

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

**Annual Report**

**01 April 2017 - 31 March 2018**



## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	North West - Liverpool East Research Ethics Committee
<b>Type of REC:</b>	Recognised REC
<b>Type of Flag:</b>	Type III (CTIMP) Until 01/01/2018, Research Tissue Bank, Paediatric
<b>Chair:</b>	Mrs Glenys Hunt (Until 16/06/2017) Miss Kimberley Saint (Appointed 27/03/2018)
<b>Vice-Chair:</b>	Miss Kimberley Saint (Until 27/03/2018) Vacant (28/03/2018 – present)
<b>Alternate Vice-Chair:</b>	Dr Peter Walton
<b>REC Manager:</b>	Ms Gemma Warren
<b>REC Assistant:</b>	Miss Nafeesa Khanam
<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:

The previous Chair, Glenys Hunt, finished her term in 2017. The Committee would like to thank Glenys for chairing the Committee brilliantly over her term and wish her luck with her PhD. Another member we have lost this year is Julia Waddon. The Committee would like to thank Julia for sharing her expertise as a Nurse Practitioner in Children's intensive care with us and wish her luck in Canada. The Committee would also like to thank Gemma and Nafeesa for managing the Committee this year and keeping us on track.

After some consideration I applied for the Chair role and was appointed. Unfortunately this now leaves the committee without a vice-chair. We are generally low on membership, leaving those on the Committee with a higher workload in terms of Proportionate Reviews and sub-committee meetings. All members have taken on the additional workload with good grace, however we do need to recruit new members urgently. We have recruited two new members in the last year, however we have lost two. We are fortunate that other Committee members in the North West region have kindly co-opted to ensure the Committee has been able to hold quorate meetings.

The lack of medically qualified member poses another challenge for the Committee. We have temporarily lost our flag for 'CTIMP studies' and we are also likely to lose our flag for 'Research involving children' as we no longer have any expert members with relevant experience. This is a great shame when we have two excellent pharmacists on the Committee whose expertise we are no longer utilising. Furthermore, given the Committee meetings are held at Alder Hey Children's Hospital, it is a great loss for the hospital. We are reliant on the HRA helping us to recruit members. All current Committee members have been using their contacts attract new members.

The majority of members have participated in training this year. The training provided by the HRA is always praised and enjoyed by those that attend. Members that have not registered any training this year have been asked to do so, as per their commitment to the REC.

The Committee is relaxed and receives good feedback from those that attend. We are also a friendly unit with close friendships being formed amongst some of the members. I hope this warm nature will attract new members to allow the Committee to prosper in the coming year.

## 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	
Mr Mike Davis	Clinical Audit & Effectiveness Lead	Lay Plus	01/02/2018	
Mr Waiel Elzamzami	Healthcare Scientist	Expert	01/07/2017	
Mrs Sue Fitzpatrick	Director	Lay	14/04/2015	
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	16/06/2017
Dr Supriya Kapas	Senior Clinical Pharmacist	Expert	03/09/2015	
Mr Alan McGarrity	Retired Police Inspector	Lay Plus	01/08/2016	
Mr Alex Newgrosh	Quality Assurance Manager	Lay Plus	16/09/2010	
Miss Kimberley Saint	Clinical Scientist - Nuclear Medicine	Expert	27/09/2012	
Mrs Julia Waddon	Advanced Nurse Practitioner	Lay	01/06/2015	20/03/2018
Dr Peter Walton	Retired Clinical Scientist	Lay	14/05/2008	

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

Name	Profession	Status	Meeting date attended
Mrs Julie Brake	Specialist Diabetes Nurse / Chair	Expert	16/02/2018
Mr James Burns	Retired Housing Committee Chair	Lay	20/04/2017 & 16/02/2018
Mrs Hannah Chambers	Retired Nurse	Lay	17/08/2017
Mrs Christine Holly	Retired Librarian	Lay Plus	16/11/2017
Mr Paul Mooney	Senior Clinical Pharmacist	Expert	16/02/2018

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

<b>Name</b>	<b>Declaration of Interest</b>	<b>Date</b>
Mr Waiel Elzamzami	Committee Member of the Rehabilitation Engineering and Biomechanics Special Interest Group (REBSIG) of the Institute of Physics and Engineering in Medicine (IPEM)	26/07/2017
Mrs Maureen Hendry	None	21/09/2017
Mrs Annette Hockney	AstraZeneca Shares	21/09/2017
Mr Alan McGarrity	None	18/08/2017
Mr Alex Newgrosh	None	21/09/2017
Mrs Julia Waddon	None	21/09/2017
Dr Peter Walton	None	14/12/2017

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

Month	Date	Number of Members Present at Meeting
April	20/04/2017	7
May	18/05/2017	8
June	15/06/2017	8
August	17/08/2017	7
September	21/09/2017	10
November	16/11/2017	9
December	14/12/2017	10
January	18/01/2018	9
February	16/02/2018	9
March	15/03/2018	9

10 full committee meetings were held during the reporting period.

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

Month	Date	Number of Members Present at Meeting
May	02/05/2017	3
May	30/05/2017	3
June	27/06/2017	3
September	26/09/2017	3
October	24/10/2017	4
December	26/12/2017	3
January	23/01/2018	3
February	27/02/2018	3
March	27/03/2018	3

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

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

Month	Date	Number of Members Present at Meeting
April	10/04/2017	3
May	08/05/2017	2
May	22/05/2017	7
May	22/05/2017	2
June	05/06/2017	2
June	19/06/2017	2
July	03/07/2017	2
July	17/07/2017	2
July	31/07/2017	2
August	14/08/2017	2
August	28/08/2017	2
September	11/09/2017	2
September	25/09/2017	2

October	09/10/2017	2
October	23/10/2017	2
November	06/11/2017	2
November	20/11/2017	2
December	11/12/2017	3
December	18/12/2017	2
January	08/01/2018	2
January	15/01/2018	2
February	05/02/2018	2
February	19/02/2018	2
February	26/02/2018	2
March	05/03/2018	2
March	19/03/2018	2

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

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

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Mr John Bridson	5
Mr Waiel Elzamzami	6
Mrs Sue Fitzpatrick	7
Mrs Maureen Hendry	8
Mrs Annette Hockney	5
Mrs Glenys J Hunt	2
Dr Supriya Kapas	5
Mr Alan McGarrity	9
Mr Alex Newgrosh	8
Miss Kimberley Saint	7
Mrs Julia Waddon	8
Dr Peter Walton	10

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Mr John Bridson	3
Mr Waiel Elzamzami	1
Mrs Sue Fitzpatrick	3
Mrs Annette Hockney	2
Mrs Glenys J Hunt	2
Dr Supriya Kapas	3
Mr Alan McGarrity	3
Miss Kimberley Saint	5
Mrs Julia Waddon	2
Dr Peter Walton	4

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Mr John Bridson	2
Mr Waiel Elzamzami	1
Mrs Sue Fitzpatrick	3
Mrs Maureen Hendry	3
Mrs Annette Hockney	5
Mrs Glenys J Hunt	4
Dr Supriya Kapas	3
Mr Alan McGarrity	2
Mr Alex Newgrosh	3



Miss Kimberley Saint	14
Mrs Julia Waddon	2
Dr Peter Walton	17

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

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Mr Waiel Elzamzami	19/10/2017	Training - Quantitative Research Methods and Statistics: A Health Research
Mr Waiel Elzamzami	18/12/2017	Induction for new Research Ethics Service Committee Members
Mr Waiel Elzamzami	18/12/2017	Equality and Diversity and Human Rights
Mr Waiel Elzamzami	16/03/2018	Assessing the Consequences (benefits and harms) of research
Mrs Sue Fitzpatrick	26/04/2017	Teaching GCP at The London Clinic
Mrs Sue Fitzpatrick	16/06/2017	Attendance at Conferences or Scientific Meetings
Mrs Sue Fitzpatrick	20/07/2017	HARP Training Course
Mrs Sue Fitzpatrick	22/08/2017	Coaching and Counselling Skills
Mrs Maureen Hendry	31/01/2018	Training - Complex Cases
Mrs Annette Hockney	08/11/2017	The Ethical Issues of Research Involving Children
Mrs Annette Hockney	18/12/2017	Equality and Diversity and Human Rights
Dr Supriya Kapas	01/08/2017	Human Tissue Act (Use of Human Samples in Research) - An Introductory Level
Dr Supriya Kapas	08/11/2017	The Ethical Issues of Research Involving Children
Dr Supriya Kapas	21/12/2017	E&D Training
Mr Alan McGarrity	04/07/2017	Research Involving Adults Who Lack Capacity (including research in emergency situations)
Mr Alan McGarrity	08/11/2017	The Ethical Issues of Research Involving Children
Mr Alan McGarrity	20/02/2018	Human Tissue Act (Use of Human Samples in Research) - An Introductory Level
Mr Alan McGarrity	01/03/2018	Regional Training Day - North West
Miss Kimberley Saint	14/09/2017	Training for New REC Chairs
Miss Kimberley Saint	24/11/2017	Training - HRA National Chairs' Day and Policy Event
Miss Kimberley Saint	13/12/2017	Equality Diversity and Human Rights

## 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	14	26.92
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	0	0.00
Others	38	73.08
<b>Total Applications Reviewed</b>	<b>52</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	0
Number of applications withdrawn prior to the meeting	1
Number of student applications reviewed	17
Number of paediatric applications reviewed	19
Number of device applications reviewed	2
Number of prisoner applications reviewed	1
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	1	1.92
Favourable Opinion with Additional Conditions	12	23.08
Unfavourable Opinion	1	1.92
Provisional Opinion	38	73.08
Provisional Opinion Pending Consultation with Referee	0	0.00
<b>Total</b>	<b>52</b>	<b>100</b>
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**

<b>Status of applications at date of generation of report</b>	<b>Number</b>	<b>%</b>
Further Information Favourable Opinion with Standard Conditions	24	46.15
Further Information Favourable Opinion with Additional Conditions	9	17.31
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	1	1.92
Favourable Opinion with Additional Conditions	12	23.08
Unfavourable Opinion	1	1.92
Provisional Opinion	3	5.77
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	2	3.85
<b>Total</b>	<b>52</b>	<b>100</b>

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

<b>Total Applications Reviewed</b>	<b>16</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	2
Number of studies withdrawn prior to the meeting	4
Number of student applications reviewed	6
Number of paediatric applications reviewed	1
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	5	31.25
Favourable Opinion with Additional Conditions	4	25.00
No Opinion transfer to full committee for review	1	6.25
Provisional Opinion	6	37.50
Unfavourable Opinion	0	0.00
<b>Total</b>	<b>16</b>	<b>100</b>

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

<b>Average number of applications reviewed per full meeting</b>	5.20
<b>Number of completed applications for full ethical review</b>	50
<b>Number of completed applications for full ethical review over 60 days</b>	0
<b>Number of completed applications over 60 days as a % of total</b>	0.00%
<b>Number of days taken to final decision – average (mean)</b>	41
<b>Number of completed proportionate review applications for ethical review</b>	15
<b>Number of completed proportionate review applications for ethical review over 21 days</b>	8
<b>Number of completed proportionate review applications over 21 days as a % of total</b>	53.33%
<b>Number of SSAs (non-Phase 1) reviewed</b>	16
<b>Number of completed applications for SSA review over 25 days</b>	1
<b>Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs</b>	6.25%
<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>	101
<b>Number of completed substantial amendments over 35 days</b>	16
<b>Number of completed substantial amendments over 35 days as a % of total substantial amendments</b>	15.84%
<b>Number of modified amendments reviewed</b>	0
<b>Number of completed modified amendments over 14 days</b>	0
<b>Number of completed modified amendments over 14 days as a % of total modified amendments</b>	0.00%
<b>Number of non substantial amendments received</b>	88
<b>Number of substantial amendments received for information</b>	4
<b>Number of substantial amendments received for new sites/PIs</b>	40
<b>Number of annual progress reports received</b>	56
<b>Number of safety reports received</b>	36
<b>Number of Serious Adverse Events received</b>	1
<b>Number of final reports received</b>	12

**Table 9.1: Breakdown of current status of all full applications reviewed within the reporting period**

<b>Further Information Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
17/NW/0234	The Role of Synaptic Plasticity in Neuropathic Pain Treatment	31
17/NW/0247	AURORA	60
17/NW/0255	Neuro-Therapeutic Interventions for Pain (NTIP) Project	42
17/NW/0313	Chronic Post-Operative Pain and Mindfulness	47
17/NW/0317	Krio	40
17/NW/0369	PRAN-16-52 Pracinostat in combination with Azacitidine in Adult AML	35
17/NW/0486	CQVM149B2208 - compare 2 doses of QVM149 vs sal/flu on bronchodilation	45
17/NW/0488	Phase 2a single blind study of multiple PC786 doses against RSV	49
17/NW/0489	Group metacognitive therapy for anxiety/depression in cancer survivors	31
17/NW/0546	C16029: Phase 2/3 Randomized, Open-Label Study in Multiple Myeloma	29
17/NW/0552	PD-RAD	51
17/NW/0649	ASPECT Study	44
17/NW/0660	Interceptive Exposure in treatment of disabling fear of pain.	53
17/NW/0661	Softened Water for Eczema Prevention (SOFTER)	60
17/NW/0662	APPRAISE ATP_Post Market Trial (0393-0021)	59
17/NW/0705	ALTER: Age UK LaTER Life Research v 1.0	58
17/NW/0710	CastleCreek Extension	59
17/NW/0711	Extension Study for BMN 250 in Patients MPS IIIB	59
18/NW/0036	The experience of moving on from a democratic therapeutic community	41
18/NW/0037	REDUCE-RISKinCD-PIBD -TRIAL	57
18/NW/0043	Dental assessment prior to allogenic stem cell transplantation	57
18/NW/0078	MRI for lung radiotherapy; a prospective study.	59
18/NW/0114	OSA recurrence in CPAP withdrawal	56
18/NW/0116	Genetics and Molecular Pathology of Central Serous Chorioretinopathy	48

<b>Further Information Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
17/NW/0020	Serum progesterone levels and medical management of miscarriage	33
17/NW/0298	Isavuconazole for CPA	45
17/NW/0318	Women's experience of anxiety during pregnancy: A qualitative study	44
17/NW/0319	Fetal Growth Restriction and mother's experiences Version 1	35

17/NW/0533	DETECT study	58
17/NW/0658	Hand Wash Study V1	40
17/NW/0694	P4 in PICU - Version 1	60
17/NW/0708	Market research - acceptability trial of a new PKU protein substitute	55
18/NW/0100	BATCH Trial	59

#### 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
17/NW/0496	Maximising the value of the UK IBD Registry	15

#### Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
17/NW/0249	Neuro protection	33
17/NW/0471	233AS102 Extension Study in ALS	14
17/NW/0483	An exploration of the OPD pathway in one prison treatment service	14
17/NW/0493	Measuring health literacy amongst people with COPD	14
17/NW/0511	ITI rFVIII Fc study in Haemophilia A Pts who failed previous ITI therapy	38
17/NW/0550	Developing allogeneic musculoskeletal therapies.	29
17/NW/0650	MRI Study of NMOSD	28
17/NW/0663	SNOT: Sampling the Nose Of Toddlers and Young Children	33
18/NW/0018	Evaluation of Renastep	33
18/NW/0019	CAT 3D : Creating Acceptable Tablets 3D	33
18/NW/0034	BPD traits, implicit theories and emotion regulation strategies	33
18/NW/0112	Dose expansion mCRC trial with Lonsurf, oxaliplatin bev, and nivolumab	38

#### Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
17/NW/0378	'Minimizing the pain of local anaesthesia'	28



<b>Provisional Opinion</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
18/NW/0175	QUADRATIC Study	n/a
18/NW/0178	Being Me with IBD	n/a
18/NW/0212	Study of the use of Personal Narratives for Reducing Restraint v. 1	n/a

<b>Provisional Opinion Pending Consultation with Referee</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>

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

<b>Withdrawn after the meeting</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
17/NW/0239	OBE3001: Canagliflozin, Phentermine, Placebo in T2DM	29
17/NW/0240	OBE3002: Canagliflozin, Phentermine, Placebo in Non-diabetics	29

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

<b>Further Information Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
17/NW/0273	Comparison of DNA between blastocoele fluid and trophectoderm cells	13
17/NW/0277	Edere version 1	30
17/NW/0348	Outcomes of Cochlear Implants in Congenitally Deafened Adults 1.2	24

<b>Further Information Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
17/NW/0279	Prospective Study of Fatty Acid Profiles and Pregnancy Outcomes	16
18/NW/0062	Nutrition self-screening tool for adult IBD outpatient clinics	23
18/NW/0065	Survey of factors affecting employment in Inflammatory Bowel Disease.	24

**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
17/NW/0408	Analysis of Chondroitin Sulfate-E in Colorectal and Breast Carcinomas	11
17/NW/0570	The effect of rectal shape and size on bladder deformation	22
18/NW/0150	VAC053B: Follow-up immunology bleed	23
18/NW/0151	UCL/Sheffield Brain Tumour Initiative	21
18/NW/0152	Health and social selection bias to participation in the NICOLA study	22

**Favourable Opinion with Additional Conditions**

REC Reference	Title	Number of Days on Clock
17/NW/0624	Implementation and evaluation of attenuation correction in PET-MR	17
17/NW/0726	Face Validity of Fatigue Scales in CFS/ME: CFQ & BRAF	27
18/NW/0064	Perceptions of e-cigarettes amongst mental health smokers	17
18/NW/0067	SASA vs 1.0 12-Dec-2017	16

**Unfavourable Opinion**

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

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
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**Withdrawn after the meeting**

REC Reference	Title	Number of Days on Clock
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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/AM24	Anti oxidants and magnesium in chronic pancreatitis	Substantial Amendment 19	22/06/2017	35
10/H1002/27/AM30	Denosumab as Adjuvant Treatment for Early-Stage Breast Cancer (D-CARE)	Substantial Amendment 28	05/05/2017	16
10/H1002/27/AM34	Denosumab as Adjuvant Treatment for Early-Stage Breast Cancer (D-CARE)	Substantial Amendment 30	25/07/2017	13
10/H1002/29/AM18	Extension study for S1P1 agonist in Multiple Sclerosis	Substantial Amendment 17	07/06/2017	23
10/H1002/29/AM19	Extension study for S1P1 agonist in Multiple Sclerosis	Substantial Amendment 18	01/07/2017	30
11/H1002/1/AM17	Tacrolimus for Prograf to Advagraf conversion in children. Version 1.0	Substantial Amendment 8	20/12/2017	36
11/NW/0572/AM11	NGAL utility in paediatric oncology patients	Substantial Amendment 6.0	17/02/2017	35
12/NW/0361/AM24	A study of Standard and New Antiepileptic Drugs – SANAD-II	Substantial Amendment 13	06/04/2017	18
12/NW/0361/AM27	A study of Standard and New Antiepileptic Drugs – SANAD-II	Substantial Amendment 14	12/06/2017	23
12/NW/0361/AM29	A study of Standard and New Antiepileptic Drugs – SANAD-II	16	01/09/2017	20
12/NW/0361/AM30	A study of Standard and New Antiepileptic Drugs – SANAD-II	17	23/08/2017	34
12/NW/0361/AM32	A study of Standard and New Antiepileptic Drugs – SANAD-II	19	26/02/2018	43
12/NW/0367/AM25	Belimumab vs placebo, plus standard therapy in paediatric SLE	18	05/07/2017	22
12/NW/0500/AM08	Health & Employment After Fifty (the HEAF Study)	6	31/10/2017	29
12/NW/0500/AM09	Health & Employment After Fifty (the HEAF Study)	7	17/01/2018	37
12/NW/0739/AM11	A Ph.I/II Dose Escalation Study and Expansion safety/efficacy study.	Substantial Amendment 8	12/05/2017	26
12/NW/0739/AM12	A Ph.I/II Dose Escalation Study and Expansion safety/efficacy study.	9	14/07/2017	13
12/NW/0739/AM13	A Ph.I/II Dose Escalation Study and Expansion safety/efficacy study.	10	28/09/2017	36
12/NW/0802/AM18	Study of Oral Laquinimod in Subjects with Multiple Sclerosis	Substantial Amendment 10	27/03/2017	30

12/NW/0814/AM16	Efficacy & Safety/Tolerability of Subcutaneous SCH900222/MK-3222	14	08/09/2017	35
12/NW/0814/AM17	Efficacy & Safety/Tolerability of Subcutaneous SCH900222/MK-3222	Substantial Amendment 15	27/11/2017	37
13/NW/0265/AM08	DESTINY	6	21/08/2017	34
13/NW/0265/AM11	DESTINY	7	16/01/2018	34
13/NW/0621/AM23	The early use of Antibiotics in at Risk Children with Influenza-ARCHIE	Substantial Amendment 17	15/05/2017	29
13/NW/0621/AM26	The early use of Antibiotics in at Risk Children with Influenza-ARCHIE	20	21/08/2017	13
14/NW/0156/AM15	OlympiAD - Olaparib monotherapy V Physicians choice chemotherapy	9	10/03/2017	25
14/NW/0203/AM03	Development of outcome measures in juvenile localised scleroderma	2	23/11/2017	22
14/NW/0302/AM07	BOTOX® for Treatment of Urinary Incontinence in patients 12-17 yrs old	4	19/06/2017	23
14/NW/0350/AM10	Nivolumab or Nivolumab + Ipilimumab vs Bevacizumab in Recurrent GBM	10	18/10/2017	33
14/NW/0350/AM11	Nivolumab or Nivolumab + Ipilimumab vs Bevacizumab in Recurrent GBM	11	19/12/2018	54
14/NW/1097/AM09	PIANO Study - PLX3397 c-KIT in advanced acral and mucosal melanoma	4	04/10/2017	25
14/NW/1292/AM11	CA209-214 Nivolumab combined with Ipilimumab versus Sunitinib in RCC	Substantial Amendment 8	04/05/2017	20
14/NW/1292/AM13	CA209-214 Nivolumab combined with Ipilimumab versus Sunitinib in RCC	10	04/09/2017	29
14/NW/1292/AM15	CA209-214 Nivolumab combined with Ipilimumab versus Sunitinib in RCC	Substantial Amendment 14	13/11/2017	18
14/NW/1358/AM14	SELINEXOR COMPARED TO PHYSICIANS CHOICE IN RELAPSED OR REFRACTORY AML	Substantial Amendment 6	16/03/2017	35
14/NW/1358/AM15	SELINEXOR COMPARED TO PHYSICIANS CHOICE IN RELAPSED OR REFRACTORY AML	7	12/06/2017	23
15/NW/0093/AM06	Dose of remifentanyl for cardiac scans under anaesthesia in children.	4	16/06/2017	28
15/NW/0093/AM08	Dose of remifentanyl for cardiac scans under anaesthesia in children.	5	20/12/2017	35
15/NW/0416/AM11	MUK Eight	11	26/06/2017	18

15/NW/0416/AM21	MUK Eight	16	06/12/2017	35
15/NW/0477/AM01	Proteomic and genomic analysis of hepatopancreaticobiliary cancers	Substantial Amendment 2.0	01/02/2018	35
15/NW/0492/AM11	Study of ACP-196 Versus Ibrutinib in previously treated CLL patients	Substantial Amendment 9	22/11/2017	41
15/NW/0624/AM04	D2270C00015 (AZD2014), Phase I, Open Label, Advanced Solid Tumours	Substantial Amendment 3	19/04/2017	19
15/NW/0726/AM01	oRChID: TRP Mechanisms Underlying Cough in Health and Disease	1	16/11/2017	32
15/NW/0931/AM03	Experimental Human Pneumococcal Carriage Model Testing New Strains	2	21/12/2017	34
15/NW/0950/AM08	CGAH: The Evolve-2 Study (Treatment for Episodic Migraine)	Substantial Amendment 5	03/05/2017	30
15/NW/0950/AM09	CGAH: The Evolve-2 Study (Treatment for Episodic Migraine)	6	28/11/2017	41
16/NW/0019/AM05	IM-201	5	03/08/2017	26
16/NW/0019/AM06	IM-201	6	02/11/2017	34
16/NW/0031/AM05	Experimental Human Pneumococcal Carriage: Aging and immunity	5	17/07/2017	33
16/NW/0031/AM06	Experimental Human Pneumococcal Carriage: Aging and immunity	6	10/10/2017	19
16/NW/0034/AM06	CA209-498: Newly Diagnosed Glioblastoma (MGMT unmethylated)	5	18/07/2017	34
16/NW/0034/AM07	CA209-498: Newly Diagnosed Glioblastoma (MGMT unmethylated)	6	17/10/2017	20
16/NW/0097/AM10	FUTURE Initiative	Substantial Amendment 4	29/11/2017	33
16/NW/0124/AM07	Experimental Human Pneumococcal Carriage: Asthma and immune function	3	03/08/2017	9
16/NW/0130/AM04	Study 1199.223 LUME BioNIS	2	27/09/2017	35
16/NW/0166/AM02	Can exercise reduce hot flushes associated with breast cancer?	Substantial Amendment 1	25/04/2017	35
16/NW/0196/AM04	CheckMate CA209-548 in pts with newly diagnosed GBM (MGMT methylated)	3	18/07/2017	34
16/NW/0196/AM06	CheckMate CA209-548 in pts with newly diagnosed GBM (MGMT methylated)	4	17/10/2017	34
16/NW/0236/AM03	Development of a PROM for orthopaedic surgery	3	11/07/2017	27

16/NW/0236/AM04	Development of a PROM for orthopaedic surgery	4	04/12/2017	28
16/NW/0275/AM05	Open-label trial with avelumab versus first line chemotherapy	Substantial Amendment 4	31/03/2017	25
16/NW/0275/AM06	Open-label trial with avelumab versus first line chemotherapy	5.5.1	01/08/2017	35
16/NW/0343/AM02	Gait analysis in cerebellar ataxia and hereditary spastic paraparesis	2	14/06/2017	20
16/NW/0364/AM02	Preputioplasty Versus Circumcision for BXO in Children	1	17/08/2017	14
16/NW/0514/AM05	Living with Cystic Fibrosis (v2)	1	17/08/2017	32
16/NW/0601/AM01	FISH MEAL	Substantial Amendment 1	17/05/2017	21
16/NW/0601/AM03	FISH MEAL	2	17/05/2017	34
16/NW/0606/AM04	Pembrolizumab in advanced renal cell carcinoma	Substantial Amendment 1	29/03/2017	39
16/NW/0606/AM05	Pembrolizumab in advanced renal cell carcinoma	Substantial Amendment 2	07/04/2017	34
16/NW/0606/AM09	Pembrolizumab in advanced renal cell carcinoma	5	09/08/2017	35
16/NW/0606/AM10	Pembrolizumab in advanced renal cell carcinoma	7	21/02/2018	43
16/NW/0617/AM02	UX023-CL301 Phase 3 KRN23 (3106-0010)	1	15/05/2017	23
16/NW/0617/AM04	UX023-CL301 Phase 3 KRN23 (3106-0010)	2	11/01/2018	18
16/NW/0724/AM02	A Qualitative Analysis to Explore Factors Influencing Patient Adherence to Prescribed OAB Medication, in UK Primary Care.	Substantial Amendment 1	27/11/2017	52
16/NW/0825/AM02	MOLTO	2	30/06/2017	14
16/NW/0825/AM03	MOLTO	3	18/09/2017	8
17/NW/0021/AM01	Seeking Care	Substantial Amendment 1	16/03/2017	15
17/NW/0036/AM01	A Phase II Study of BGBC007 in combination with Pembrolizumab	1	28/07/2017	11
17/NW/0036/AM03	A Phase II Study of BGBC007 in combination with Pembrolizumab	Substantial Amendment 3	24/11/2017	45
17/NW/0038/AM05	1002-047 Hyperlipidemia Study	Substantial Amendment 3	22/05/2017	45
17/NW/0038/AM10	1002-047 Hyperlipidemia Study	6	03/08/2017	22
17/NW/0038/AM13	1002-047 Hyperlipidemia Study	8	15/02/2018	35
17/NW/0090/AM02	The REALE (Recognising Emotions and links to Life Experiences) Study	1	04/08/2017	17
17/NW/0170/AM01	IMMPACT	1	23/10/2017	30

17/NW/0172/AM07	GED-0301-CD-003 - ACTIVE CROHN'S DISEASE	4	14/09/2017	35
17/NW/0196/AM01	Crossover Evaluation of Eye Drops in Symptomatic Lens Wearers (Part 2)	Substantial Amendment 1	22/05/2017	36
17/NW/0247/AM01	AURORA	1	12/07/2017	15
17/NW/0247/AM02	AURORA	2	06/12/2017	35
17/NW/0249/AM01	Neuro protection	1	20/12/2017	35
17/NW/0255/AM01	Neuro-Therapeutic Interventions for Pain (NTIP) Project	1	19/06/2017	25
17/NW/0255/AM02	Neuro-Therapeutic Interventions for Pain (NTIP) Project	2	14/09/2017	35
17/NW/0255/AM04	Neuro-Therapeutic Interventions for Pain (NTIP) Project	3	13/11/2017	28
17/NW/0273/AM01	Comparison of DNA between blastocoele fluid and trophectoderm cells	Substantial Amendment 1	30/11/2017	34
17/NW/0317/AM01	Krio	1	23/11/2017	34
17/NW/0318/AM01	Women's experience of anxiety during pregnancy: A qualitative study	1	22/09/2017	35
17/NW/0318/AM02	Women's experience of anxiety during pregnancy: A qualitative study	2	07/11/2017	33
17/NW/0369/AM01	PRAN-16-52 Pracinostat in combination with Azacitidine in Adult AML	Substantial Amendment 1	24/11/2017	45
17/NW/0488/AM01	Phase 2a single blind study of multiple PC786 doses against RSV	1	09/10/2017	28
17/NW/0661/AM04	Softened Water for Eczema Prevention (SOFTER)	1	12/02/2018	34
18/NW/0062/AM01	Nutrition self-screening tool for adult IBD outpatient clinics	1	07/03/2018	36

### Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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**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
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**Unfavourable opinion timeline**

<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>
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**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 21 day timeline**

REC Reference	Title	Number of Days on Clock
17/NW/0277	Edere version 1	30
17/NW/0348	Outcomes of Cochlear Implants in Congenitally Deafened Adults 1.2	24
17/NW/0570	The effect of rectal shape and size on bladder deformation	22
17/NW/0726	Face Validity of Fatigue Scales in CFS/ME: CFQ & BRAF	27
18/NW/0062	Nutrition self-screening tool for adult IBD outpatient clinics	23
18/NW/0065	Survey of factors affecting employment in Inflammatory Bowel Disease.	24
18/NW/0150	VAC053B: Follow-up immunology bleed	23
18/NW/0152	Health and social selection bias to participation in the NICOLA study	22

**SSAs (non Phase 1) over 25 day timeline**

REC Reference	Title	Number of Days on Clock
17/NW/0524	A randomized, double-blind, double-dummy, active-controlled, 3-period complete cross-over study to assess the bronchodilator effect and safety of two doses of QVM149 compared to a fixed dose combination of salmeterol/fluticasone in patients with asthma	35

**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
11/H1002/1/AM17	Tacrolimus for Prograf to Advagraf conversion in children. Version 1.0	8	20/12/2017	36
12/NW/0361/AM32	A study of Standard and New Antiepileptic Drugs – SANAD-II	19	26/02/2018	43
12/NW/0500/AM09	Health & Employment After Fifty (the HEAF Study)	7	17/01/2018	37
12/NW/0739/AM13	A Ph.I/II Dose Escalation Study and Expansion safety/efficacy	10	28/09/2017	36

	study.			
12/NW/0814/AM17	Efficacy & Safety/Tolerability of Subcutaneous SCH900222/MK-3222	Substantial Amendment 15	27/11/2017	37
14/NW/0350/AM11	Nivolumab or Nivolumab + Ipilimumab vs Bevacizumab in Recurrent GBM	11	19/12/2018	54
15/NW/0492/AM11	Study of ACP-196 Versus Ibrutinib in previously treated CLL patients	Substantial Amendment 9	22/11/2017	41
15/NW/0950/AM09	CGAH: The Evolve-2 Study (Treatment for Episodic Migraine)	6	28/11/2017	41
16/NW/0606/AM04	Pembrolizumab in advanced renal cell carcinoma	Substantial Amendment 1	29/03/2017	39
16/NW/0606/AM10	Pembrolizumab in advanced renal cell carcinoma	7	21/02/2018	43
16/NW/0724/AM02	A Qualitative Analysis to Explore Factors Influencing Patient Adherence to Prescribed OAB Medication, in UK Primary Care.	Substantial Amendment 1	27/11/2017	52
17/NW/0036/AM03	A Phase II Study of BGBC007 in combination with Pembrolizumab	Substantial Amendment 3	24/11/2017	45
17/NW/0038/AM05	1002-047 Hyperlipidemia Study	Substantial Amendment 3	22/05/2017	45
17/NW/0196/AM01	Crossover Evaluation of Eye Drops in Symptomatic Lens Wearers (Part 2)	Substantial Amendment 1	22/05/2017	36
17/NW/0369/AM01	PRAN-16-52 Pracinostat in combination with Azacitidine in Adult AML	Substantial Amendment 1	24/11/2017	45
18/NW/0062/AM01	Nutrition self-screening tool for adult IBD outpatient clinics	1	07/03/2018	36

### Modified Amendments over 14 day timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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