study (TyDeS)	27
17/NW/0044	Liverpool study of Respiratory Immunity in Children	28
17/NW/0045	Study of XOMA 358 in Patients with Congenital hyperinsulinism	62
17/NW/0056	Physical activity and cardiovascular risk in pregnancy. Version 2	30

Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
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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/NW/0270	Cohort participants views on the development of Dementia Platform UK	22
16/NW/0493	12712B Cont. Ext. study of Vortioxetine in patients (7-17yrs) with MDD	16

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/NW/0340	Prevalence of Chronic Oedema in Obese Patients (Final Version 1)	19
16/NW/0427	Pneumonia Patient Registry (Liverpool)	19
16/NW/0465	Patient Concerns Inventory in head and neck cancer clinics	16
16/NW/0578	VENTURE (Version 2.0)	19
16/NW/0771	Repetitive sensory stimulation after a stroke.	28
16/NW/0852	Patients with Social Deprivation present late with Dementia	20
17/NW/0042	Home-based HIT Study	26

Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock

Provisional Opinion		
REC Reference	Title	Number of Days on Clock

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

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

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

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

Further Information Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
16/NW/0307	Eating Habits of Adult Sickle Cell Patients in Crisis in the UK	2
16/NW/0327	Folate status in pregnancy	6
16/NW/0707	Femoroacetabular Impingement Strength & Symptoms (FISS) Study	12
16/NW/0761	Frailty Assessment in Chronic Kidney Disease	11
16/NW/0767	Correlation Between Peripheral VBG and ABG in Children during GA	10
16/NW/0899	Postnatal Maternal Experiences	7
17/NW/0062	Immunophenotypic characterisation of normal bone marrow	7
17/NW/0192	Sequential assessment of LV function following reperfusion of a STEMI	11

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
16/NW/0342	Comparing ventricular function in Athletes Heart and HCM patients.	5
16/NW/0424	Oral Health Care Programs in Older Adults	7
16/NW/0503	Incidence study of Birdshot Retinochoroidopathy in the UK v1	6
16/NW/0573	Development of the DAFNEplus intervention: User Testing Study	6
16/NW/0760	Ultrasound in inflammatory muscle disease	7
16/NW/0849	Molecular Approach to Non-Tuberculous Mycobacterial Assessment	8
17/NW/0077	Retrospective Database Analysis of IMLYGIC [®] for Treatment of Melanoma	4
17/NW/0148	The Retrospective Dementia Patient Categorisation Study (RetroDeC)	2

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
16/NW/0326	Evaluating the headache pathway	8
16/NW/0426	FAVER Version 1.0	6
16/NW/0504	Neurofibromatosis 2 Outcome Measure Study	5
16/NW/0577	Exploring effects of acute stress on attention and visual cognition	7
16/NW/0704	An Intervention to Support Carers of those with Heart Failure	8
16/NW/0854	Behcet's Syndrome in the UK	8
16/NW/0898	Does the novel "Vacuderm" tourniquet improve cannulation success?	4
17/NW/0067	Multi-Feature US in NAFLD and HCC: A Proof of Concept Study	9
17/NW/0078	PSR-NV	6
17/NW/0119	InS:PIRE- Questionnaire Study	14

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
09/H1001/38/AM15	Pharmacogenetics of Statin-Induced Muscle Toxicity	13	05/01/2017	8
09/H1005/29/AM23	PACIFICO	16	29/03/2016	5
10/H1005/74/AM17	UK Lung Cancer Screening Trial (UKLS)- Version: 1	17	10/08/2016	6
10/H1005/81/AM16	Ocrelizumab in adults with Primary Progressive Multiple Sclerosis	F	27/06/2016	7
11/NW/0246/AM31	STAR: Standard vs Modified Drug Therapy in Renal Cancer	6	24/05/2016	18
11/NW/0412/AM12	Comparing long term safety of LCM vs CBZ-CR in patients from SP0993	Not given	26/01/2015	22
11/NW/0619/AM13	Extension to LAL-CL01 in patients with liver dysfunction due to LAL de	6	20/09/2016	14
12/NW/0045/AM25	MAJIC	19	17/05/2016	3
12/NW/0045/AM26	MAJIC	20	19/09/2016	12
12/NW/0214/AM20	TAILoR: TelmisArtan and InsuLin Resistance in HIV	16	05/09/2016	14
12/NW/0263/AM13	MEK115306 A study of dabrafeniib, trametinib & combination in melanoma	8	16/08/2016	7
12/NW/0350/AM06	Novel Urinary Markers of Renal Injury in Children with Cancer NUMeRICC	5	25/08/2016	1
12/NW/0502/AM21	Ibrutinib versus ofatumumab in relapsed/refractory CLL or SLL	7	28/09/2016	18
12/NW/0502/AM22	Ibrutinib versus ofatumumab in relapsed/refractory CLL or SLL	10.1	27/01/2017	8
12/NW/0751/AM09	DAHANCA 21 (version 1)	8	12/04/2016	5
13/NW/0153/AM09	CiPHER	7	18/05/2016	20
13/NW/0153/AM10	CiPHER	8	13/10/2016	4
13/NW/0280/AM18	INjection versus SplinTing in Carpal Tunnel Syndrome (INSTinCTS)	15	08/08/2016	2
13/NW/0283/AM18	Global Leaders Study V1.0	14	06/06/2016	10
13/NW/0338/AM02	Medtronic Registry for Epilepsy (MORE)	1	05/08/2016	5
13/NW/0392/AM05	Mr Bubbles	4	01/07/2016	1
13/NW/0501/AM15	Oral Azacitidine in Subjects with AML in Complete Remission	17	03/11/2016	23
13/NW/0567/AM06	Suitability of Nitisinone in Alkaptonuria(SONIA2)	3	08/09/2016	12
13/NW/0692/AM11	CARMELINA DM CV outcome study 1218.22	IB v14	17/06/2016	4
13/NW/0692/AM13	CARMELINA DM CV outcome study 1218.22	Protocol version 3,	13/02/2017	18

		Amendment		
13/NW/0699/AM05	Phase 2 efficacy study of CC-4047+dexamethasone in renal impairment	22.0	06/07/2016	15
14/NW/0004/AM01	Corneal confocal microscopy in burning mouth syndrome	1	25/07/2016	2
14/NW/0014/AM01	The Use of Human Primary Cells for Anti-Infectives Drug Discovery	1	01/11/2016	4
14/NW/0020/AM11	Standard dose versus higher and extended dose of Radium 223 in CRPC.	8	20/06/2016	1
14/NW/0028/AM01	Identifying best composite prognosticators in fibrosing lung diseases	1	22/11/2016	20
14/NW/0028/AM02	Identifying best composite prognosticators in fibrosing lung diseases	2	13/12/2016	7
14/NW/0196/AM03	PAZOFOS	3	21/03/2016	5
14/NW/0277/AM15	BreatheMOR-HF:Morphine for breathlessness in heart failure Version 1	10	21/12/2016	1
14/NW/0277/AM16	BreatheMOR-HF:Morphine for breathlessness in heart failure Version 1	11	28/02/2017	4
14/NW/0332/AM01	Advanced MRI in epilepsy	1	25/07/2016	0
14/NW/0340/AM06	Dapagliflozin energy balance in T2D	6	24/02/2017	7
14/NW/0352/AM07	Pfizer TOFA A3921133-Tofa versus TNFi in Rheumatoid Arthritis	6	20/04/2016	19
14/NW/0352/AM08	Pfizer TOFA A3921133-Tofa versus TNFi in Rheumatoid Arthritis	6	08/11/2016	14
14/NW/0352/AM09	Pfizer TOFA A3921133-Tofa versus TNFi in Rheumatoid Arthritis	6	07/03/2017	9
14/NW/1019/AM05	CPAP with or without liraglutide in sleep apnoea and diabetes	5	18/05/2016	0
14/NW/1019/AM06	CPAP with or without liraglutide in sleep apnoea and diabetes	6	24/03/2017	7
14/NW/1052/AM07	Efficacy and safety of PF-06438179 in rheumatoid arthritis	Form v4	13/06/2016	8
14/NW/1052/AM08	Efficacy and safety of PF-06438179 in rheumatoid arthritis	Not given	20/01/2017	38
14/NW/1128/AM03	Molecular profiling for lymphoma	4	13/09/2016	2
14/NW/1128/AM04	Molecular profiling for lymphoma	5	25/01/2017	2
14/NW/1199/AM02	Botulinum toxin-A versus tolterodine for idiopathic overactive bladder	2	08/06/2016	12
14/NW/1208/AM03	Ischaemic preconditioning training in Type 2 Diabetes	3	29/06/2016	1
14/NW/1208/AM04	Ischaemic preconditioning training in Type 2 Diabetes	4	28/10/2016	10
14/NW/1219/AM17	Nerve Root Block Versus Surgery (NERVES)	9 (amend 14)	15/04/2016	3

14/NW/1219/AM23	Nerve Root Block Versus Surgery (NERVES)	19	01/11/2016	31
14/NW/1323/AM03	PIVOTAL	3	27/06/2016	2
14/NW/1323/AM04	PIVOTAL	4	07/11/2016	24
14/NW/1323/AM05	PIVOTAL	5	22/03/2017	6
14/NW/1433/AM01	Control Norovirus Transmission And Influenza study (CONTAIN)	1	22/07/2016	0
14/NW/1464/AM05	Phase I Clinical testing of the Postpartum Haemorrhage Butterfly	2.6	19/08/2016	4
14/NW/1488/AM08	AD-4833/TOMM40_303 Extension Alzheimer's Disease study	6	16/06/2016	5
14/NW/1488/AM10	AD-4833/TOMM40_303 Extension Alzheimer's Disease study	8	12/12/2016	8
15/NW/0008/AM04	BIO BEHÄTETS	3	03/11/2016	24
15/NW/0028/AM05	A Phase 3 Study to Investigate the long term safety and efficacy of ZS	6	22/03/2016	13
15/NW/0032/AM05	Imaging cerebral neuroinflammation in CVD (IN-CVD)	3	11/04/2016	2
15/NW/0032/AM07	Imaging cerebral neuroinflammation in CVD (IN-CVD)	4.0	02/02/2017	10
15/NW/0103/AM01	ASSESSING STATUS OF VISUAL CORTEX IN PATIENTS WITH MACULAR DISEASE 1.0	1	12/05/2016	5
15/NW/0103/AM04	ASSESSING STATUS OF VISUAL CORTEX IN PATIENTS WITH MACULAR DISEASE 1.0	4	13/03/2017	3
15/NW/0160/AM04	ABC08: Ph Ib Acelarin + cisplatin in advanced biliary tract cancer	4	27/05/2016	5
15/NW/0160/AM05	ABC08: Ph Ib Acelarin + cisplatin in advanced biliary tract cancer	5	22/12/2016	2
15/NW/0178/AM01	Reliability and validity of the Hempel Neurological Examination	2	05/07/2016	44
15/NW/0294/AM02	NIHR TRF: saliva self-sampling in diabetes to monitor periodontitis	1	19/07/2016	1
15/NW/0406/AM05	TIP	5	02/12/2016	13
15/NW/0484/AM03	Retained Placenta Study : Part Two	3	25/04/2016	2
15/NW/0537/AM03	Perinatal Access to Resources and Support (PEARS) Study	3	19/05/2016	4
15/NW/0537/AM05	Perinatal Access to Resources and Support (PEARS) Study	5	14/10/2016	6
15/NW/0539/AM01	Computer vision algorithms for diabetic foot ulcer detection	1	09/02/2017	4
15/NW/0543/AM07	Tulip Study: Anifrolumab in Adults with Active SLE	2	06/07/2016	9
15/NW/0545/AM03	DexEnceph 1.0	2	29/03/2016	1
15/NW/0550/AM02	Metabolic phenotypes	1	16/12/2016	11
15/NW/0550/AM03	Metabolic phenotypes	2	09/03/2017	0
15/NW/0551/AM05	ITSMYasthma RCT	4	07/04/2016	4

15/NW/0551/AM06	ITSMMyAsthma RCT	5	26/09/2016	8
15/NW/0551/AM08	ITSMMyAsthma RCT	6	16/12/2016	10
15/NW/0668/AM06	FUTURE 5	1	03/08/2016	1
15/NW/0668/AM08	FUTURE 5	2	31/10/2016	7
15/NW/0671/AM09	A Phase 2 study of Enzalutamide in Advanced Hepatocellular	5	12/05/2016	4
15/NW/0671/AM10	A Phase 2 study of Enzalutamide in Advanced Hepatocellular	6	01/09/2016	27
15/NW/0671/AM11	A Phase 2 study of Enzalutamide in Advanced Hepatocellular	7	13/09/2016	3
15/NW/0750/AM02	Assessing lung fibrosis with magnetic resonance imaging	2	28/09/2016	6
15/NW/0876/AM01	Validation of Macimorelin as Test for Adult Growth Hormone Deficiency	5	23/05/2016	10
15/NW/0876/AM03	Validation of Macimorelin as Test for Adult Growth Hormone Deficiency	3	29/06/2016	5
15/NW/0910/AM02	Measurement of saccades in Myasthenia Gravis	2	17/05/2016	1
15/NW/0917/AM02	EMR100070-005: Avelumab vs platinum-based doublet in first line NSCLC	1	14/09/2016	4
15/NW/0917/AM04	EMR100070-005: Avelumab vs platinum-based doublet in first line NSCLC	3	19/01/2017	7
15/NW/0917/AM05	EMR100070-005: Avelumab vs platinum-based doublet in first line NSCLC	4	03/03/2017	5
15/NW/0922/AM03	Defining and measuring Fear of Childbirth	3	03/03/2017	6
15/NW/0934/AM01	Biomarkers in pregnant inflammatory bowel disease patients	1	25/07/2016	2
15/NW/0985/AM01	Perspectives on Accessing Type 2 Diabetes Services. Version 1.	1	10/08/2016	1
15/NW/0985/AM02	Perspectives on Accessing Type 2 Diabetes Services. Version 1.	3	13/10/2016	8
16/NW/0006/AM01	SATURN: Effect of Secukinumab in the treatment of psoriatic arthritis	1	01/04/2016	4
16/NW/0006/AM02	SATURN: Effect of Secukinumab in the treatment of psoriatic arthritis	2	16/02/2017	18
16/NW/0022/AM07	Phase III study of Pembrolizumab in metastatic non-squamous NSCLC	3	05/04/2016	24
16/NW/0022/AM08	Phase III study of Pembrolizumab in metastatic non-squamous NSCLC	4	20/07/2016	7
16/NW/0022/AM10	Phase III study of Pembrolizumab in metastatic non-squamous NSCLC	5	27/01/2017	7
16/NW/0071/AM04	Study of Patidegib Gel 2%, 4%, and Vehicle in Gorlin	4	24/05/2016	11

	Syndrome Patients			
16/NW/0071/AM05	Study of Patidegib Gel 2%, 4%, and Vehicle in Gorlin Syndrome Patients	Not given	16/09/2016	23
16/NW/0071/AM06	Study of Patidegib Gel 2%, 4%, and Vehicle in Gorlin Syndrome Patients	5	07/09/2016	5
16/NW/0073/AM02	Metacognitive beliefs and processes in distress in MND	1	19/04/2016	4
16/NW/0076/AM01	Validation study of the SystmOne GP database	1	15/08/2016	2
16/NW/0137/AM02	Wearable dark-adaptometer in normal adult healthy volunteers - v.1.0	1	27/01/2017	8
16/NW/0147/AM02	ODYSSEY DM - DYSLIPIDEMIA	1.0	15/08/2016	2
16/NW/0147/AM03	ODYSSEY DM - DYSLIPIDEMIA	1	30/08/2016	17
16/NW/0147/AM04	ODYSSEY DM - DYSLIPIDEMIA	1	06/09/2016	10
16/NW/0150/AM06	DETECT I	1	01/11/2016	4
16/NW/0150/AM09	DETECT I	3	14/12/2016	11
16/NW/0200/AM02	TALENT (GETNE1509) V.3.0 05/nov/2015	2	11/08/2016	6
16/NW/0218/AM02	QVA149 lung function study	1	04/08/2016	12
16/NW/0232/AM02	12709A Ph3 study of vortioxetine in paed patients(7-11yrs) with MDD	2	05/08/2016	13
16/NW/0233/AM01	12710A Ph 3 study of vortioxetine in paed patients(12-17yrs) with MDD	1	05/08/2016	28
16/NW/0245/AM01	Patient and Public Involvement (PPI): Feedback Cycle	1	04/04/2016	9
16/NW/0245/AM02	Patient and Public Involvement (PPI): Feedback Cycle	1	27/03/2017	1
16/NW/0254/AM02	12712A Extension study of vortioxetine in patients (7-18yrs) with MDD	2	05/08/2016	28
16/NW/0254/AM04	12712A Extension study of vortioxetine in patients (7-18yrs) with MDD	2	16/02/2017	18
16/NW/0301/AM01	Improving stretching interventions for children with cerebral palsy	1	26/07/2016	4
16/NW/0301/AM02	Improving stretching interventions for children with cerebral palsy	2	16/02/2017	22
16/NW/0331/AM01	AMPLIFY	1	21/06/2016	8
16/NW/0331/AM02	AMPLIFY	2	19/07/2016	8
16/NW/0396/AM02	Minidex	1	01/09/2016	1
16/NW/0428/AM01	Phase 2 Open Label Study of SNF472 in Calciphylaxis Patients	1	29/06/2016	4
16/NW/0428/AM02	Phase 2 Open Label Study of SNF472 in Calciphylaxis Patients	2	01/08/2016	8
16/NW/0428/AM03	Phase 2 Open Label Study of SNF472 in Calciphylaxis Patients	3	08/08/2016	8

16/NW/0428/AM04	Phase 2 Open Label Study of SNF472 in Calciphylaxis Patients	4	03/11/2016	21
16/NW/0465/AM01	Patient Concerns Inventory in head and neck cancer clinics	1	29/11/2016	11
16/NW/0493/AM02	12712B Cont. Ext. study of Vortioxetine in patients (7-17yrs) with MDD	2	28/08/2016	6
16/NW/0493/AM03	12712B Cont. Ext. study of Vortioxetine in patients (7-17yrs) with MDD	Not given	17/10/2016	9
16/NW/0495/AM03	A8851008 study of Anidulafungin in children with Invasive Candidiasis	9	07/02/2017	6
16/NW/0500/AM01	Speech-language therapy for child social communication disorder	1	22/09/2016	13
16/NW/0500/AM02	Speech-language therapy for child social communication disorder	2	02/11/2016	5
16/NW/0500/AM03	Speech-language therapy for child social communication disorder	3	21/12/2016	0
16/NW/0504/AM02	Neurofibromatosis 2 Outcome Measure Study	2	07/12/2016	6
16/NW/0578/AM01	VENTURE (Version 2.0)	1	18/11/2016	9
16/NW/0628/AM01	A phase 1b/2 study of DS-1040b in patients with acute ischaemic stroke	1	12/07/2016	11
16/NW/0629/AM02	CF START	2	10/10/2016	7
16/NW/0680/AM01	Stress and Wellbeing after Childbirth (STRAWB2)	1	21/03/2017	1
16/NW/0761/AM01	Frailty Assessment in Chronic Kidney Disease	0.2	07/12/2016	2
16/NW/0761/AM02	Frailty Assessment in Chronic Kidney Disease	2	16/01/2017	1
16/NW/0764/AM01	Investigating the effect of IMT in children and adults with CF	1	10/03/2017	7
16/NW/0789/AM01	Long term prophylaxis against acute attacks of Hereditary Angioedema	1	07/12/2016	1
17/NW/0119/AM01	InS:PIRE- Questionnaire Study	1	23/02/2017	17
97/141/AM42	The Liverpool Lung Project	51	15/11/2016	24

Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
09/H1005/29/AM26	PACIFICO	17	15/02/2017	30
12/NW/0263/AM12	MEK115306 A study of dabrafeniib, trametinib & combination in melanoma	8	01/04/2016	3
15/NW/0103/AM02	ASSESSING STATUS OF VISUAL CORTEX IN PATIENTS WITH MACULAR DISEASE 1.0	2	10/10/2016	8

15/NW/0537/AM04	Perinatal Access to Resources and Support (PEARS) Study	4	25/07/2016	1
15/NW/0710/AM01	Questionnaire Study of Arabin Pessary Experience v.1	1	21/03/2016	3
15/NW/0747/AM02	BI1302.5 Study-BI695502 safety and efficacy in NS Cell Lung Cancer	1	23/09/2016	28

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/NW/0263/AM12/1	MEK115306 A study of dabrafeniib, trametinib & combination in melanoma	8 modified	13/04/2016	0
15/NW/0103/AM02/1	ASSESSING STATUS OF VISUAL CORTEX IN PATIENTS WITH MACULAR DISEASE 1.0	2	27/10/2016	3
15/NW/0537/AM04/1	Perinatal Access to Resources and Support (PEARS) Study	4	30/08/2016	7
15/NW/0747/AM02/1	BI1302.5 Study-BI695502 safety and efficacy in NS Cell Lung Cancer	1	03/11/2016	0

Unfavourable opinion timeline				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
15/NW/0710/AM01/1	Questionnaire Study of Arabin Pessary Experience v.1	1 modified	16/08/2016	12

Table 11: Items exceeding timelines**Full applications for ethical review over 60 day timeline**

REC Reference	Title	Number of Days on Clock
17/NW/0045	Study of XOMA 358 in Patients with Congenital hyperinsulinism	62

Proportionate review applications for ethical review over 21 day timeline

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

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

REC Reference	Title	Number of Days on Clock
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Substantial Amendments over 35 day timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
14/NW/1052/AM08	Efficacy and safety of PF-06438179 in rheumatoid arthritis	Not given	20/01/2017	38
15/NW/0178/AM01	Reliability and validity of the Hempel Neurological Examination	2	05/07/2016	44

Modified Amendments over 14 day timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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