NHS
Health Research Authority

Research Ethics Service

North West - Greater Manchester Central Research Ethics Committee

Annual Report

01 April 2017 - 31 March 2018

Part 1 – Committee Membership and Training

Name of REC:	North West - Greater Manchester Central Research Ethics Committee
Type of REC:	RECs recognised to review CTIMPS in Healthy Volunteers - Type i, RECs recognised to review CTIMPS in Patients - Type iii
Type of Flag:	Establishing Research Tissue Banks, Phase 1 Studies in Healthy Volunteers, Phase 1 Studies in Patients, Research Involving Children
Chair:	Dr Barbara Potrata (until 01/03/2018 – currently on Break in Service) Dr George Gkimpas (Previously Vice Chair, Acting Chair from 01/03/2018, appointed as Chair 26/03/2018)
Vice-Chair:	Dr George Gkimpas (Previously Vice Chair, Acting Chair from 01/03/2018, appointed as Chair 26/03/2018)
Alternate Vice-Chair:	Vacant (01/04/2018 to present, application in progress)
REC Manager:	Miss Katherine Ashley
REC Assistant:	Ms Harriet Wood
Committee Address:	3rd Floor Barlow House 4 Minshull Street Manchester M1 3DZ
Telephone:	0207 104 8225 / 0207 104 8345
Email:	nrescommittee.northwest-gmcentral@nhs.net

Chair's overview of the past year:

This was quite an interesting year for the Greater Manchester Central REC. Dr Potrata stepped down from her role as Chair and has taken a break in service to pursue research opportunities overseas. Dr George Gkimpas, Vice Chair stepped into the role of Chair temporarily but was appointed as Chair permanently as of March 2018 and the Committee welcomed Dr Gkimpas's appointment.

We have welcomed two new members Dr Fay Hartley and Miss Isabelle Butcher to the Committee and we wished the best to former member Ian Taylor who left the Committee earlier in the year due to relocation. Five members are due to enter their 2nd term in 2018 and we are delighted that they wish to continue for another 5 years. Mr John Addison has kindly stepped up to apply for the post of Vice Chair and Dr Peter Kimliuk the post of alternate Vice Chair. Our REC has also participated in the HRA pilot programme for the upcoming EU Clinical Trials Regulations update and we are looking forward to starting reviewing full applications under the new regulations.

North West - Greater Manchester Central Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Mr J Addison	Retired Librarian	Lay Plus	01/05/2013	
Miss Isabelle Butcher	PhD Researcher	Lay	01/03/2018	
Mr K Cook	Qi Gong Teacher	Lay	01/05/2013	
Dr George Gkimpas	Clinical Fellow	Expert	01/02/2016	
Mrs D Hamburger	Retired Social Worker	Lay Plus	01/05/2013	
Dr Fay Hartley	Pharmacist	Expert	01/09/2017	
Dr Peter Klimiuk	Consultant Rheumatologist	Expert	01/08/2013	
Mr Rodney Lighton	Retired Software Engineer	Lay Plus	01/05/2013	
Dr Bernadette Lomas	Doctor, ST6 in Anaesthesia	Expert	01/03/2017	
Mrs F E Maders	Retired Clinical Trials Co-ordinator for Radiology	Expert	01/07/2012	04/05/2017
Dr Barbara Potrata	Research Fellow	Lay Plus	17/11/2008	
Dr Penelope Stanford	Senior Lecturer	Expert	09/01/2012	
Mr I A T Taylor	Consulting Engineer	Lay Plus	04/09/2012	04/09/2017

North West - Greater Manchester Central Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended
Mrs Seonaid Beddows	Research Governance and Administration Manager	Lay	11/12/2017
Professor Carol Haigh	Professor of Nursing	Expert	09/10/2017
Mr Alan McGarrity	Retired Police Inspector	Lay Plus	12/02/2018
Dr Peter Owen	Retired Mathematics Lecturer	Lay Plus	14/08/2017
Mrs Sue Fitzpatrick	Director	Lay	12/02/2018

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

Name	Declaration of Interest	Date
Mr John Addison	None	31/03/2018
Miss Isabelle Butcher	Committee member is a doctoral researcher at the University of Manchester. Her PhD is funded by the Medical Research Council.	05/03/2018
Mr Ken Cook	None	31/03/2018
Dr George Gkimpas	Member sits on the board of Occupational Allergy Interests Group of EAACI.	12/03/2018
Mrs D Hamburger	None	12/03/2018
Dr Fay Hartley	None	07/09/2017
Dr Peter Kimiuk	None	31/03/2018
Mr Rodney Lighton	None	12/03/2018
Dr Bernadette Lomas	None	12/03/2018
Dr Barbara Potrata	None	31/03/2018
Dr Penelope Stanford	Chair of the Royal College of Nursing Ophthalmic Forum. Lay Advisor for the Epilepsy Action Charity. Joint collaborator in research study funded by the international Glaucoma Association.	12/03/2018

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

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

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
October	16/10/2017	3
December	18/12/2017	3
January	15/01/2018	4
February	19/02/2018	4
March	19/03/2018	3

5 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	05/04/2017	2
April	19/04/2017	2
May	03/05/2017	2
May	17/05/2017	2
May	31/05/2017	2
June	14/06/2017	2
June	28/06/2017	2
July	12/07/2017	2
July	26/07/2017	2
August	09/08/2017	2
August	23/08/2017	2
September	06/09/2017	2
September	20/09/2017	2
October	04/10/2017	2
October	06/10/2017	3
October	18/10/2017	2
November	01/11/2017	2

November	15/11/2017	2
November	29/11/2017	2
December	13/12/2017	2
December	27/12/2017	2
January	18/01/2018	2
February	01/02/2018	2
February	15/02/2018	2
March	01/03/2018	2
March	15/03/2018	2
March	29/03/2018	2

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

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

0

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

Name	Number of Meetings Attended
Mr J Addison	8
Miss Isabelle Butcher	1
Mr K Cook	6
Dr George Gkimpas	7
Mrs D Hamburger	7
Dr Fay Hartley	6
Dr Peter Klimiuk	8
Mr Rodney Lighton	10
Dr Bernadette Lomas	6
Mrs F E Maders	1
Dr Barbara Potrata	8
Dr Penelope Stanford	6
Mr I A T Taylor	1

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

Name	Number of Meetings Attended
Mr J Addison	4
Dr George Gkimpas	4
Dr Fay Hartley	2
Mr Rodney Lighton	2
Dr Bernadette Lomas	2
Dr Barbara Potrata	1
Dr Penelope Stanford	2

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

Name	Number of Meetings Attended
Mr J Addison	7
Mr K Cook	1
Dr George Gkimpas	18
Mrs D Hamburger	3
Dr Peter Klimiuk	5
Mr Rodney Lighton	5
Dr Barbara Potrata	12
Dr Penelope Stanford	4

Training 01 April 2017 - 31 March 2018

Name of Member	Date	Event(s) attended
Mr J Addison	08/11/2017	Ethical Issues of Research Involving Children
Mrs Seonaid Beddows	29/09/2017	Regional Training Day - Nottingham
Mr K Cook	08/06/2017	Equality Diversity and Human Rights Training
Dr George Gkimpas	24/11/2017	Training - HRA National Chairs' Day and Policy Event
Dr George Gkimpas	16/01/2018	Training for New REC Chairs
Mrs D Hamburger	23/05/2017	Equality and Diversity
Mrs D Hamburger	01/06/2017	GCP Training
Mrs D Hamburger	01/09/2017	Supervision pf Undergraduate and PhD students
Mrs D Hamburger	26/09/2017	Training - Assessing the Consequences (benefits and harms) of Research: a Health Research Authority workshop
Mrs D Hamburger	31/01/2018	Complex Cases
Mrs D Hamburger	12/03/2018	PI - From Administration to Discharge in Major Trauma
Dr Fay Hartley	01/09/2017	Equality, Diversity and Human Rights
Dr Fay Hartley	02/09/2017	Royal Pharmaceutical Society Annual Conference - Network, influence, share insights and knowledge.
Dr Fay Hartley	20/09/2017	Research involving participants lacking mental capacity
Dr Fay Hartley	27/10/2017	Research involving Human Tissue
Dr Fay Hartley	28/10/2017	Research involving exposure to ionising radiation
Dr Fay Hartley	31/10/2017	Medical Devices
Dr Fay Hartley	01/11/2017	Use of HRA Schedule of Events
Dr Fay Hartley	03/11/2017	Confidentiality and information governance considerations in research
Dr Fay Hartley	08/11/2017	The Ethical Issues of Research Involving Children
Dr Fay Hartley	17/11/2017	Senate Assembly Manchester meeting
Dr Fay Hartley	29/11/2017	REC Regional Training Day
Dr Fay Hartley	30/11/2017	Genetic and Genomic Research
Dr Fay Hartley	25/01/2018	Complex Cases
Dr Fay Hartley	20/02/2018	Training - Human Tissue Act (Use of Human Samples in Research)
Dr Fay Hartley	01/03/2018	Regional Training Day - North West
Dr Fay Hartley	06/03/2018	Assessing the Consequences (benefits and harms) of

		Research
Dr Peter Klimiuk	02/06/2017	Case report published in Rheumatology: Preparation of manuscript
Dr Peter Klimiuk	05/07/2017	Chairman Training Steering Committee: Reviewing trial data and the efficacy of compression gloves in Rheumatoid Arthritis
Dr Peter Klimiuk	27/09/2017	Training for GP's in Oldham on Denosumab: Prepartaion of training symposium on the treatment of Osteoporosis
Dr Peter Klimiuk	01/03/2018	Teaching session for MSC in Rheumatology: 2 hour teaching preparation
Mr Rodney Lighton	30/11/2017	Genetic and Genomic Research
Mr Rodney Lighton	31/01/2018	Complex Cases
Dr Bernadette Lomas	19/06/2017	Equality, Diversity & Human Rights
Dr Bernadette Lomas	19/06/2017	Induction for new Research Ethics Service Committee members
Dr Bernadette Lomas	21/09/2017	RES Committee Members Induction
Dr Barbara Potrata	14/09/2017	Training for New REC Chairs
Dr Barbara Potrata	08/11/2017	Ethical Issues of Research Involving Children
Dr Penelope Stanford	14/06/2017	Good Clinical Practice

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	9	18.37
Phase 1	8	16.33
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	1	2.04
Research Database (including renewals)	0	0.00
Others	31	63.27
Total Applications Reviewed	**49**	**100**

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

Number of applications made invalid by the REC Manager	1
Number of applications withdrawn prior to the meeting	17
Number of student applications reviewed	15
Number of paediatric applications reviewed	7
Number of device applications reviewed	1
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	1
Number of applications reviewed that are funded by the US DHHS	0
Number of qualitative applications reviewed	10

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	0	0.00
Favourable Opinion with Additional Conditions	20	40.82
Unfavourable Opinion	0	0.00
Provisional Opinion	29	59.18
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	**49**	**100**
Number of studies sent back to full committee meeting for final opinion	0	

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

Status of applications at date of generation of report	Number	%
Further Information Favourable Opinion with Standard Conditions	19	38.78
Further Information Favourable Opinion with Additional Conditions	7	14.29
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	20	40.82
Unfavourable Opinion	0	0.00
Provisional Opinion	3	6.12
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	**49**	**100**

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

Total Applications Reviewed	**9**

Table 6: **Breakdown of PRS applications and other activity during reporting period:**

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

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	0	0.00
Favourable Opinion with Additional Conditions	2	22.22
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	6	66.67
Unfavourable Opinion	1	11.11
Total	**9**	**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	4.90
Number of completed applications for full ethical review	49
Number of completed applications for full ethical review over 60 days	0
Number of completed applications over 60 days as a % of total	0.00%
Number of days taken to final decision – average (mean)	34

Number of completed proportionate review applications for ethical review	9
Number of completed proportionate review applications for ethical review over 21 days	2
Number of completed proportionate review applications over 21 days as a % of total	22.22%

Number of SSAs (non-Phase 1) reviewed	6
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	7
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	129
Number of completed substantial amendments over 35 days	0
Number of completed substantial amendments over 35 days as a % of total substantial amendments	0.00%

Number of modified amendments reviewed	2
Number of completed modified amendments over 14 days	0
Number of completed modified amendments over 14 days as a % of total modified amendments	0.00%

Number of non substantial amendments received	93
Number of substantial amendments received for information	0
Number of substantial amendments received for new sites/PIs	18
Number of annual progress reports received	79
Number of safety reports received	62
Number of Serious Adverse Events received	0
Number of final reports received	24

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**
17/NW/0171	ALLECRA - AAI101 and Cefepime [ELF] in Healthy Volunteers	37
17/NW/0188	The AAA Get Fit Trial ver1	34
17/NW/0209	Mini-COMET	43
17/NW/0254	Ph3 Placebo-Controlled Trial-Adjuvant MK-3475 in RCC Post Nephrectomy	59
17/NW/0283	GC-SHealD (Glucocorticoids and Skin Healing in Diabetes) v1.1	40
17/NW/0321	Screening for LALD in liver patients	31
17/NW/0371	Efficacy and Safety study of NI-071 and RemicadeÂ®(Infliximab) for RA	32
17/NW/0467	Maternal Obesity: Exploring Women's Experiences	58
17/NW/0484	GSK3511294 – first doses in humans	48
17/NW/0485	F901318- Phase 1 Safety tolerability & PK study	20
17/NW/0492	LGUCQ self-report tool: men's views on symptom disclosure	44
17/NW/0542	Decision making about prognostication in patients with uveal melanoma	39
17/NW/0579	PK of Oral Doses of Brivaracetam in Healthy Volunteers (QCL117991)	21
17/NW/0632	Southampton Research Biorepository (SRB)	44
18/NW/0014	An exploration of stories of people who are end of life aged 16-24 yrs	28
18/NW/0015	Clinical trial to evaluate a new Hepatitis B vaccine (CONSTANT study)	36
18/NW/0023	Patients' experiences of an unexpected percutaneous dilatational trach	33
18/NW/0027	TMS for Pain in Parkinson's Disease. Version 1.0	34
18/NW/0079	Online Remote Behavioural Intervention for Tics (ORBIT)	50

Further Information Favourable Opinion with Additional Conditions		
REC Reference	**Title**	**Number of Days on Clock**
17/NW/0218	Self-Harm in Secure Mental Health Hospitals: Exper of Care Environments	57
17/NW/0411	Bioavailability Study of LY3314814 in Healthy Subjects using IV tracer	58
17/NW/0472	Painful neuropathy in Dementia	34
17/NW/0594	Survival of root canal treated teeth restored with ceramic onlays	46
17/NW/0652	Cross sectional biomarker kinetic study in children with MPS	48
17/NW/0653	Biomarker kinetic study in children with MPSIH treated with HSCT	47
18/NW/0022	Developing a Core Outcome Set for Cauda Equina Syndrome	45

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**

Favourable Opinion with Additional Conditions		
REC Reference	**Title**	**Number of Days on Clock**
17/NW/0198	OP-103 OCEAN Trial: Melflufen in Patients with Multiple Myeloma	29
17/NW/0211	Resilience to suicidal thoughts and behaviours in psychosis	29
17/NW/0297	The Development of an Adult, Burn Specific Patient Concerns Inventory	28
17/NW/0334	MRI in Lung Cancer Patients	24
17/NW/0364	NNIBS	23
17/NW/0374	4310 - explorer™4 efficacy and safety of concizumab in inhibitor pts	20
17/NW/0423	Validating cerebral saturation monitoring during neonatal transport	25
17/NW/0481	Evaluation of the Oldham IAPT Plus Active Monitoring Service	25
17/NW/0490	Development of diet sheets for infants with CHD	25
17/NW/0504	RECOGNISE	25
17/NW/0505	The Impact of Living with Home Enteral Tube Feeding	21
17/NW/0595	Rheumatoid arthritis adrenal recovery study v1	20
17/NW/0695	Swallowing in Trans-oral Surgery for Oro-pharyngeal Cancer	25
18/NW/0004	A SAD MAD study of LEO 138559	22
18/NW/0025	BIA 5-1058 4 period crossover in Healthy volunteers	22
18/NW/0031	NET-02	25
18/NW/0044	Models of Nociceptive Plasticity in Chronic Pain (MoNoPly)	28
18/NW/0053	Investigation of drug-drug interaction between rifampin and GWP42003-P	21
18/NW/0054	Effects of Itraconazole and Fluconazole on Pharmacokinetics of VX-445	21
18/NW/0073	Women's perception of risk following reduced fetal movements	28

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

Provisional Opinion		
REC Reference	**Title**	**Number of Days on Clock**
18/NW/0168	Ultrasound-guided vacuum-assisted excision of breast cancers	n/a
18/NW/0179	INDUCE (INTELLIN and Diabetic Ulcer)	n/a
18/NW/0181	Resilience to suicidal ideation and behaviours in schizophrenia	n/a

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

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

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

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**
18/NW/0119	COG-PBC	23
18/NW/0121	POP -Active	24
18/NW/0124	ExeRTiOn- The Weight management in Renal Transplant Online Study	21
18/NW/0197	Investigation of neuropsychological markers for dementia 1	19

Further Information Favourable Opinion with Additional Conditions		
REC Reference	**Title**	**Number of Days on Clock**
17/NW/0603	Exploring weaning decisions taken by parents (version one)	16
18/NW/0040	Effects of time on the stability of iron and renal function tests.	17

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**

Favourable Opinion with Additional Conditions		
REC Reference	**Title**	**Number of Days on Clock**
17/NW/0717	Pancreatic exocrine deficiency in diabetes	9
18/NW/0196	LIMA (Liquid biopsies and Imaging for improved cancer care)	18

Unfavourable Opinion		
REC Reference	**Title**	**Number of Days on Clock**
18/NW/0041	Genomic evolution of oral atypical verrucous hyperplasia	16

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

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

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

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

Favourable opinion				
Amendment REC Reference	**Title**	**Version**	**Date**	**Number of Days on Clock**
06/Q1407/94/AM12	study of Clinical and Genetic Risk Factors for Encapsulating Peritone	12 2/03/2017	10/04/2017	6
07/H1008/153/AM06	Secondary Screening for Early Pancreatic cancer in HP (v.1)	Substantial Amendment 4 - Change in CI	24/10/2017	7
08/H1008/25/AM21	Predicting Response to Methotrexate in Rheumatoid Arthritis	11, 18/01/2018	26/01/2018	14
08/H1008/25/AM22	Predicting Response to Methotrexate in Rheumatoid Arthritis	12, 14/03/2018	19/03/2018	13
09/H1008/81/AM47	Breast cancer risk assessment and validation in The NHSBSP (PROCAS)	25 11.08.2017	16/08/2017	34
09/H1008/81/AM48	Breast cancer risk assessment and validation in The NHSBSP (PROCAS)	26 27.11.2017	27/11/2017	21
10/H1008/73/AM14	HGT-SAN-067	Protocol Amendment 8: 01 February 2017	23/05/2017	26
11/NW/0016/AM22	SBC-102 in children with growth failure due to LAL deficiency	No 15: Patient Card - ICF Patient Travel and Reimbursement	18/04/2017	14
11/NW/0016/AM23	SBC-102 in children with growth failure due to LAL deficiency	No 16: Additional Greenphire Patient Travel and Reimbursement Docs	17/07/2017	21
11/NW/0080/AM14	Masitinib vs Imatinib in first line metastatic GIST - AB04030 v4.0 UK2	Voluntary halt to recruitment	04/07/2017	15
11/NW/0080/AM15	Masitinib vs Imatinib in first line metastatic GIST - AB04030 v4.0 UK2	2017/11/14	14/11/2017	29
11/NW/0428/AM04	Off-the-shelf use of toric IOLs (Version 2)	3. 06/01/2017	28/07/2017	20
11/NW/0659/AM14	PK comparison of Advagraf and Prograf in children	APL Amendment U - Reference Safety Information 2017/12/18	20/12/2017	16

11/NW/0773/AM16	Intrathecal Enzyme Replacement Therapy for MPS II Extension Study	HGH-HIT-046 amendment 9 dated	08/05/2017	16
11/NW/0773/AM18	Intrathecal Enzyme Replacement Therapy for MPS II Extension Study	HGT-HIT-046, Amendment 9, dated 03 January 2017	15/12/2017	14
12/NW/0157/AM10	Ipilimumab dose comparison study in Metastatic Melanoma	CA184-169, substantial Amendment 9	01/07/2017	9
12/NW/0694/AM10	A0221047 Paediatric NDO study	Fesoterodine Investigator's Brochure, dated June 2017	25/07/2017	13
12/NW/0694/AM12	A0221047 Paediatric NDO study	General Practitioner Letter for Cohort 2 v1.0 dated 17-Nov-17 and Instructions for subjects to measure urine v1.0 dated 15-Nov-17	05/12/2017	22
12/NW/0766/AM26	PREDNOS 2	Amendment 13	06/04/2017	13
12/NW/0766/AM29	PREDNOS 2	Amendment 15 - 2017/08/02	10/08/2017	21
12/NW/0827/AM12	Euro Ewing 2012	SA11	23/06/2017	19
12/NW/0827/AM13	Euro Ewing 2012	SA12	25/08/2017	28
13/NW/0006/AM18	Phase III study of Brentuximab vedotin in T-cell lymphoma patients	Investigator's Brochure version 15, dated 11 Oct 2017	12/12/2017	21
13/NW/0032/AM16	AZD9291 in patients with advanced NSCLC, following EGFR TKI therapy	D5160C00001 CSP edition 7 and AZD9291 IB edition 7	27/04/2017	18
13/NW/0032/AM17	AZD9291 in patients with advanced NSCLC, following EGFR TKI therapy	Investigator Brochure Edition 8	31/05/2017	29
13/NW/0032/AM18	AZD9291 in patients with advanced NSCLC, following EGFR TKI therapy	Substantial Amendment 12	21/11/2017	29

13/NW/0032/AM19	AZD9291 in patients with advanced NSCLC, following EGFR TKI therapy	Investigator's Brochure Edition 9_2018/01/25	16/02/2018	26
13/NW/0068/AM11	OUTPASS - OUtcomes of Treatment in Psoriatic Arthritis Study Syndicate	Substantial Amendment 4, 4th August 2017	16/08/2017	13
13/NW/0068/AM14	OUTPASS - OUtcomes of Treatment in Psoriatic Arthritis Study Syndicate	Amendment 5, 22nd November 2017	07/12/2017	26
13/NW/0199/AM09	AMG 145 in patients with Severe Familial Hypercholesterolemia	Amendment 8	12/10/2017	14
13/NW/0208/AM12	ARROVEN - brentuximab vedotin PASS, version 1.1 dated on 14 June 2012	Amendment 4 , 20July2017	28/07/2017	15
13/NW/0297/AM13	Hypertriglyceridaemia - cause and effects	7 (18.05.2017)	30/05/2017	14
13/NW/0297/AM14	Hypertriglyceridaemia - cause and effects	8 (01/08/2017)	15/08/2017	18
13/NW/0297/AM16	Hypertriglyceridaemia - cause and effects	9 (21.10.2017)	09/11/2017	13
13/NW/0698/AM12	LDK378 vs Chemo in newly diagnosed untreated ALK+ NSCLC patients	Substantial Amendment 2017/08/07	08/08/2017	26
13/NW/0698/AM13	LDK378 vs Chemo in newly diagnosed untreated ALK+ NSCLC patients	Substantial Amendment 26/10/2017	26/10/2017	11
13/NW/0698/AM14	LDK378 vs Chemo in newly diagnosed untreated ALK+ NSCLC patients	08-2018/01/31	31/01/2018	33
14/NW/0176/AM18	The Paediatric EVICELÂ® Bleeding Study	MREC SA09 2018/03/02	02/03/2018	14
14/NW/0193/AM06	Neurodevelopment of Babies Born to Mothers with Epilepsy (NaME)Study	Substantial Amendment 3 01.10.2017	01/10/2017	31
14/NW/0321/AM21	Sebelipase Alfa in Infants with Rapidly Progressive LAL Deficiency	Parent ICF - 2017/10/24	27/11/2017	5
14/NW/1042/AM04	The Pesticide Users' Health Study (v1)	Amendment number 3, 24 November 2017	30/11/2017	21
14/NW/1331/AM02	Argus II Retinal Prosthesis System Dry AMD Feasibility Study	Amendment Number: 2 Date: 20/04/2017	02/06/2017	33

15/NW/0009/AM16	Denosumab in Children With Osteogenesis Imperfecta	Substantial Amendment 9 - PIS ICF Update	04/08/2017	13
15/NW/0009/AM17	Denosumab in Children With Osteogenesis Imperfecta	Substantial Amendment 10	20/09/2017	12
15/NW/0009/AM18	Denosumab in Children With Osteogenesis Imperfecta	Substantial Amendment 11, Increase in UK Sample Size_2018/02/21	21/02/2018	19
15/NW/0010/AM04	SLUMBRS (Version 1)	2. 26/05/17	30/05/2017	14
15/NW/0015/AM09	MEDI4736 in NSCLC (D4191C00001, PACIFIC Study)	SA08 - IB Ed11, Re-Treatment ICF	02/08/2017	28
15/NW/0015/AM11	MEDI4736 in NSCLC (D4191C00001, PACIFIC Study)	SA09 - CSP05, CSP06, IB ed12, Updated Re-Treatment PIS	31/01/2018	12
15/NW/0015/AM12	MEDI4736 in NSCLC (D4191C00001, PACIFIC Study)	SA10 - GDPR Letters 2018/03/05	05/03/2018	17
15/NW/0022/AM06	Bone anchored maxillary protraction (BAMP)RCT	Amendment 2, 8 December 2017	08/12/2017	23
15/NW/0067/AM08	ASCEND- Peds	SA-004	02/10/2017	18
15/NW/0152/AM10	MetaPHer	Substantial Amendment 4	17/03/2017	32
15/NW/0152/AM11	MetaPHer	Herceptin (trastuzumab) Investigator's Brochure (IB) version 18, October 2017	05/12/2017	23
15/NW/0152/AM12	MetaPHer	IB v17 (Feb 2018)	22/03/2018	17
15/NW/0172/AM06	REmote MOnitoring in Rheumatoid Arthritis (REMORA) v1.0	SA03 - April 2017	07/04/2017	13
15/NW/0172/AM07	REmote MOnitoring in Rheumatoid Arthritis (REMORA) v1.0	SA04 - June 2017	14/06/2017	21
15/NW/0431/AM09	Open-label phase II trial with a pan_FGFR Tyrosine Kinase Inhibitor	Protocol Amendment 4 - 2017/05	12/06/2017	20

15/NW/0431/AM10	Open-label phase II trial with a pan_FGFR Tyrosine Kinase Inhibitor	42756493BLC2001-08/11/2017	08/11/2017	12
15/NW/0431/AM11	Open-label phase II trial with a pan_FGFR Tyrosine Kinase Inhibitor	Protocol Amendment 5 - 4275649	05/12/2017	17
15/NW/0468/AM11	ACP-196 as mono and combination therapy in untreated CLL patients	Number: Protocol V4, dated 06March2017, IB edition 6.0, dated 06 February 2017, Main ICF version 5.1 dated 05April2017, Pregnant partner ICF v3.0 dated 30Mar2017 and PK ICF v4.0 dated 30Mar2017	10/04/2017	15
15/NW/0468/AM12	ACP-196 as mono and combination therapy in untreated CLL patients	Version: 6.1 Date: 2017/09/01	29/11/2017	22
15/NW/0638/AM02	A Smart COPD-SPOC monitor for interactive management of COPD	Substantial Amendment 1; 01.05.2017	03/05/2017	29
15/NW/0685/AM02	Nottingham Health Science Biobank (NHSB)	1.0 21st July 2017	04/08/2017	14
15/NW/0685/AM03	Nottingham Health Science Biobank (NHSB)	3.0 - 26/10/2017	26/10/2017	21
15/NW/0685/AM04	Nottingham Health Science Biobank (NHSB)	2.0 26/10/2017	26/10/2017	20
15/NW/0691/AM04	Phase 1 OL study of AZD0156 monotherapy or with combination therapies	Substantial Amendment 2 - Appointment of new Chief Investigator	29/03/2017	27
15/NW/0748/AM02	Clients' experiences of the St Marys SARC: A qualitative study	2 24/05/2017	26/05/2017	35
15/NW/0779/AM06	ALXN1210-PNH-201: ALXN1210 Phase 2 study in patients with PNH	UKSA4 - ALXN1210-PNH-201 prot amendment 3.1 (UK Specific)	26/04/2017	19
15/NW/0779/AM08	ALXN1210-PNH-201: ALXN1210 Phase 2 study in patients with PNH	SA05 - IB Ed6, updated PIS	06/12/2017	17

15/NW/0779/AM09	ALXN1210-PNH-201: ALXN1210 Phase 2 study in patients with PNH	SA6, protocol V4.1 (UK), ICF v6.0	06/02/2018	27
15/NW/0854/AM06	IV Administration of 14C-LY2606368	Updated IB 2017	08/05/2017	17
15/NW/0854/AM07	IV Administration of 14C-LY2606368	Change to Chief Investigator	30/05/2017	14
15/NW/0912/AM09	PACT-G	Amendment number 5; 06.09.2017	15/09/2017	29
16/NW/0012/AM02	HOMAGE	8.0, 2017-03-24	30/03/2017	26
16/NW/0041/AM09	SOLAR-1: alpelisib + fulvestrant in advanced breast cancer	CBYL719C2301 PA04 substantial amendment	04/01/2018	20
16/NW/0149/AM05	K1-70 – Safety Study in Subjects with Graves' Disease.	Substantial Amendment 3 - 2017/06/13	13/06/2017	12
16/NW/0149/AM06	K1-70 – Safety Study in Subjects with Graves' Disease.	Substantial Amendment 4 2017/11/06	06/11/2017	25
16/NW/0149/AM08	K1-70 – Safety Study in Subjects with Graves' Disease.	Substantial Amendment 5- 2018/01/10	10/01/2018	14
16/NW/0151/AM06	Study of the Effect of AUT00206 in healthy male - ketamine challengeV1	AUT021206 - 2017/05/19	19/05/2017	20
16/NW/0169/AM05	First line treatment of metastatic bowel cancer with S95005 & Avastin	Amendment n°3 to the Participant Information and Consent Form, final version dated 11th May 2017	19/05/2017	14
16/NW/0169/AM07	First line treatment of metastatic bowel cancer with S95005 & Avastin	Substantial Amendment n°1 to the Reference Safety Information of Avastin®, final version dated 2nd June 2017	15/09/2017	16

16/NW/0169/AM08	First line treatment of metastatic bowel cancer with S95005 & Avastin	Investigator's Brochure n°3– Final Version dated 14th October 2017	08/12/2017	22
16/NW/0228/AM10	R475-PN-1523 Fasinumab in patients with knee or hip osteoarthritis	R475-PN-1523 Protocol, version 05, dated 16 March 2017	11/05/2017	9
16/NW/0228/AM13	R475-PN-1523 Fasinumab in patients with knee or hip osteoarthritis	UK Main Patient Information Sheet and Consent Form - 2017/06/15	30/06/2017	31
16/NW/0459/AM01	The ELDERS Study - Immunotherapy in Elderly Cancer Patients	Substantial Amendment 1_21 March 2017	28/03/2017	15
16/NW/0459/AM03	The ELDERS Study - Immunotherapy in Elderly Cancer Patients	Substantial Amendment 2_23 Jan	29/01/2018	15
16/NW/0498/AM05	EPZ-6438: IV microtracer and ADME Study	SA3 IB V7	21/04/2017	20
16/NW/0498/AM06	EPZ-6438: IV microtracer and ADME Study	SA4 Protocol V4 2017/11/06	28/11/2017	23
16/NW/0576/AM02	Evaluate efficacy and safety of 4 doses of CHF6001DPI in COPD patients	SA01 (SmPC version 2.0, 18 Oct	16/05/2017	9
16/NW/0587/AM02	VESPA study	v3.0, 18/05/17	19/05/2017	21
16/NW/0592/AM03	Next Level: Method of Levels for Psychosis	Substantial amendment 3, 05/09/2017	13/09/2017	23
16/NW/0602/AM03	Protocol 9785-CL-0335	9785-CL-0335 - Patient Recruitment Materials - 2017/04/13	13/04/2017	24
16/NW/0602/AM04	Protocol 9785-CL-0335	Substantial amendment 02 2018/02/21	21/02/2018	14
16/NW/0718/AM02	Respiratory Distress Symptom Intervention (RDSI)	02 21/07/2017	31/07/2017	29
16/NW/0876/AM03	The effects of RPL554 in addition to tiotropium in COPD patients	Substantial Amendment 01 (EC)	28/04/2017	13

17/NW/0008/AM02	Natural History Study of CBSDH	Substantial Amendment 1, 29 December 2017	02/01/2018	19
17/NW/0012/AM03	LILACS	LILACS Amendment 4	30/08/2017	22
17/NW/0012/AM04	LILACS	LILACS Amendment 5 - 2018/02/0	12/02/2018	21
17/NW/0058/AM01	MAPS-2: Metoclopramide and SOD mouth paste to prevent pneumonia vs 1	2017/11/06	15/11/2017	8
17/NW/0058/AM03	MAPS-2: Metoclopramide and SOD mouth paste to prevent pneumonia vs 1	3 - 2018/01/25	30/01/2018	14
17/NW/0084/AM04	A Phase I study of Y14 in adult subjects	SA1 Protocol V2	15/09/2017	22
17/NW/0084/AM05	A Phase I study of Y14 in adult subjects	SA2 PIC site letter	01/03/2018	33
17/NW/0112/AM01	Communication about the psychosexual consequences of breast cancer	amendment 1 30th October 2017	03/11/2017	15
17/NW/0168/AM01	CA209-744: Nivolumab and brentuximab vedotin for cHL	SA1 dated 26 May 2017	30/05/2017	14
17/NW/0168/AM03	CA209-744: Nivolumab and brentuximab vedotin for cHL	SA03	01/12/2017	22
17/NW/0169/AM01	The evaluation of a new recovery measure within inpatient CAMHS	SA1, 16/11/2017	20/11/2017	24
17/NW/0171/AM01	ALLECRA - AAI101 and Cefepime [ELF] in Healthy Volunteers	SA(1)14_Jun_17	14/06/2017	30
17/NW/0171/AM02	ALLECRA - AAI101 and Cefepime [ELF] in Healthy Volunteers	SA(2)07_Aug_17	07/08/2017	28
17/NW/0171/AM03	ALLECRA - AAI101 and Cefepime [ELF] in Healthy Volunteers	SA(3)03_Oct_17	10/10/2017	10
17/NW/0188/AM01	The AAA Get Fit Trial ver1	1. 19/07/2017	27/07/2017	17
17/NW/0198/AM01	OP-103 OCEAN Trial: Melflufen in Patients with Multiple Myeloma	EC SA1: IB Edition 7.1	04/05/2017	22
17/NW/0198/AM02	OP-103 OCEAN Trial: Melflufen in Patients with Multiple Myeloma	EC SA2: Protocol Amendment version 2.0, GP Letter V2.0 & ICFs version 2.0	13/09/2017	19
17/NW/0254/AM02	Ph3 Placebo-Controlled Trial-Adjuvant MK-3475 in RCC Post Nephrectomy	SA02 - Main PIS/CF update	11/08/2017	24
17/NW/0254/AM03	Ph3 Placebo-Controlled Trial-Adjuvant MK-3475 in RCC Post Nephrectomy	SA03 – IB15 & PIS/CF v5	12/10/2017	17
17/NW/0254/AM04	Ph3 Placebo-Controlled Trial-Adjuvant MK-3475 in RCC Post	SA04 - Protocol 01	05/12/2017	20

	Nephrectomy	+ PIS/ICF06		
17/NW/0254/AM06	Ph3 Placebo-Controlled Trial-Adjuvant MK-3475 in RCC Post Nephrectomy	SA06 - PIS/CF 7 2018/03/09	09/03/2018	14
17/NW/0364/AM01	NNIBS	Amendment no 1 , date 23.01.18	02/02/2018	28
17/NW/0371/AM01	Efficacy and Safety study of NI-071 and Remicade®(Infliximab) for RA	Sub Amd 1	01/11/2017	19
17/NW/0374/AM01	44310 - explorer™4 efficacy and safety of concizumab in inhibitor pts	Substantial Protocol Amendment	18/12/2017	16
17/NW/0484/AM01	GSK3511294 – first doses in humans	SA01 2017/12/18	18/12/2017	15
17/NW/0484/AM02	GSK3511294 – first doses in humans	SA02- 2018/02/07	02/03/2018	21
17/NW/0485/AM02	F901318- Phase 1 Safety tolerability & PK study	Protocol V2.0 update - 2018/01/16	19/01/2018	19
17/NW/0485/AM03	F901318- Phase 1 Safety tolerability & PK study	Amendment 2_Prototol V3.0	16/03/2018	24
17/NW/0505/AM01	The Impact of Living with Home Enteral Tube Feeding	1 (07/02/2018)	09/02/2018	20
18/NW/0004/AM01	A SAD MAD study of LEO 138559	SA1 Protocol V2	16/03/2018	24
18/NW/0025/AM01	BIA 5-1058 4 period crossover in Healthy volunteers	Amendment 1- MHRA GNA Updates	07/03/2018	16

Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
14/NW/0001/AM17	Continuation Study of Prophylactic BAX 855 in PTP with Haemophilia A	UK EC Substantial Amendment #1	21/09/2017	35
15/NW/0691/AM05	Phase 1 OL study of AZD0156 monotherapy or with combination therapies	Substantial Amendment 3 - protocol v4 dated 06Jun2017 and IB AZD2281 v14	08/08/2017	15
16/NW/0228/AM16	R475-PN-1523 Fasinumab in patients with knee or hip osteoarthritis	R475-PN-1523 Protocol version 06 - 2017/10/02	28/11/2017	31

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**
14/NW/0001/AM17/1	Continuation Study of Prophylactic BAX 855 in PTP with Haemophilia A	UK EC Substantial Amendment #1	08/12/2017	2
15/NW/0691/AM05/1	Phase 1 OL study of AZD0156 monotherapy or with combination therapies	MODIFIED AMENDMENT: SA3, protocol v4 06Jun2017, IB AZD2281 v14	04/10/2017	12

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

Table 11: **Items exceeding timelines**

Full applications for ethical review over 60 day timeline		
REC Reference	**Title**	**Number of Days on Clock**

Proportionate review applications for ethical review over 21 day timeline		
REC Reference	**Title**	**Number of Days on Clock**
18/NW/0119	COG-PBC	23
18/NW/0121	POP-Active	24

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

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

Substantial Amendments over 35 day timeline				
Amendment REC Reference	**Title**	**Version**	**Date**	**Number of Days on Clock**

Modified Amendments over 14 day timeline				
Amendment REC Reference	**Title**	**Version**	**Date**	**Number of Days on Clock**