

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

Annual Report

01 April 2016 - 31 March 2017



Part 1 – Committee Membership and Training

Name of REC:	North West - Liverpool East Research Ethics Committee
Type of REC:	Recognised REC
Type of Flag:	Type III (CTIMP), Tissue Bank, Paediatric
Chair:	Mrs Glenys J Hunt
Vice-Chair:	Professor Neil Pender 01 April 2016 - 27 August 2016 Miss Kimberley Saint 03 March 2017 - Current
Alternate Vice-Chair:	Dr Peter Walton
REC Manager:	Mr Matthew Rogerson (01 April 2016 – 20 March 2017) Ms Gemma Warren (20 March 2017 – Current)
REC Assistant:	Miss Amber Ecclestone (01 April 2016 – 30 June 2016) Miss Laila Sarwar (01 September 2016 – 28 February 2017) Miss Nafeesa Khanam (01 March 2017 – Current)
Committee Address:	Barlow House 3rd Floor 4 Minshull Street Manchester M1 3DZ
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Chair's overview of the past year:

It has been a busy year for Liverpool East REC again. This year there have been 9 full meetings (the tenth having to be cancelled due to lack of applications); 10 Proportionate Reviews and 22 sub-committees meetings. I have attended 35 out of the 41 meetings, as well as reviewing most of the amendments for the provisional opinions - so no wonder I feel as if it has been a busy year! All the committee have worked hard, but I would especially like to thank the alternate vice-chair, Peter, who acted as vice-chair after Neil left in August, and has attended only one less meeting than me.

Once again we have had a number of changes in the committee over the year, with 4 members leaving and 3 joining - one of whom sadly passed away after being with us for just a few months. In addition one member had to take a leave of absence for personal reasons. We do need to recruit more members, especially clinicians, and more especially paediatric clinicians. Towards the end of the year there was more disruption when the REC manager and assistant changed. Despite that we have managed to deal with the work very efficiently. We were only outside the 60 day timeline for full applications on 1 occasion, out of 44 applications, and similarly 1 PR out of 23 was over 21 days (our figures show the advantage of the change of timeline from 14 to 21 days).

Out of the 44 full applications we have reviewed 12 were CTIMPs, 10 were paediatric and there was 1 research tissue bank, so our flagging, and specialist knowledge was put to good use.

A major change over the last year has been the move to paperless, which has met with varying reactions. I personally can see the advantage to the HRA in this, but some members (including myself), find paper much easier and more convenient to read and to reference for the meeting.

Many of our committee members have not managed to attend any training sessions this year, which is a shame, but people are all busy and it is difficult for them to find the time.

This will be my last report as Chair, and I would just like to express my thanks to all the committee members and RES staff who have helped make the task that bit easier over the last 5 years.

North West - Liverpool East Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Mr John Bridson	Clinical Ethicist	Expert	21/06/2007	
Dr Zoe Edwards	Clinical Psychologist	Expert	21/02/2011	21/08/2016
Mrs Sue Fitzpatrick	Director	Lay	14/04/2015	
Mrs Elizabeth Gordon	Retired Magistrate	Lay Plus	01/06/2013	15/02/2017
Mrs Maureen Hendry	Pharmacist	Expert	12/07/2010	
Mrs Annette Hockney	Retired Clinical Pharmacology Alliance Director	Lay	01/10/2016	
Mrs Glenys J Hunt	Solicitor	Lay Plus	22/08/2005	
Dr Supriya Kapas	Senior Clinical Pharmacist	Expert	03/09/2015	
Mr Alan McGarrity	Retired Police Inspector	Lay Plus	01/08/2016	
Mrs Theresa Moorcroft	Paediatric Research Nurse Manager	Expert	01/02/2016	13/02/2017
Mr Alex Newgrosh	Quality Assurance Manager	Lay Plus	16/09/2010	
Professor Neil Pender	Professor of Orthodontics	Expert	27/08/2005	27/08/2016
Mr David Powell	Honorary Consultant Clinical Psychologist	Expert	01/07/2016	23/12/2016
Miss Kimberley Saint	Clinical Scientist - Nuclear Medicine	Expert	27/09/2012	
Mrs Julia Waddon	Advanced Nurse Practitioner	Expert	01/06/2015	
Dr Peter Walton	Retired Research Consultant	Lay	14/05/2008	

North West - Liverpool East Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended
Mr Peter Owen	Retired Mathematics Lecturer	Lay Plus	19/01/2017

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

Name	Declaration of Interest	Date
Mr John Bridson	Member of the Board of Trustees of the UK Clinical Ethics Network. As an employee of the Royal Liverpool and Broadgreen University Hospitals NHS Trust (RLBUHT), they are a member of RLBUHT Techniques and Medical Devices Group and also RLBUHT Cardiology Research Ethics Committee.	31/03/2017
Mrs Sue Fitzpatrick	None -Role No Change Senior collaborative consultant for the UK Need for Nutrition Education/Innovation Programme (NNEdPro) – I will be involved in the training of personnel to allow them to conduct clinical research. I provide training courses for Liverpool Women's hospital and other hospitals and trusts for personnel involved in research but I do not actually conduct research. I am a Director of Redtree People with the aim of helping and training new persons in the sector. I was Director and Head of Education and Training for the Institute of Clinical Research but again in a training capacity I was not actively involved in conducting research. I do provide training, mainly GCP training to NHS hospital trusts including to R&D personnel. I also conduct training within pharmaceutical companies	31/03/2017
Mrs Maureen Hendry	None	23/02/2017
Mrs Annette Hockney	AstraZeneca shares	23/02/2017
Mrs Glenys J Hunt	Currently a post-grad researcher in the School of Law & Social Justice, UoL Member of Liverpool University research Ethics Sub-Committee for Physical Interventions	23/02/2017
Dr Supriya Kapas	Pharmacist advisor, and named pharmacist, for employing hospital Trust R&D department for all clinical trials QA officer for the employing Trust for use of human tissues/blood products as CTIMPs; ATMPs Freelance biomedical writer.	31/03/2017
Mr Alan McGarrity	Shareholdings in organisations involved in or possibly seeking to be involved in the conduct of research. None directly, but may hold some via unit or investment trusts. Otherwise none declared	31/03/2017
Mr Alex Newgrosh	None	31/03/2017
Mr David Powell	None declared	16/09/2016
Miss Kimberley Saint	I am a Trustee of the Institute of Physics and Engineering in Medicine (IPEM). This is my Professional Body. It is a charity, so as well as being listed as a Director of the Body with Companies House, I am also registered as a Trustee with the Charities Commission. IPEM will directly conduct research. However, they do offer	31/03/2017

	<p>sponsorship for research. I am personally not involved in the process of judging or offering that sponsorship. However I feel it best to declare this interest. I am a Medical Physicist working in a Nuclear Medicine department within the NHS. We are active in research in my department. I am currently the PI of a project that gained ethical approval. I would of course immediately notify my REC manager if I felt a conflict of interest would arise. E.g. I ensured when putting in my IRAS form for this project that I would not be seen as the REC I sat on or was managed by any of the REC managers/assistants I know.</p>	
Mrs Julia Waddon	None declared.	31/03/2017
Dr Peter Walton	None	23/02/2017

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

Month	Date	Number of Members Present at Meeting
April	21/04/2016	10
May	19/05/2016	9
June	16/06/2016	7
August	18/08/2016	8
September	15/09/2016	9
November	17/11/2016	10
January	19/01/2017	9
February	16/02/2017	10
March	16/03/2017	9

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	28/04/2016	3
May	30/05/2016	3
June	27/06/2016	4
August	01/08/2016	3
August	29/08/2016	3
September	26/09/2016	3
November	29/11/2016	3
January	03/01/2017	3
February	27/02/2017	3
March	27/03/2017	3

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

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

Month	Date	Number of Members Present at Meeting
April	14/04/2016	2
May	02/05/2016	2
May	10/05/2016	3
May	16/05/2016	2
May	30/05/2016	2
June	27/06/2016	2
July	11/07/2016	2
July	26/07/2016	2
August	22/08/2016	2
September	05/09/2016	2

September	19/09/2016	2
October	24/10/2016	2
November	09/11/2016	2
November	21/11/2016	2
December	06/12/2016	2
December	19/12/2016	2
January	09/01/2017	2
January	24/01/2017	2
February	06/02/2017	2
February	20/02/2017	2
March	06/03/2017	2
March	20/03/2017	2

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

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

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

Name	Number of Meetings Attended
Mr John Bridson	2
Dr Zoe Edwards	2
Mrs Sue Fitzpatrick	9
Mrs Elizabeth Gordon	7
Mrs Maureen Hendry	5
Mrs Annette Hockney	4
Mrs Glenys J Hunt	9
Dr Supriya Kapas	5
Mr Alan McGarrity	5
Mrs Theresa Moorcroft	2
Mr Alex Newgrosh	7
Professor Neil Pender	2
Mr David Powell	2
Miss Kimberley Saint	4
Mrs Julia Waddon	6
Dr Peter Walton	9

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

Name	Number of Meetings Attended
Mr John Bridson	1
Dr Zoe Edwards	1
Mrs Sue Fitzpatrick	4
Mrs Elizabeth Gordon	2
Mrs Maureen Hendry	3
Mrs Glenys J Hunt	5
Dr Supriya Kapas	2
Mr Alan McGarrity	1
Mr Alex Newgrosh	2
Miss Kimberley Saint	3
Mrs Julia Waddon	2
Dr Peter Walton	5

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

Name	Number of Meetings Attended
Mr John Bridson	1
Mrs Glenys J Hunt	21

Professor Neil Pender	2
Miss Kimberley Saint	1
Dr Peter Walton	20

Training 01 April 2016 - 31 March 2017

Name of Member	Date	Event(s) attended
Mrs Maureen Hendry	24/05/2016	Introduction to Phase 1 Research - Trials & Regulation
Mrs Glenys J Hunt	06/04/2016	Quantitative Research Methods and Statistics: A Health Research Authority Workshop
Mrs Glenys J Hunt	23/11/2016	North West Chairs Meeting
Mrs Glenys J Hunt	01/12/2016	National Training Day for Chairs
Mr Alan McGarrity	15/09/2016	Committee Members Induction
Miss Kimberley Saint	31/01/2017	Equality & Diversity Programme

PART 2: REC WORKLOAD AND ACTIVITY DURING THE REPORTING PERIOD

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

Applications for full ethical review – Study Type	Number	%
Clinical Trial of Investigational Medicinal Product	12	27.27
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	1	2.27
Research Database (including renewals)	0	0.00
Others	31	70.45
Total Applications Reviewed	44	100

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

Number of applications made invalid by the REC Manager	2
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	16
Number of paediatric applications reviewed	10
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	5

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	4.55
Favourable Opinion with Additional Conditions	9	20.45
Unfavourable Opinion	4	9.09
Provisional Opinion	29	65.91
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	44	100
Number of studies sent back to full committee meeting for final opinion	1	

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	24	54.55
Further Information Favourable Opinion with Additional Conditions	5	11.36
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	4	9.09
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	44	100

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

Total Applications Reviewed	23
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Table 6: Breakdown of PRS applications and other activity during reporting period:

Number of applications made invalid by the REC Manager	3
Number of studies withdrawn prior to the meeting	0
Number of student applications reviewed	10
Number of paediatric applications reviewed	2
Number of device applications reviewed	1
Number of qualitative applications reviewed	5

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

Decisions taken at proportionate review sub-committee meetings	Number	%
Favourable Opinion with Standard Conditions	6	26.09
Favourable Opinion with Additional Conditions	1	4.35
No Opinion transfer to full committee for review	2	8.70
Provisional Opinion	14	60.87
Unfavourable Opinion	0	0.00
Total	23	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	4.89
Number of completed applications for full ethical review	44
Number of completed applications for full ethical review over 60 days	1
Number of completed applications over 60 days as a % of total	2.27%
Number of completed applications for full ethical review over 40 days	13
Number of completed applications over 40 days as a % of total	29.55%
Number of days taken to final decision – average (mean)	36
Number of completed proportionate review applications for ethical review	20
Number of completed proportionate review applications for ethical review over 14 days (Please note the timeline for the review of PR applications was extended from 14 to 21 calendar days in December 2016)	8
Number of completed proportionate review applications for ethical review over 21 days	1
Number of completed proportionate review applications over 14 days as a % of total	40.00%
Number of SSAs (non-Phase 1) reviewed	1
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	103
Number of completed substantial amendments over 35 days	6
Number of completed substantial amendments over 35 days as a % of total substantial amendments	5.83%
Number of completed substantial amendments over 28 days	26
Number of completed substantial amendments over 28 days as a % of total substantial amendments	25.24%
Number of modified amendments reviewed	4
Number of completed modified amendments over 14 days	1
Number of completed modified amendments over 14 days as a % of total modified amendments	25.00%
Number of non substantial amendments received	100

Number of substantial amendments received for information	3
Number of substantial amendments received for new sites/PIs	32
Number of annual progress reports received	56
Number of safety reports received	45
Number of Serious Adverse Events received	3
Number of final reports received	19

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/0271	Preterm Arginine INTake study	39
16/NW/0275	Open-label trial with avelumab versus first line chemotherapy	37
16/NW/0291	SMART therapy for auditory hallucinations	34
16/NW/0305	Dysport for the treatment of urinary incontinence in patients with NDO	36
16/NW/0347	SWITCH: Weight Management Study	47
16/NW/0349	Touch processing in adults with autism spectrum disorders (v2)	35
16/NW/0364	Preputioplasty Versus Circumcision for BXO in Children	37
16/NW/0377	The LQTS Study	34
16/NW/0480	Exercise and Nutrition Interventions in Age-related Sarcopenia	25
16/NW/0606	Pembrolizumab in advanced renal cell carcinoma	46
16/NW/0617	UX023-CL301 Phase 3 KRN23 (3106-0010)	51
16/NW/0620	Pro2tect-Correction _ Version 2.0 Amendment 1 _ 17 March 2016	47
16/NW/0621	Pro2tect-Conversion _ Version 2.0 (Amendment 1) dated 17 March 2016	51
16/NW/0633	CMS Study	85
16/NW/0664	Study to investigate the effects of AZD8871 in patients with COPD	50
16/NW/0731	Top-down Infliximab in Kids with Crohn's disease (TISKids)	42
16/NW/0825	MOLTO	33
17/NW/0036	A Phase II Study of BGBC007 in combination with Pembrolizumab	56
17/NW/0085	APaS-1 Adult Protection against Streptococcus pneumoniae study 1 v1.0	38
17/NW/0090	The REALE (Recognising Emotions and links to Life Experiences) Study	52
17/NW/0114	Shared Reading as an Intervention for Self-harm Version 1.0	38
17/NW/0118	Assessing Fall Risk on Stairs	30
17/NW/0170	IMPACT	30
17/NW/0176	How is well-being constructed and reflected upon in cancer survivors?	42

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
16/NW/0287	The feasibility of a continuous fetal monitoring device	37
16/NW/0293	PERSIST-AVR	48
16/NW/0647	Social isolation and social cognition in thought disorder	26
17/NW/0038	1002-047 Hyperlipidemia Study	57

17/NW/0172	GED-0301-CD-003 - ACTIVE CROHN'S DISEASE	34
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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/0801	Exploring distribution of referrals to a Clinical Genetics Service v.1	25
17/NW/0035	PKU Start	27

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/NW/0460	Service Users' Experience of Physical Intervention V1	15
16/NW/0612	Experiences of falls in domestic settings and use of ambulance service	34
16/NW/0810	Liverpool Blood Diseases Bank	21
16/NW/0826	FEVER qualitative study	25
17/NW/0029	Nose and throat study	27
17/NW/0054	Hand to nose Version 1	27
17/NW/0095	Incidence of JSLE in CYP and their Access to Care in the UK and ROI	20
17/NW/0115	MIT study version 1.0	16
17/NW/0173	SWiM App Study	21

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
16/NW/0348	Pain processing in Autism Spectrum Disorder Version 1	28
16/NW/0445	Interactions between adipose tissue and endometrium	20
16/NW/0613	Self-disgust and Obsessive Compulsive Disorder	34
16/NW/0857	Interactions between adipose tissue and endometrium	27

Provisional Opinion

REC Reference	Title	Number of Days on Clock
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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/0343	Gait analysis in cerebellar ataxia and hereditary spastic paraparesis	18
16/NW/0454	Time-Limited Therapy for Complex Trauma	21
16/NW/0508	Features of ADHD in children with ASD	13
16/NW/0514	Living with Cystic Fibrosis (v2)	20
16/NW/0516	Oxidative Stress Response in Patients with Severe Aortic Stenosis	15
16/NW/0601	FISH MEAL	30
16/NW/0650	Acromegaly & Multijoint Disease	9
16/NW/0716	Cloudy with a Chance of Pain: Version 1	13
16/NW/0723	Development of Options Grids for Basal Cell Carcinoma	9
16/NW/0728	Better nights, fresh days – Field test - Ver1.0	12
16/NW/0861	Physical and ultrasound examination of arteriovenous fistulae (AVF)	13
16/NW/0863	PARTNER Study	15

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
16/NW/0512	Psychological distress in disfiguring dermatological abnormalities	8

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/0346	Chlamydial antibodies in infection	14
16/NW/0603	The Myocardium in HLHS	18
16/NW/0654	Evaluation of improvements to NHS orthopaedic care	7
16/NW/0859	Biomechanical cadaver studies	11
17/NW/0021	Seeking Care	15
17/NW/0196	Crossover Evaluation of Eye Drops in Symptomatic Lens Wearers (Part 2)	7

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
16/NW/0724	Medication Adherence in Patients with Over Active Bladder	6

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
17/NW/0141	Delivering secondhand smoke interventions in primary care (DeSSIP)	14

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
08/H1002/71/AM14	Combination antibiotic therapy in treatment of active Crohn's disease	Amendment 9	31/05/2016	16
10/H1002/27/AM24	Denosumab as Adjuvant Treatment for Early-Stage Breast Cancer (D-CARE)	Substantial Amendment 23	03/08/2016	30
10/H1002/27/AM28	Denosumab as Adjuvant Treatment for Early-Stage Breast Cancer (D-CARE)	26	22/12/2016	32
10/H1002/29/AM15	Extension study for S1P1 agonist in Multiple Sclerosis	12	30/06/2016	14
10/H1002/29/AM16	Extension study for S1P1 agonist in Multiple Sclerosis	Amendment 13 - UK V2 - 22/11/2016	22/11/2016	30
10/H1002/29/AM17	Extension study for S1P1 agonist in Multiple Sclerosis	IBv11 Amendment 1	30/11/2016	28
10/H1002/57/AM10	MAGIC STUDY (MOLECULAR GENETICS OF ADVERSE DRUG REACTIONS IN CHILDREN)	Substantial Amendment 7, 11/03/2016	12/03/2016	22
10/H1002/77/AM02	Enteric nervous system stem cell behaviour in mature muscle models	2	29/09/2016	62
10/H1002/80/AM20	Subcutaneous Insulin: Pumps or Injections (SCIPI) Version Number 3.0	Substantial Amendment 18	13/09/2016	9
11/H1002/1/AM14	Tacrolimus for Prograf to Advagraf conversion in children. Version 1.0	APL Amendment T (Part C)	04/08/2016	28
11/H1002/1/AM15	Tacrolimus for Prograf to Advagraf conversion in children. Version 1.0	7	25/01/2017	20
12/NW/0137/AM04	Everolimus in patients with non functioning NETs (RADIANT-4)	CRAD001T2302, v03	29/06/2016	14
12/NW/0297/AM06	Prospective observational study of quality of life in Gout version 1.0	Amendment 5	12/09/2016	10
12/NW/0361/AM17	A study of Standard and New Antiepileptic Drugs – SANAD-II	10	07/06/2016	24
12/NW/0367/AM20	Belimumab vs placebo, plus standard therapy in paediatric SLE	15	12/12/2016	27
12/NW/0500/AM07	Health & Employment After Fifty (the HEAF Study)	5	20/12/2016	30
12/NW/0739/AM10	A Ph.I/II Dose Escalation Study and Expansion safety/efficacy study.	SA REC UK07 - 10/08/2016	10/08/2016	23
12/NW/0802/AM16	Study of Oral Laquinimod in Subjects with Multiple Sclerosis	09	02/12/2016	46

12/NW/0814/AM12	Efficacy & Safety/Tolerability of Subcutaneous SCH900222/MK-3222	Substantial amendment 7.0 - 08	08/11/2016	8
13/NW/0265/AM06	DESTINY	5	07/06/2016	22
13/NW/0621/AM16	The early use of Antibiotics in at Risk Children with Influenza-ARCHIE	Substantial Amendment 012	11/08/2016	22
13/NW/0621/AM18	The early use of Antibiotics in at Risk Children with Influenza-ARCHIE	14	13/09/2016	9
13/NW/0621/AM21	The early use of Antibiotics in at Risk Children with Influenza-ARCHIE	Substantial Amendment16	22/02/2017	21
13/NW/0851/AM01	PROTEOMIC ANALYSIS OF CYSTIC FLUID OF CRANIOPHARYNGIOMA IN CHILDREN	Substantial Amendment 1, 2nd February 2016	08/06/2016	30
14/NW/0203/AM01	Development of outcome measures in juvenile localised scleroderma	1	11/01/2017	10
14/NW/0302/AM06	BOTOX® for Treatment of Urinary Incontinence in patients 12-17 yrs old	Substantial Amendment: Study Website	07/06/2016	31
14/NW/0350/AM07	Nivolumab or Nivolumab + Ipilimumab vs Bevacizumab in Recurrent GBM	Substantial Amendment EC 07	06/09/2016	17
14/NW/0350/AM08	Nivolumab or Nivolumab + Ipilimumab vs Bevacizumab in Recurrent GBM	8	21/10/2016	14
14/NW/0350/AM09	Nivolumab or Nivolumab + Ipilimumab vs Bevacizumab in Recurrent GBM	09	09/12/2016	34
14/NW/1016/AM01	The value and cost of different forms of oral health information	SA01 18.03.2016	18/03/2016	29
14/NW/1097/AM08	PIANO Study - PLX3397 c-KIT in advanced acral and mucosal melanoma	3	13/12/2016	31
14/NW/1189/AM03	ACTION: Cancer patient involvement in medical decision making V 1.0	2	21/11/2016	35
14/NW/1292/AM10	CA209-214 Nivolumab combined with Ipilimumab versus Sunitinib in RCC	7	11/10/2016	24
14/NW/1427/AM04	Effects of inhaled CVT-301 in Subjects with Parkinson's disease	Substantial Amendment 3	21/04/2016	12
14/NW/1427/AM05	Effects of inhaled CVT-301 in Subjects with Parkinson's disease	Substantial Amendment 4	29/06/2016	28
14/NW/1460/AM06	LAIV and EHPC	4	16/07/2016	27
14/NW/1474/AM05	Antimicrobial Hernia Repair Device Clinical Study 13-10	3	20/09/2016	28

14/NW/1474/AM06	Antimicrobial Hernia Repair Device Clinical Study 13-10	4	06/02/2017	26
14/NW/1497/AM04	GARMIN-II: double-blind randomised controlled trial of lesogaberan in cough	1	13/02/2017	19
15/NW/0035/AM02	Behçet's syndrome in children and young people in the United Kingdom	One Year Follow Up Questionnaire	20/04/2016	10
15/NW/0035/AM04	Behçet's syndrome in children and young people in the United Kingdom	Amendment 2 4.7.16	04/07/2016	25
15/NW/0045/AM03	Systems Medicine Analysis of Inflammatory Bowel Disease	1	01/02/2017	25
15/NW/0225/AM02	SAFE: intervention development and pilot RCT.	Amendment 2 (9/6/2016)	13/06/2016	25
15/NW/0425/AM01	Establishing a model for HPV-positive Gynaecological Cancer Research	1.2	03/10/2016	26
15/NW/0492/AM06	Study of ACP-196 Versus Ibrutinib in previously treated CLL patients	Protocol Amendment 3	22/04/2016	24
15/NW/0492/AM07	Study of ACP-196 Versus Ibrutinib in previously treated CLL patients	Substantial Amendment - IB v5.	26/07/2016	37
15/NW/0492/AM10	Study of ACP-196 Versus Ibrutinib in previously treated CLL patients	Substantial Amendment 8	10/03/2017	17
15/NW/0624/AM03	D2270C00015 (AZD2014), Phase I, Open Label, Advanced Solid Tumours	2	02/02/2017	13
15/NW/0631/AM07	OKAH-193 - Varicella vaccine study in the second year of life	Substantial Amendment 3	06/04/2016	15
15/NW/0631/AM09	OKAH-193 - Varicella vaccine study in the second year of life	SA04	09/05/2016	15
15/NW/0637/AM02	Compass Phase II Version 1	02	02/06/2016	6
15/NW/0697/AM10	LPS13931: Outcomes in insulin naïve patients with uncontrolled T2DM	Amendment 7	18/04/2016	15
15/NW/0697/AM12	LPS13931: Outcomes in insulin naïve patients with uncontrolled T2DM	Substantial Amendment 09	30/06/2016	20
15/NW/0697/AM15	LPS13931: Outcomes in insulin naïve patients with uncontrolled T2DM	Substantial Amendment 11	08/08/2016	30
15/NW/0698/AM11	LPS14060: transition to Toujeo in basal insulin treated T2DM patients	Amendment 7	18/04/2016	15
15/NW/0698/AM14	LPS14060: transition to Toujeo in basal insulin treated T2DM patients	SA09	30/06/2016	20
15/NW/0698/AM17	LPS14060: transition to Toujeo in basal insulin treated T2DM patients	Substantial Amendment 10	08/08/2016	30

15/NW/0838/AM02	Lost and Found: In-Hospital Way-Finding Study v.1	Substantial Amendment 2	06/04/2016	15
15/NW/0931/AM01	Experimental Human Pneumococcal Carriage Model Testing New Strains	Substantial Amendment 1	15/08/2016	26
15/NW/0948/AM02	ENTO + VCR in Adult Subjects with Non-Hodgkin Lymphoma	SA#2	20/04/2016	13
15/NW/0948/AM03	ENTO + VCR in Adult Subjects with Non-Hodgkin Lymphoma	SA#3	03/10/2016	32
15/NW/0950/AM03	CGAH: The Evolve-2 Study (Treatment for Episodic Migraine)	I5Q-MC-CGAH- New and updated patient tools	13/04/2016	19
15/NW/0950/AM05	CGAH: The Evolve-2 Study (Treatment for Episodic Migraine)	I5Q-MC-CGAH-IB and PISICF update	25/05/2016	24
15/NW/0950/AM07	CGAH: The Evolve-2 Study (Treatment for Episodic Migraine)	4	31/01/2017	25
15/NW/0951/AM02	Self management barriers & facilitators in COPD	1	05/05/2016	29
16/NW/0019/AM02	IM-201	Substantial amendment 4.0 - Protocol amendment 6.0 – 26/10/2016	26/10/2016	35
16/NW/0031/AM02	Experimental Human Pneumococcal Carriage: Aging and immunity	2, 13/04/2016	13/04/2016	19
16/NW/0031/AM03	Experimental Human Pneumococcal Carriage: Aging and immunity	Recruitment/PIS Information on web page	10/05/2016	16
16/NW/0031/AM04	Experimental Human Pneumococcal Carriage: Aging and immunity	Substantial Amendment 4 – 18/01/2017	18/01/2017	27
16/NW/0034/AM02	CA209-498: Newly Diagnosed Glioblastoma (MGMT unmethylated)	SA02	28/06/2016	28
16/NW/0034/AM03	CA209-498: Newly Diagnosed Glioblastoma (MGMT unmethylated)	SA03	31/08/2016	14
16/NW/0034/AM04	CA209-498: Newly Diagnosed Glioblastoma (MGMT unmethylated)	04	28/11/2016	14
16/NW/0036/AM01	A Phase IIa Study of MIV-711 in Knee Joint Osteoarthritis	Protocol v2.0 dated 13 January 2016, Main ICF v2.0 dated 12 April 2016 and Optional	14/04/2016	19

		Pharmacogenetic ICF v2.0 dated 12 April 2016		
16/NW/0036/AM02	A Phase IIa Study of MIV-711 in Knee Joint Osteoarthritis	Substantial Amendment 02	19/08/2016	26
16/NW/0097/AM01	FUTURE Initiative	Amendment 01	06/05/2016	20
16/NW/0097/AM03	FUTURE Initiative	Substantial Amendment 2	14/07/2016	22
16/NW/0097/AM04	FUTURE Initiative	Substantial Amendment 3 – 18/01/2016	18/01/2016	36
16/NW/0124/AM01	Experimental Human Pneumococcal Carriage: Asthma and immune function	Substantial Amendment 01	10/05/2016	16
16/NW/0124/AM05	Experimental Human Pneumococcal Carriage: Asthma and immune function	Amendment 2	27/07/2016	41
16/NW/0178/AM01	Factors affecting clinical outcomes post-lower limb bypass	amendment 1, 13/04/2016	14/04/2016	19
16/NW/0187/AM01	Phase III study of Ruxolitinib in Early Myelofibrosis	Substantial Amendment 01	16/06/2016	22
16/NW/0187/AM02	Phase III study of Ruxolitinib in Early Myelofibrosis	Addition of PIC Sites	29/09/2016	35
16/NW/0196/AM01	CheckMate CA209-548 in pts with newly diagnosed GBM (MGMT methylated)	Substantial Amendment 1	27/05/2016	35
16/NW/0196/AM02	CheckMate CA209-548 in pts with newly diagnosed GBM (MGMT methylated)	02	29/11/2016	14
16/NW/0236/AM02	Development of a PROM for orthopaedic surgery	Substantial Amendment 2	23/05/2016	17
16/NW/0238/AM03	DRAKO Non-interventional Study	Substantial Amendment 1	03/03/2017	20
16/NW/0271/AM01	Preterm Arginine INTake study	2.0	19/11/2016	36
16/NW/0275/AM01	Open-label trial with avelumab versus first line chemotherapy	SA01	28/06/2016	24
16/NW/0275/AM02	Open-label trial with avelumab versus first line chemotherapy	SA2- Patient material	12/08/2016	21
16/NW/0275/AM04	Open-label trial with avelumab versus first line chemotherapy	3	23/11/2016	7
16/NW/0305/AM04	Dysport for the treatment of urinary incontinence in patients with NDO	3	01/12/2016	35
16/NW/0305/AM06	Dysport for the treatment of urinary incontinence in patients	4	06/02/2017	19

	with NDO			
16/NW/0305/AM07	Dysport for the treatment of urinary incontinence in patients with NDO	Substantial Amendment 5	10/03/2017	19
16/NW/0347/AM01	SWITCH: Weight Management Study	Amendment 01 26/08/2016	26/08/2016	8
16/NW/0612/AM03	Experiences of falls in domestic settings and use of ambulance service	Substantial Amendment 1	10/02/2017	11
16/NW/0620/AM02	Pro2tect-Correction _ Version 2.0 Amendment 1 _ 17 March 2016	Substantial amendment 1 - Protocol Amendment 2 – Version 3	18/04/2016	24
16/NW/0621/AM02	Pro2tect-Conversion _ Version 2.0 (Amendment 1) dated 17 March 2016	Substantial amendment 1 - Protocol Amendment 2 – Version 3	18/04/2016	24
16/NW/0664/AM01	Study to investigate the effects of AZD8871 in patients with COPD	Substantial Amendment1 – 10/11/2015	10/11/2016	18
16/NW/0664/AM02	Study to investigate the effects of AZD8871 in patients with COPD	Substantial Amendment 2	07/03/2017	20
16/NW/0825/AM01	MOLTO	1.0	22/12/2016	12
16/NW/0826/AM01	FEVER qualitative study	Substantial Amendment 1	07/03/2017	29

Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
12/NW/0802/AM15	Study of Oral Laquinimod in Subjects with Multiple Sclerosis	7	14/10/2016	21
16/NW/0343/AM01	Gait analysis in cerebellar ataxia and hereditary spastic paraparesis	1	16/12/2016	35

Table 10.2: Breakdown of current status of all modified amendments reviewed within the reporting period

Favourable opinion timeline				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
12/NW/0802/AM15/1	Study of Oral Laquinimod in Subjects with Multiple Sclerosis	SA#8	18/11/2016	13
14/NW/1188/AM02/2	The validity of informed consent for inguinal hernia surgery	modified amendment 2 part 2 25/03/16	25/03/2016	14
16/NW/0343/AM01/2	Gait analysis in cerebellar ataxia and hereditary spastic paraparesis	Modified Amendment 2	20/03/2017	30

Unfavourable opinion timeline				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
16/NW/0343/AM01/1	Gait analysis in cerebellar ataxia and hereditary spastic paraparesis	1 30/01/2017	30/01/2017	14

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

REC Reference	Title	Number of Days on Clock
16/NW/0633	CMS Study	85

Proportionate review applications for ethical review over 21 day timeline

REC Reference	Title	Number of Days on Clock
16/NW/0601	FISH MEAL	30

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
10/H1002/77/AM02	Enteric nervous system stem cell behaviour in mature muscle models	2	29/09/2016	62
12/NW/0802/AM16	Study of Oral Laquinimod in Subjects with Multiple Sclerosis	09	02/12/2016	46
15/NW/0492/AM07	Study of ACP-196 Versus Ibrutinib in previously treated CLL patients	Substantial Amendment – IB v5	26/07/2016	37
16/NW/0097/AM04	FUTURE Initiative	3	18/01/2016	36
16/NW/0124/AM05	Experimental Human Pneumococcal Carriage: Asthma and immune function	Amendment 2	27/07/2016	41
16/NW/0271/AM01	Preterm Arginine INTake study	2.0	19/11/2016	36

Modified Amendments over 14 day timeline				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
16/NW/0343/AM01/2	Gait analysis in cerebellar ataxia and hereditary spastic paraparesis	Modified Amendment 2	20/03/2017	30

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