

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

**Annual Report**

**01 April 2015 - 31 March 2016**



## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	North West - Liverpool East Research Ethics Committee
<b>Type of REC:</b>	CTIMP in patients Phase III
<b>Type of Flag:</b>	Paediatric, Tissue Banks
<b>Chair:</b>	Mrs Glenys J Hunt
<b>Vice-Chair:</b>	Professor Neil Pender
<b>Alternate Vice-Chair:</b>	Dr Peter Walton
<b>REC Manager:</b>	Miss Helen Penistone (1 April 2015 – 7 August 2016) Mr Matt Rogerson (1 February 2016 – 31 March 2016)
<b>REC Assistant:</b>	Miss Ewa Grzegorska (1 April 2015 – 29 February 2016) Miss Amber Ecclestone (1 March 2016 – 31 March 2016)
<b>Committee Address:</b>	Barlow House 3rd Floor 4 Minshull Street Manchester M1 3DZ
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## Chair's overview of the past year:

This has been a difficult year for the committee with regard to personnel. We were without a permanent REC Manager for 6 months, and we were low on numbers, being just quorate at 2 meetings, and only 1 over at another 3. However we have had three new members during the year, and they fitted in well with the committee, and soon established themselves. All the committee members have continued to work very hard and we are grateful to them all, so that we met almost all time targets, and the ones we missed were only by a short margin. Particular thanks go to Maureen Hendry as she has done a lot of the work on the CTIMPS, which accounted for 15 out of the total 40 applications dealt with. Now Supriya has joined us, Maureen's workload may be eased.

It is noticeable that we did not give any unfavourable opinions during the year, I think that is a reflection of the improvement in quality generally of applications and also an indication of the ethos of our committee that we try to help researchers proceed with their research whenever we possibly can.

## 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	
Mrs Sue Fitzpatrick	Director	Lay	14/04/2015	
Mrs Elizabeth Gordon	Retired Magistrate	Lay Plus	01/06/2013	
Mrs Maureen Hendry	Pharmacist	Expert	12/07/2010	
Mrs Glenys J Hunt	Solicitor	Lay Plus	22/08/2005	
Dr Supriya Kapas	Senior Clinical Pharmacist	Expert	03/09/2015	
Mrs Theresa Moorcroft	Paediatric Research Nurse Manager	Expert	01/02/2016	
Professor Ebrahim Khalil Naderali	Professor of Human Physiology	Expert	21/02/2011	03/06/2015
Mr Alex Newgrosh	Quality Assurance Manager	Lay Plus	16/09/2010	
Professor Neil Pender	Professor of Orthodontics	Expert	27/08/2005	
Miss Kimberley Saint	Clinical Scientist	Expert	27/09/2012	
Mrs Julia Waddon	Advanced Nurse Practitioner	Expert	01/06/2015	
Dr Peter Walton	Retired Lay Member	Lay	14/05/2008	

## North West - Liverpool East Research Ethics Committee: Deputy Members

Name	Profession	Status	Meeting date attended

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

Name	Profession	Status	Meeting date attended
Mr Christopher Houston	Retired Lay Member	Lay Plus	Full REC 18/06/2015

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

<b>Name</b>	<b>Declaration of Interest</b>	<b>Date</b>
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), I am a member of the:- RLBUHT Techniques and Medical Devices Group- RLBUHT Cardiology Research Committee	21/01/2016
Dr Zoe Edwards	None declared	21/01/2016
Mrs Sue Fitzpatrick	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	11/01/2016
Mrs Elizabeth Gordon	None declared.	09/01/2016
Mrs Maureen Hendry	None declared	21/12/2015
Mrs Glenys J Hunt	Member of Liverpool University research Ethics Sub-Committee for Physical Interventions	22/12/2015
Dr Supriya Kapas	Pharmacist advisor and named pharmacist for employing hospital trust R&D department re: clinical trials involving human cells as CTIMPs. Freelance biomedical writer.	18/01/2016
Mr Alex Newgrosh	None declared.	21/01/2016
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 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 Nuclear medicine department within the NHS. We are active in research in my department. I am currently the PI of a project that recently 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	11/02/2016

	at the REC I sat on or was managed by any of the REC managers/assistants I know.	
Mrs Julia Waddon	None declared.	21/01/2016
Dr Peter Walton	None declared	11/01/2016

### Meetings for Full Ethical Review 01 April 2015 - 31 March 2016:

Month	Date	Number of Members Present at Meeting
April	16/04/2015	7
May	21/05/2015	8
June	18/06/2015	8
August	20/08/2015	8
September	17/09/2015	10
December	10/12/2015	11
January	21/01/2016	10
February	18/02/2016	7
March	17/03/2016	10

9 full committee meetings were held during the reporting period.

### Proportionate Review Sub-Committee Meetings held during 01 April 2015 - 31 March 2016:

Month	Date	Number of Members Present at Meeting
June	30/06/2015	3
August	05/08/2015	3
September	08/09/2015	4
October	14/10/2015	4
November	30/11/2015	3
December	21/12/2015	3
January	21/01/2016	3
February	29/02/2016	3
March	28/03/2016	3

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

### Sub-Committee Meetings held during 01 April 2015 - 31 March 2016:

Month	Date	Number of Members Present at Meeting
April	02/04/2015	2
April	16/04/2015	2
April	30/04/2015	2
May	11/05/2015	2
May	27/05/2015	2
June	11/06/2015	2
June	18/06/2015	2
July	02/07/2015	3
July	16/07/2015	2
July	30/07/2015	2
August	20/08/2015	2
September	03/09/2015	2
September	17/09/2015	3

October	01/10/2015	2
October	15/10/2015	2
November	19/11/2015	2
December	03/12/2015	2
December	17/12/2015	2
January	07/01/2016	2
January	21/01/2016	2
February	04/02/2016	2
February	18/02/2016	2
March	03/03/2016	2
March	17/03/2016	2
March	31/03/2016	2

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

#### Details of inquorate meeting held:01 April 2015 - 31 March 2016

None



**Attendance of Members at full committee meetings:01 April 2015 - 31 March 2016**

<b>Name</b>	<b>Number of Meetings Attended</b>
Mr John Bridson	6
Dr Zoe Edwards	4
Mrs Sue Fitzpatrick	7
Mrs Elizabeth Gordon	7
Mrs Maureen Hendry	7
Mrs Glenys J Hunt	7
Dr Supriya Kapas	4
Mrs Theresa Moorcroft	2
Professor Ebrahim Khalil Naderali	1
Mr Alex Newgrosh	8
Professor Neil Pender	5
Miss Kimberley Saint	6
Mrs Julia Waddon	5
Dr Peter Walton	9

**Attendance of Members at proportionate review sub-committee meetings: 01 April 2015 - 31 March 2016**

<b>Name</b>	<b>Number of Meetings Attended</b>
Mr John Bridson	2
Mrs Sue Fitzpatrick	2
Mrs Elizabeth Gordon	4
Mrs Maureen Hendry	3
Mrs Glenys J Hunt	3
Dr Supriya Kapas	1
Mr Alex Newgrosh	2
Professor Neil Pender	3
Miss Kimberley Saint	4
Mrs Julia Waddon	1
Dr Peter Walton	4

**Attendance of Members at sub-committee meetings: 01 April 2015 - 31 March 2016**

<b>Name</b>	<b>Number of Meetings Attended</b>
Mrs Glenys J Hunt	21
Professor Neil Pender	14
Dr Peter Walton	17

**Training 01 April 2015 - 31 March 2016**

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Dr Zoe Edwards	15/10/2015	Assessing the Consequences (benefits and harms) of Research
Mrs Sue Fitzpatrick	08/06/2015	Equality and Diversity
Mrs Sue Fitzpatrick	15/06/2015	Induction
Mrs Maureen Hendry	15/10/2015	Assessing the Consequences (benefits and harms) of Research
Dr Supriya Kapas	04/11/2015	Committee Members Induction
Miss Kimberley Saint	19/11/2015	Personal Data in Research - A Workshop
Mrs Julia Waddon	17/08/2015	Training - Equality and Diversity (elearning)
Mrs Julia Waddon	10/02/2016	Training - Committee Members Induction
Mrs Glenys Hunt	16/11/2016	NREAP Chairs Meeting

## 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	15	37.50
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	1	2.50
Research Database (including renewals)	0	0.00
Others	24	60.00
<b>Total Applications Reviewed</b>	<b>40</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	3
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	11
Number of paediatric applications reviewed	4
Number of device applications reviewed	3
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	0
Number of applications reviewed that are funded by the US DHHS	0
Number of qualitative applications reviewed	4

**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	5	12.50
Favourable Opinion with Additional Conditions	7	17.50
Unfavourable Opinion	0	0.00
Provisional Opinion	28	70.00
Provisional Opinion Pending Consultation with Referee	0	0.00
<b>Total</b>	<b>40</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	23	57.50
Further Information Favourable Opinion with Additional Conditions	2	5.00
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	5	12.50
Favourable Opinion with Additional Conditions	7	17.50
Unfavourable Opinion	0	0.00
Provisional Opinion	1	2.50
Provisional Opinion Pending Consultation with Referee	0	0.00
Further Information response not complete	1	2.50
No decision entered on system	0	0.00
Number of studies withdrawn after the meeting	1	2.50
<b>Total</b>	<b>40</b>	<b>100</b>

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

<b>Total Applications Reviewed</b>	<b>21</b>
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**Table 6: Breakdown of PRS applications and other activity during reporting period:**

Number of applications made invalid by the REC Manager	9
Number of studies withdrawn prior to the meeting	0
Number of student applications reviewed	8
Number of paediatric applications reviewed	2
Number of device applications reviewed	0
Number of qualitative applications reviewed	3

**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	7	33.33
Favourable Opinion with Additional Conditions	3	14.29
No Opinion transfer to full committee for review	3	14.29
Provisional Opinion	8	38.10
Unfavourable Opinion	0	0.00
<b>Total</b>	<b>21</b>	<b>100</b>

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

<b>Average number of applications reviewed per full meeting</b>	4.44
<b>Number of completed applications for full ethical review</b>	39
<b>Number of completed applications for full ethical review over 60 days</b>	0
<b>Number of completed applications over 60 days as a % of total</b>	0.00%
<b>Number of completed applications for full ethical review over 40 days</b>	2
<b>Number of completed applications over 40 days as a % of total</b>	5.00%
<b>Number of days taken to final decision – average (mean)</b>	31
<b>Number of completed proportionate review applications for ethical review</b>	18
<b>Number of completed proportionate review applications for ethical review over 14 days</b>	4
<b>Number of completed proportionate review applications over 14 days as a % of total</b>	22.22%
<b>Number of SSAs (non-Phase 1) reviewed</b>	1
<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>	96
<b>Number of completed substantial amendments over 35 days</b>	0
<b>Number of completed substantial amendments over 35 days as a % of total substantial amendments</b>	0.00%
<b>Number of completed substantial amendments over 28 days</b>	5
<b>Number of completed substantial amendments over 28 days as a % of total substantial amendments</b>	5.21%
<b>Number of modified amendments reviewed</b>	2
<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 minor amendments received</b>	65
<b>Number of substantial amendments received for information</b>	0
<b>Number of substantial amendments received for new sites/PIs</b>	32
<b>Number of annual progress reports received</b>	91

<b>Number of safety reports received</b>	41
<b>Number of Serious Adverse Events received</b>	6
<b>Number of final reports received</b>	26

**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>
15/NW/0430	Ellipse IM HTO Study	33
15/NW/0477	Proteomic and genomic analysis of hepatopancreaticobiliary cancers	37
15/NW/0492	Study of ACP-196 Versus Ibrutinib in previously treated CLL patients	37
15/NW/0495	Oxygen cost of chair based exercise in cardiac patients. Version 1.	31
15/NW/0624	D2270C00015 (AZD2014), Phase I, Open Label, Advanced Solid Tumours	27
15/NW/0631	OKAH-193 - Varicella vaccine study in the second year of life	40
15/NW/0637	Compass Phase II Version 1	22
15/NW/0696	The VITAL study	30
15/NW/0697	LPS13931: Outcomes in insulin naïve patients with uncontrolled T2DM	39
15/NW/0698	LPS14060: transition to Toujeo in basal insulin treated T2DM patients	39
15/NW/0945	QUIDS qualitative study	36
15/NW/0948	ENTO + VCR in Adult Subjects with Non-Hodgkin Lymphoma	29
15/NW/0950	CGAH: The Evolve-2 Study (Treatment for Episodic Migraine)	30
16/NW/0019	IM-201	34
16/NW/0034	CA209-498: Newly Diagnosed Glioblastoma (MGMT unmethylated)	28
16/NW/0036	A Phase IIa Study of MIV-711 in Knee Joint Osteoarthritis	40
16/NW/0097	FUTURE Initiative	31
16/NW/0124	Experimental Human Pneumococcal Carriage: Asthma and immune function	34
16/NW/0130	Study 1199.223 LUME BioNIS	32
16/NW/0166	Can exercise reduce hot flushes associated with breast cancer?	48
16/NW/0182	Pilot validation study of a screening tool used with ABI patients	29
16/NW/0186	Liverpool School of Tropical Medicine Research Tissue Bank (LSTM-RTB)	44
16/NW/0187	Phase III study of Ruxolitinib in Early Myelofibrosis	33

<b>Further Information Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
15/NW/0416	MUK Eight	22
15/NW/0418	The feasibility of self-acupuncture for patients with chronic pain	22

**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
15/NW/0629	Risk stratification in suspected acute coronary syndrome	21
16/NW/0027	Children with LD: Experiences of Clinical Procedures	28
16/NW/0090	PAKMAN	25
16/NW/0111	Social deprivation, shame, and the voice-hearing relationship Version2	25
16/NW/0196	CheckMate CA209-548 in pts with newly diagnosed GBM (MGMT methylated)	26

#### Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/NW/0425	Establishing a model for HPV-positive Gynaecological Cancer Research	20
15/NW/0510	The Holding Children Study	24
15/NW/0628	CAURAL AZD9291+MEDI4736 in Combination for NSCLC in 2nd Line or higher	21
15/NW/0924	RoVI Study	26
15/NW/0931	Experimental Human Pneumococcal Carriage Model Testing New Strains	26
16/NW/0031	Experimental Human Pneumococcal Carriage: Aging and immunity	28
16/NW/0040	Severe asthma, relationships & intimacy. The patient's perspective.	28

#### Unfavourable Opinion

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

REC Reference	Title	Number of Days on Clock
15/NW/0726	oRChiD: TRP Mechanisms Underlying Cough in Health and Disease	n/a

#### Provisional Opinion Pending Consultation with Referee

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

REC Reference	Title	Number of Days on Clock
16/NW/0120	Cardiac Adaptation to Normal and Short-term Overload Training Periods	n/a

**Withdrawn after the meeting**

REC Reference	Title	Number of Days on Clock
15/NW/0693	Gastric residual volume in critically ill children: the GRAPHIC study	43

**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
15/NW/0656	Passive Fluenz Tetra Safety Surveillance	17
15/NW/0664	The use of Basophil Activation Testing in Peri-Operative Anaphylaxis	15
15/NW/0828	Accu-rate	17
15/NW/0836	Exercise and Neurodegeneration Related to G4C2 Expansion of C9ORF72	14
15/NW/0838	Lost and Found: In-Hospital Way-Finding Study v.1	16
15/NW/0955	Evaluation of IFUs for creatinine and uric acid patient meters	14
15/NW/0956	Disclosure and Ankylosing Spondylitis - version 1	13
16/NW/0067	Patient experience of music in surgical admissions lounge	8

**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
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15/NW/0739	HLA antibodies following blood transfusion	14
15/NW/0994	REVEAL version 1	10
16/NW/0069	Visual Aura in Children and Adolescents with Migraine	14
16/NW/0235	PPI Exposure and Antibiotic Resistance: PEAR (Version 1.02)	8
16/NW/0236	Development of a PROM for orthopaedic surgery	7
16/NW/0237	The validity and reliability of rebound tonometry in children (4)	2
16/NW/0238	DRAKO Non-interventional Study	7

#### **Favourable Opinion with Additional Conditions**

<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
15/NW/0568	Properties of human pericytes (including student study) Version 2	11
15/NW/0951	Self-management barriers & facilitators in COPD	12
16/NW/0178	Factors affecting clinical outcomes post-lower limb bypass	14

#### **Unfavourable Opinion**

<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
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#### **Provisional Opinion**

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

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

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

<b>Favourable opinion</b>				
<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>
06/Q1502/4/AM22	Anti oxidants and magnesium in chronic pancreatitis	Substantial Amendment 17	26/02/2016	30
06/Q1502/77/AM03	UK Juvenile Systemic Lupus Erythematosus Cohort Study & Repository	Substantial Amendment 4	01/01/2016	28
08/H1002/42/AM03	Cancer biomarkers in saliva: establishing a control group	Amendment 3	09/02/2015	10
08/H1002/83/AM03	Loss of immunity to varicella zoster in acute lymphoblastic leukaemia	Change in Chief Investigator	05/12/2014	17
09/H1002/67+5/AM01	Collection and storage of tissue for research	Substantial Amendment 1	19/06/2015	12
09/H1002/80/AM12	ML22780 Advanced Triple Negative Study	SA#2015/02 - Avastin	31/03/2015	24
10/H1002/27/AM22	Denosumab as Adjuvant Treatment for Early-Stage Breast Cancer (D-CARE)	Amendment 22 - Protocol	15/05/2015	19
10/H1002/29/AM13	Extension study for S1P1 agonist in Multiple Sclerosis	Amendment 2 to IB version 9	01/04/2015	23
10/H1002/29/AM14	Extension study for S1P1 agonist in Multiple Sclerosis	Protocol Am 6_IBv10 AM 1	26/11/2015	10
10/H1002/49/AM04	Investigation of myometrial contractility	Substantial Amendment 4	29/02/2016	15
11/NW/0572/AM09	NGAL utility in paediatric oncology patients	Substantial Amendment 5	10/07/2015	12
12/NW/0169/AM04	CARS Study (version 1.0)	Amendment 4 10/02/2016	14/03/2016	21
12/NW/0361/AM12	A study of Standard and New Antiepileptic Drugs – SANAD-II	Substantial Amendment 7 (Documents)	22/07/2015	28
12/NW/0367/AM14	Belimumab vs placebo, plus standard therapy in paediatric SLE	Substantial Amendment 11	28/04/2015	14
12/NW/0367/AM16	Belimumab vs placebo, plus standard therapy in paediatric SLE	Substantial Amendment 13	15/02/2016	14

12/NW/0500/AM05	Health & Employment After Fifty (the HEAF Study)	Substantial Amendment 3	18/12/2015	21
12/NW/0500/AM06	Health & Employment After Fifty (the HEAF Study)	Substantial Amendment 4	02/02/2016	13
12/NW/0717/AM09	Fosaprepitant PK/PD CINV in Pediatric Cancer Patients	Substantial Amendment 08	11/05/2015	23
12/NW/0717/AM10	Fosaprepitant PK/PD CINV in Pediatric Cancer Patients	SA09	08/07/2015	13
12/NW/0739/AM06	A Ph.I/II Dose Escalation Study and Expansion safety/efficacy study.	SA UK REC 05	23/12/2015	30
12/NW/0739/AM08	A Ph.I/II Dose Escalation Study and Expansion safety/efficacy study.	SA UK REC 06	02/03/2016	16
12/NW/0802/AM10	Study of Oral Laquinimod in Subjects with Multiple Sclerosis	Global Protocol Amendment 3	24/03/2015	20
12/NW/0802/AM11	Study of Oral Laquinimod in Subjects with Multiple Sclerosis	Five	26/08/2015	20
12/NW/0802/AM13	Study of Oral Laquinimod in Subjects with Multiple Sclerosis	6	16/03/2016	26
12/NW/0814/AM10	Efficacy & Safety/Tolerability of Subcutaneous SCH900222/MK-3222	Participant Auto Injector Inst	10/07/2015	11
12/NW/0814/AM11	Efficacy & Safety/Tolerability of Subcutaneous SCH900222/MK-3222	Protocol Amendment 7 & Updated	02/02/2016	14
13/NW/0088/AM02	Can exercise training speed up artery recovery following PCI?	Substantial Amendment 2	24/07/2015	11
13/NW/0265/AM05	DESTINY	Amendment 4	17/04/2015	19
13/NW/0612/AM21	Benralizumab treatment in patients with uncontrolled asthma (SIROCCO)	Substantial Amendment 11 - Protocol	08/06/2015	25
13/NW/0621/AM08	The early use of Antibiotics in at Risk Children with Influenza-ARCHIE	ARCHIE_SA007	18/06/2015	14
13/NW/0621/AM12	The early use of Antibiotics in at Risk Children with Influenza-ARCHIE	ARCHIE_SA010	23/03/2016	34
13/NW/0738/AM04	Humox Study	Substantial Amendment 3	01/12/2015	3
13/NW/0831/AM15	CV - Long-term Safety of Naldemedine for the Treatment of OIC	Substantial Amendment, ProtAm3	26/02/2015	24
13/NW/0831/AM16	CV - Long-term Safety of Naldemedine for the Treatment of	Substantial	15/06/2015	21

	OIC	Amendment - Change		
13/NW/0831/AM17	CV - Long-term Safety of Naldemedine for the Treatment of OIC	Substantial Amendment - Update	04/08/2015	19
14/NW/0018/AM04	Cinryze in Prevention of Angioedema Attacks in Children	Protocol Amendment 4	26/03/2015	25
14/NW/0018/AM06	Cinryze in Prevention of Angioedema Attacks in Children	Substantial Amendment - HAE UK	16/09/2015	11
14/NW/0156/AM07	OlympiAD - Olaparib monotherapy V Physicians choice chemotherapy	Substantial Amendment 4	05/06/2015	14
14/NW/0156/AM09	OlympiAD - Olaparib monotherapy V Physicians choice chemotherapy	D0819C0003	13/11/2015	17
14/NW/0350/AM04	Nivolumab or Nivolumab + Ipilimumab vs Bevacizumab in Recurrent GBM	Substantial Amendment 04	01/05/2015	33
14/NW/0350/AM05	Nivolumab or Nivolumab + Ipilimumab vs Bevacizumab in Recurrent GBM	Substantial Amendment 05	16/09/2015	12
14/NW/0350/AM06	Nivolumab or Nivolumab + Ipilimumab vs Bevacizumab in Recurrent GBM	Substantial Amendment EC06	10/03/2016	20
14/NW/0355/AM03	Safety, Tolerability and Efficacy Study of Pneumococcal Vaccine	Substantial Amendment 3	10/07/2015	27
14/NW/1071/AM01	Endotracheal suctioning in post-operative cardiac infants	19.03.2015	19/03/2015	28
14/NW/1097/AM04	PIANO Study - PLX3397 c-KIT in advanced acral and mucosal melanoma	Substantial Amendment 01	16/07/2015	21
14/NW/1189/AM01	ACTION:Cancer patient involvement in medical decision making V 1.0	Amendment Number 1.0	09/04/2015	14
14/NW/1206/AM02	EAGLE	Amendment 2	17/12/2015	8
14/NW/1239/AM03	Guselkumab in Psoriasis following inadequate Ustekinumab response	Amendment 2	13/05/2015	14
14/NW/1239/AM05	Guselkumab in Psoriasis following inadequate Ustekinumab response	Amendment 3	02/02/2016	11
14/NW/1289/AM01	Menstrual disturbance associated with HIV/AIDS	Substantial Amendment 1	23/03/2015	13
14/NW/1292/AM04	CA209-214 Nivolumab combined with Ipilimumab versus Sunitinib in RCC	Substantial Amendment SA 04	07/05/2015	22

14/NW/1292/AM06	CA209-214 Nivolumab combined with Ipilimumab versus Sunitinib in RCC	Substantial Amendment 05	03/08/2015	21
14/NW/1292/AM07	CA209-214 Nivolumab combined with Ipilimumab versus Sunitinib in RCC	Six	03/09/2015	12
14/NW/1358/AM02	SELINEXOR COMPARED TO PHYSICIANS CHOICE IN RELAPSED OR REFRACTORY AML	KCP 330 008 -3	16/03/2015	28
14/NW/1358/AM06	SELINEXOR COMPARED TO PHYSICIANS CHOICE IN RELAPSED OR REFRACTORY AML	KCP-330-008 - Substantial Amen	30/06/2015	28
14/NW/1358/AM07	SELINEXOR COMPARED TO PHYSICIANS CHOICE IN RELAPSED OR REFRACTORY AML	Substantial Amendment 5	30/07/2015	25
14/NW/1358/AM09	SELINEXOR COMPARED TO PHYSICIANS CHOICE IN RELAPSED OR REFRACTORY AML	Substantial Amendment 5 - Protocol	02/09/2015	28
14/NW/1427/AM02	Effects of inhaled CVT-301 in Subjects with Parkinson's disease	Substantial Amendment - Change	15/04/2015	15
14/NW/1427/AM03	Effects of inhaled CVT-301 in Subjects with Parkinson's disease	Protocol Amendment	18/12/2015	21
14/NW/1437/AM02	The Pharmacoeconomics of Age-inappropriate Formulations (AiFs)	Substantial Amendment 1	05/06/2015	28
14/NW/1455/AM02	Non-specific Effects of Typhoid Vaccination	Substantial Amendment 1	20/05/2015	14
14/NW/1460/AM02	LAIV and EHPC	Amendment 4896	15/04/2015	13
14/NW/1460/AM03	LAIV and EHPC	Substantial Amendment 2	04/09/2015	23
14/NW/1460/AM04	LAIV and EHPC	Substantial Amendment 3	11/12/2015	5
14/NW/1474/AM02	Antimicrobial Hernia Repair Device Clinical Study 13-10	Substantial Amendment A_02	08/04/2015	14
15/NW/0021/AM01	BBC	BBC Amendment 1	22/06/2015	14
15/NW/0023/AM01	Social identity and pulmonary rehabilitation	Amendment 1	05/05/2015	17
15/NW/0052/AM01	BeaCh: interactions between bronchoconstriction and cough in asthma	Substantial Amendment 1	10/06/2015	8
15/NW/0055/AM02	ReFLeCT	15/NW/0055/AM02	24/03/2015	19
15/NW/0055/AM03	ReFLeCT	Protocol	11/02/2016	12

		Amendment 3 & 4		
15/NW/0146/AM01	Pilot Study of Repeated Mucosal Sampling on EHPC model	Substantial Amendment 1	10/07/2015	16
15/NW/0225/AM01	SAFE: intervention development and pilot RCT.	Substantial Amendment 1	29/09/2015	11
15/NW/0226/AM01	Home administration of benralizumab in patients with severe asthma	Substantial Amendment 1	29/04/2015	16
15/NW/0416/AM03	MUK Eight	HM13/10993/P/150909	14/09/2015	14
15/NW/0492/AM03	Study of ACP-196 Versus Ibrutinib in previously treated CLL patients	Two	03/06/2015	15
15/NW/0624/AM02	D2270C00015 (AZD2014), Phase I, Open Label, Advanced Solid Tumours	SA1 - updated PIS-ICF	13/11/2015	6
15/NW/0628/AM01	CAURAL AZD9291+MEDI4736 in Combination for NSCLC in 2nd Line or higher	Temporary Halt of Study	01/10/2015	11
15/NW/0631/AM01	OKAH-193 - Varicella vaccine study in the second year of life	Substantial Amendment 1	28/09/2015	11
15/NW/0637/AM01	Compass Phase II Version 1	Substantial Amendment 1	09/12/2015	22
15/NW/0696/AM03	The VITAL study	Substantial Amendment 1 - Amen	19/01/2016	13
15/NW/0697/AM03	LPS13931: Outcomes in insulin naïve patients with uncontrolled T2DM	Substantial Amendment 2	12/11/2015	15
15/NW/0697/AM04	LPS13931: Outcomes in insulin naïve patients with uncontrolled T2DM	Substantial Amendment 3	18/12/2015	21
15/NW/0697/AM06	LPS13931: Outcomes in insulin naïve patients with uncontrolled T2DM	Substantial Amendment 4	01/02/2016	17
15/NW/0698/AM03	LPS14060: transition to Toujeo in basal insulin treated T2DM patients	Substantial Amendment 2	12/11/2015	15
15/NW/0698/AM04	LPS14060: transition to Toujeo in basal insulin treated T2DM patients	Substantial Amendment 3	18/12/2015	21
15/NW/0698/AM06	LPS14060: transition to Toujeo in basal insulin treated T2DM patients	Substantial Amendment 4	01/02/2016	17
15/NW/0836/AM01	Exercise and Neurodegeneration Related to G4C2 Expansion	Substantial	29/10/2015	20



	of C9ORF72	Amendment 1		
15/NW/0838/AM01	Lost and Found: In-Hospital Way-Finding Study v.1	Substantial Amendment 1	24/02/2016	4
15/NW/0948/AM01	ENTO + VCR in Adult Subjects with Non-Hodgkin Lymphoma	updated Main Study PIS ICF	15/03/2016	20
15/NW/0950/AM01	CGAH: The Evolve-2 Study (Treatment for Episodic Migraine)	Protocol amendment a - PISICF	05/02/2016	14
16/NW/0031/AM01	Experimental Human Pneumococcal Carriage: Aging and immunity	1, 18/03/2016	20/03/2016	21
16/NW/0034/AM01	CA209-498: Newly Diagnosed Glioblastoma (MGMT unmethylated)	Substantial Amendment 1	23/02/2016	7
16/NW/0040/AM01	Severe asthma, relationships & intimacy. The patient's perspective.	Substantial Amendment 1	24/02/2016	5

#### Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
11/H1002/10/AM32	REPOSE V1	Substantial Amendment 21	17/04/2015	30
12/NW/0585/AM10	Trastuzumab Emtansine (T-DM1) 2nd line Metastatic Gastric Study	Substantial Amendment #8 - Protocol	12/05/2015	28
14/NW/1188/AM02	The validity of informed consent for inguinal hernia surgery	Substantial Amendment 2	04/01/2016	16

**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/0585/AM10/1	Trastuzumab Emtansine (T-DM1) 2nd line Metastatic Gastric Study	8	27/08/2015	11

<b>Unfavourable opinion timeline</b>				
<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>
14/NW/1188/AM02/1	The validity of informed consent for inguinal hernia surgery	Modified Amendment 2	10/02/2016	10

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

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

REC Reference	Title	Number of Days on Clock
15/NW/0656	Passive Fluenz Tetra Safety Surveillance	17
15/NW/0664	The use of Basophil Activation Testing in Peri-Operative Anaphylaxis	15
15/NW/0828	Accu-rate	17
15/NW/0838	Lost and Found: In-Hospital Way-Finding Study v.1	16

**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
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**Modified Amendments over 14 day timeline**

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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