

North West - Haydock Research Ethics Committee

Annual Report

01 April 2016 - 31 March 2017



Part 1 – Committee Membership and Training

Name of REC:	North West - Haydock Research Ethics Committee
Type of REC:	RECs recognised to review CTIMPS in patients - Type III
Type of Flag:	<ul style="list-style-type: none">• Establishing Research Databases• Establishing Research Tissue Banks• Phase 1 Studies in Patients• Research Involving Adults Lacking Capacity
Chair:	Dr Tim S Sprosen
Vice-Chair:	No Vice-Chair appointed at time of report
Alternate Vice-Chair:	Dr Valerie E Siddall
REC Manager:	Ms Rachel Katzenellenbogen
REC Assistant:	Mr Ewan Waters (01/04/2016-06/03/2017) Ms Laila Sarwar (06/03/2017-31/03/2017)
Committee Address:	3rd Floor - Barlow House 4 Minshull Street Manchester M1 3DZ
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Chair's overview of the past year:

The Haydock Committee continues to benefit greatly from having a diverse range of expertise within our members; that membership has been stable over the last 12 months with 8 Expert members, 1 Lay member and 3 Lay Plus members.

Our committee is flagged for CTIMPs and for studies carried out under the Mental Capacity Act, but we also see a significant number of Research Tissue Banks, Research Databases and Qualitative Studies and so we have ample opportunity for the broad range of knowledge and experience of our Committee members to come to the fore.

We are indebted to our volunteer Committee members who give their time and expertise so willingly. This is underlined by the knowledge that some members have been taking leave from work or their private practices to attend meetings. Our members have always read the applications thoroughly and are excellent at separating out the big issues from the minor ones so that we can focus efficiently in the time we have available with the researchers. Our diverse membership enhances the quality of the debate we have, which is always thorough, well-informed, lively and constructive. We pride ourselves on giving constructive advice to researchers and we have some evidence of them valuing our contribution in that we have noted that we get a lot of "repeat business". It is always a pleasure to see these returners since it allows us to hear the progress with their previous studies that we have approved.

The Committee now reviews Substantial Amendments and Proportionate Review applications in meetings separate to our main monthly meeting and we have found that this allows us to give them the full attention they deserve.

Our REC Manager, Rachel Katzenellenbogen, does a sterling job in the monthly meetings in keeping us on track and having at her fingertips the information we might need to make our decisions. Rachel excels at drafting accurate and timely minutes of oftentimes complex discussions. However, we are all aware that what we see of Rachel in the meeting is only the tip of the iceberg in terms of the critical role she plays day-in and day-out in support of the Committee's work and ensuring we meet our targets. Rachel is very skilled in dealing with people and this comes to the fore in liaising with researchers, especially those who may not agree with our opinion.

We were sorry to farewell to our very able REC Assistant, Ewan Water who transferred to another North West Committee following a re-organisation. And in his place we welcomed back an old friend, Laila Sawar who has taken up the reins to support Rachel and the rest of the Committee.

Finally, I am delighted to report that our Chair, Dr Tim Sprosen, has recently joined the National Research Ethics Advisors' Panel and we look forward to hearing his regular updates about their deliberations and the opportunity to feed directly into NREAP discussions.

North West - Haydock Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Mrs Moyra Ann Baldwin	Retired Senior Lecturer - Oncology	Lay	07/11/2013	
Ms Carole Burgess	Director of Lifelong Learning (retired)	Lay Plus	01/07/2016	27/02/2017
Mr Stephen Edgar	Designer	Lay Plus	13/11/2009	
Dr Michael U Eshiett	Consultant Physician in Neurological Rehabilitation	Expert	23/09/2009	
Mr Simon Hill	Pharmacist	Expert	01/06/2015	
Dr Ben Johnson	Consultant Psychiatrist	Expert	20/08/2010	
Dr Ezzat Kozman	Consultant Gynaecologist	Expert	01/05/2013	
Dr Lorraine Lighton	Retired Consultant in Communicable Disease Control	Expert	01/08/2016	
Mr Charles Otim	Research Support Officer	Lay Plus	21/09/2010	
Dr David Pilling	Consultant Radiologist	Expert	10/12/2010	
Miss Anna Sekula	Nurse	Expert	05/02/2015	
Dr Valerie E Siddall	Retired Senior Manager - Pharmaceutical Industry	Lay Plus	05/11/2009	
Dr Tim S Sprosen	Epidemiologist	Expert	07/12/2006	
Dr Zhe Wang	Medical Statistician	Expert	01/01/2016	

North West - Haydock Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended
Dr Peter Owen	Retired Mathematics Lecturer	Lay Plus	14/06/2016 12/07/2016

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

Name	Declaration of Interest	Date
Mrs Moyra Ann Baldwin	None	19/01/2017
Ms Carole Burgess	None	12/07/2016
Mr Stephen Edgar	Member of NIHR I4I product awards panel Member of EME board	29/11/2016
Dr Michael U Eshiett	None	28/03/2017
Mr Simon Hill	None	30/03/2017
Dr Ben Johnson	None	31/03/2017
Dr Ezzat Kozman	None	28/03/2017
Dr Lorraine Lighton	Chair of GM West REC	03/08/2016
Mr Charles Otim	None	28/03/2017
Dr David Pilling	None	03/03/2017
Miss Anna Sekula	Current employment with the Christie NHS Foundation Trust as R&D coordinator, representing the sponsor and providing oversight to sponsored trials. Previous Employment with GSK Clinical Trials.	17/03/2017
Dr Valerie E Siddall	Shareholdings in organisations involved in or possibly seeking to be involved in the conduct of research - indirectly through unit trust holdings. Member of the Nuffield Department of Population Health's Participant Panel Occasional consultancy work on publications including publication ethics	08/02/2017
Dr Tim S Sprosen	Associate Professor at Nuffield Department of Population Health, University of Oxford Member of Steering Committee for UK Biobank Member of International Scientific Advisory Board for Abu Dhabi Cohort	08/06/2016
Dr Zhe Wang	Involved in academic research at Oxford University.	11/03/2017

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

Month	Date	Number of Members Present at Meeting
April	12/04/2016	8
May	10/05/2016	8
June	14/06/2016	8
July	12/07/2016	8
August	09/08/2016	7
October	11/10/2016	7
November	08/11/2016	8
December	13/12/2016	7
February	14/02/2017	10
March	14/03/2017	7

10 full committee meetings were held during the reporting period.

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

Month	Date	Number of Members Present at Meeting
April	12/04/2016	3
May	10/05/2016	3
June	14/06/2016	3
July	12/07/2016	3
August	11/08/2016	3
September	20/09/2016	3
October	11/10/2016	3
December	13/12/2016	3
February	07/02/2017	3
March	08/03/2017	3

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

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

Month	Date	Number of Members Present at Meeting
April	12/04/2016	3
April	15/04/2016	2
April	26/04/2016	2
May	10/05/2016	2
May	24/05/2016	2
June	14/06/2016	2
July	05/07/2016	2
July	07/07/2016	7
July	12/07/2016	3
July	26/07/2016	2
August	09/08/2016	3

August	23/08/2016	2
August	30/08/2016	2
September	13/09/2016	2
September	29/09/2016	2
October	11/10/2016	2
October	18/10/2016	2
October	25/10/2016	2
November	08/11/2016	2
November	22/11/2016	3
November	29/11/2016	3
December	13/12/2016	3
December	27/12/2016	2
January	10/01/2017	2
January	13/01/2017	6
January	24/01/2017	2
January	31/01/2017	2
February	14/02/2017	2
February	21/02/2017	2
March	07/03/2017	2
March	21/03/2017	2

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

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

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

Name	Number of Meetings Attended
Mrs Moyra Ann Baldwin	7
Ms Carole Burgess	1
Mr Stephen Edgar	8
Dr Michael U Eshiett	4
Mr Simon Hill	2
Dr Ben Johnson	3
Dr Ezzat Kozman	10
Dr Lorraine Lighton	1
Mr Charles Otim	7
Dr David Pilling	8
Miss Anna Sekula	1
Dr Valerie E Siddall (Alternate Vice-Chair)	8
Dr Tim S Sprosen	7
Dr Zhe Wang	9

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

Name	Number of Meetings Attended
Mrs Moyra Ann Baldwin	2
Mr Stephen Edgar	7
Dr Ben Johnson	1
Dr Ezzat Kozman	2
Mr Charles Otim	1
Miss Anna Sekula	5
Dr Valerie E Siddall	2
Dr Tim S Sprosen	10

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

Name	Number of Meetings Attended
Mrs Moyra Ann Baldwin	3
Mr Stephen Edgar	3
Dr Ben Johnson	4
Dr Ezzat Kozman	11
Mr Charles Otim	1
Dr David Pilling	3
Miss Anna Sekula	6
Dr Valerie E Siddall	19

Dr Tim S Sprosen	24
Dr Zhe Wang	2

Training 01 April 2016 - 31 March 2017

Name of Member	Date	Event(s) attended
Mrs Moyra Ann Baldwin	07/02/2017	MCA Training
Dr Ben Johnson	06/07/2016	Local Training Day
Dr Ezzat Kozman	29/08/2016	MCA Training
Miss Anna Sekula	21/09/2016	Delivered presentation at the Christie Patient Centred Research Conference
Miss Anna Sekula	02/11/2016	MCA - training slides and related guidance
Miss Anna Sekula	02/11/2016	Met with clinicians visiting the Christie from Chile
Dr Tim S Sprosen	06/07/2016	Local Training Day - York Regional Day
Dr Zhe Wang	28/04/2016	Research Data and Confidentiality

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	15	30.61
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	4	8.16
Research Database (including renewals)	3	6.12
Others	27	55.10
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	4
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	11
Number of paediatric applications reviewed	3
Number of device applications reviewed	2
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	13
Number of applications reviewed that are funded by the US DHHS	0
Number of qualitative applications reviewed	6

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	6	12.24
Favourable Opinion with Additional Conditions	19	38.78
Unfavourable Opinion	3	6.12
Provisional Opinion	19	38.78
Provisional Opinion Pending Consultation with Referee	2	4.08
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	16	32.65
Further Information Favourable Opinion with Additional Conditions	5	10.20
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	6	12.24
Favourable Opinion with Additional Conditions	19	38.78
Unfavourable Opinion	3	6.12
Provisional Opinion	0	0.00
Provisional Opinion Pending Consultation with Referee	0	0.00
Further Information response not complete	0	0.00
No decision entered on system	0	0.00
Number of studies withdrawn after the meeting	0	0.00
Total	49	100

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

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

Number of applications made invalid by the REC Manager	4
Number of studies withdrawn prior to the meeting	0
Number of student applications reviewed	12
Number of paediatric applications reviewed	7
Number of device applications reviewed	0
Number of qualitative applications reviewed	5

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

Decisions taken at proportionate review sub-committee meetings	Number	%
Favourable Opinion with Standard Conditions	9	39.13
Favourable Opinion with Additional Conditions	8	34.78
No Opinion transfer to full committee for review	3	13.04
Provisional Opinion	3	13.04
Unfavourable Opinion	0	0.00
Total	23	100

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

Average number of applications reviewed per full meeting	4.90
Number of completed applications for full ethical review	49
Number of completed applications for full ethical review over 60 days	1
Number of completed applications over 60 days as a % of total	2.04%
Number of completed applications for full ethical review over 40 days	5
Number of completed applications over 40 days as a % of total	10.20%
Number of days taken to final decision – average (mean)	29
Number of completed proportionate review applications for ethical review	20
Number of completed proportionate review applications for ethical review over 21 days	1
Number of completed proportionate review applications over 21 days as a % of total	5%
Number of SSAs (non-Phase 1) reviewed	29
Number of completed applications for SSA review over 25 days	2
Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs	6.90%
Number of SSAs (Phase 1) reviewed	0
Number of completed applications for SSA review over 14 days	0
Number of completed applications for SSA review over 14 days as % of all Phase 1 SSAs	0.00%
Number of substantial amendments reviewed	165
Number of completed substantial amendments over 35 days	1
Number of completed substantial amendments over 35 days as a % of total substantial amendments	0.61%
Number of completed substantial amendments over 28 days	18
Number of completed substantial amendments over 28 days as a % of total substantial amendments	10.91%
Number of modified amendments reviewed	1
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	115
Number of substantial amendments received for information	1
Number of substantial amendments received for new sites/PIs	65
Number of annual progress reports received	114
Number of safety reports received	31
Number of Serious Adverse Events received	0

Number of final reports received	29
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Table 9.1: Breakdown of current status of all full applications reviewed within the reporting period

Further Information Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
16/NW/0253	M13-542 Phase 3 ABT-494 study in Mod/Severe RA with Bio-IR	46
16/NW/0267	UK Early Mitral Surgery Trial	63
16/NW/0272	Phase 1 study of ADCT-301 in Lymphoma patients	21
16/NW/0458	INtravascular cathETER Assessment of Released Thrombin (IN HEART)	49
16/NW/0528	The nature of autonomy when living with dementia: A Q-study (v.1)	34
16/NW/0529	HAAFE study	35
16/NW/0671	AIPAC	30
16/NW/0714	Home-based electrostimulation-induced muscle activation in SCI v1.2	34
16/NW/0736	Plastic and Reconstructive Surgery Research Skin and Tissue Bank	30
16/NW/0737	ALXN1210 vs eculizumab study in paroxysmal nocturnal haemoglobinuria	38
16/NW/0741	AZTEC-CF	32
16/NW/0802	Can e-learning help people manage their type 2 diabetes	38
16/NW/0806	The PBRU Liverpool Pancreatic Diseases Control Biobank	57
16/NW/0807	EMERALD	33
17/NW/0050	The study of hydration status and complex symptoms in advanced cancer	34
17/NW/0180	INCYTE, Efficacy and Safety of INCB054828 in Cholangiocarcinoma	25

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
16/NW/0758	A Realist Evaluation of Open Visiting within an Acute Trust	36
16/NW/0869	Health Monitoring Using Smart Meters	31
16/NW/0877	A Safety and Tolerability Study of LY3303560 in Alzheimer's Disease	56
17/NW/0144	Eye photo in Parkinson's disease	29
17/NW/0175	PRTX-100 in ITP	35

Further Information Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock

Favourable Opinion with Standard Conditions

REC Reference	Title	Number of Days on Clock
16/NW/0274	UK Biobank: a large scale prospective epidemiological resource	16
16/NW/0536	Double Icodextrin Dose in PD patients the Dido study	24
16/NW/0600	retrospective-prospective cohort study to observe Safinamide safety	22
16/NW/0803	(HOMEWARD (Phase 2 - Case Studies)	22
17/NW/0007	STH Respiratory Medicine Research Database	28
17/NW/0060	UK Computer Aided Theragnostics (ukCAT)	28

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/NW/0230	BARONET	21
16/NW/0379	LY2801653 and LY3009806 - Advanced or Metastatic Biliary Tract Cancer	17
16/NW/0380	Ocular Oncology Biobank	18
16/NW/0388	What matters to frail older people (and their carers) in primary care	17
16/NW/0389	Effective Home Support Dementia Care: DESCANT v.1	16
16/NW/0452	Pathways to Care	27
16/NW/0455	Mental health student nurse communication (V1)	27
16/NW/0467	Sunlight exposure and vitamin D in the ageing population (2)	27
16/NW/0474	Doctor-patient communication in HNC patients of varying SES	27
16/NW/0487	Street Triage : The Service Users Perspective.	24
16/NW/0519	Open-Label study of Fragmin in Children with Venous Thromboembolism	24
16/NW/0557	CHronic HypERTension and L-citRulline studY (CHERRY)	21
16/NW/0558	Treatment of Endogenous Cushing's Syndrome Version 4.0	21
16/NW/0562	Pharmacokinetics of cefuroxime in post-operative cardiac infants	19
16/NW/0609	Grip strength and frailty in stroke- feasibility study	20
16/NW/0792	Exploring digital exclusion in mental health service users	23
17/NW/0105	PREM-SBC	28
17/NW/0129	The Health and Occupation Research Network	28
17/NW/0160	The Chelsea Critical Care Physical Assessment in neurorehabilitation	23

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
16/NW/0141	Pharmacy recruited Objective Management of Inhaler Technique (POMIT-1)	21
16/NW/0463	Electrostimulation-induced muscle activation and pressure ulcers v1.1	24

17/NW/0108	Sharing books with children	28
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Provisional Opinion		
REC Reference	Title	Number of Days on Clock

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

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

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

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

Further Information Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
16/NW/0372	Repeated re-referral: perspectives and experiences	13
16/NW/0374	Experiences of Adolescents with Mental Health Issues at Horse Riding	17
17/NW/0167	Thermal Imaging of Brown Adipose Tissue in Humans (TIBATH study)	24

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock

Further Information Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock

Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
16/NW/0294	Informant information in the assessment of cognitive difficulties	19
16/NW/0295	Spirometry in shared care: COPD prevalence in substance misuse clinics	18
16/NW/0296	Breathe Magic	14
16/NW/0378	TF and PAR-2 tumour expression levels in patients with i-PE	14
16/NW/0473	Smartphone Technology and falls rehabilitation: Version 1.	18
16/NW/0475	RHINESSA version 1	14
16/NW/0615	Experiences of social interaction and communication after a CST group	13
16/NW/0674	Effectiveness of the Incredible Years parent training programme (V1)	14
16/NW/0880	Evaluation of a childhood obesity intervention in Manchester, Version 1	14

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
16/NW/0534	DevPROM	15
16/NW/0535	Establishing prospective Asparaginase activity monitoring	20
16/NW/0618	The role of the professions in self-referral physiotherapy	10
16/NW/0675	Investigating the Locus Coeruleus in Alzheimer's Disease using MRI	18
16/NW/0677	Patient understanding of atrial fibrillation and stroke risk	17
16/NW/0738	Use of the TEN Test in children with mild/moderate hearing loss	16
16/NW/0883	Exercise, physical activity and quality of life amongst COPD patients	17
17/NW/0164	EUROSTAD	19

Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock

Provisional Opinion		
REC Reference	Title	Number of Days on Clock

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

Withdrawn after the meeting

REC Reference	Title	Number of Days on Clock
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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
00/8/034/AM25	UK collaborative trial of ovarian cancer screening	Amendment number 7	20/12/2016	20
00/8/053/AM26	Prospective observational study of the long-term hazards of anti-TNF therapy in rheumatoid arthritis	07/07/2016	07/07/2016	22
00/8/053/AM27	Prospective observational study of the long-term hazards of anti-TNF therapy in rheumatoid arthritis	23	12/07/2016	16
00/8/053/AM28	Prospective observational study of the long-term hazards of anti-TNF therapy in rheumatoid arthritis	Amendment 24	26/10/2016	17
01/8/090/AM12	Trust-based survey on inpatients in acute NHS hospitals	07/06/2016	07/06/2016	27
02/8/001/AM01	Genetic Study of Tylosis and Familial Oesophageal Cancer	amendment no. 1	01/09/2016	15
02/8/100/AM03	Survey of emergency departments in acute NHS hospital trusts in England	Amendment number 3	11/08/2016	26
02/8/104/AM16	A prospective study of childhood onset inflammatory arthritis	07/06/2016	07/06/2016	27
02/8/104/AM17	A prospective study of childhood onset inflammatory arthritis	Amendment No 9	01/10/2016	20
02/8/104/AM18	A prospective study of childhood onset inflammatory arthritis	Amendment 10, 2017-01-20	20/01/2017	22
03/8/056/AM11	PET trial in Hodgkin's disease	4	20/04/2016	18
03/8/087/AM11	ASCEND: A randomised 2x2 factorial study of aspirin versus placebo, and	24/08/2016	24/08/2016	27
03/8/087/AM12	ASCEND: A randomised 2x2 factorial study of aspirin versus placebo, and	12	04/10/2016	26
03/8/087/AM13	ASCEND: A randomised 2x2 factorial study of aspirin versus placebo, and	ASCEND Amendment 13	14/01/2011	33
07/MRE08/1/AM08	Survey of women's experience of NHS maternity services	06 January 2017	06/01/2017	16
08/H1010/63/AM09	The development of novel and improved cellular therapies	Amendment 3	07/03/2016	16
08/H1010/90/AM16	COSMOS Mobile Phone and Health Study (version 1)	12	21/04/2016	7
09/H1010/2+5/AM04	Vascular Governance North West Database (VGNW)	3	15/11/2016	10
09/H1010/59/AM09	Icatibant Outcome Survey (IOS). (Firazyr® Patient Registry)	Amendment 6	07/12/2016	27
10/H1010/58/AM13	efficacy & safety of pazopanib as adjuvant therapy in renal cancer	6	25/04/2016	24

11/H1010/4/AM14	Identifying genes and autoantibodies associated with ILD.	Amendment 9	13/10/2016	8
11/NW/0298/AM31	Phase III GA101 or rituximab plus chemo in 1st line indolent NHL	SA#14	30/03/2016	24
11/NW/0298/AM34	Phase III GA101 or rituximab plus chemo in 1st line indolent NHL	11	18/11/2016	17
11/NW/0382/AM10	UK Biobank: a large scale prospective epidemiological resource	10	24/03/2016	28
11/NW/0489/AM18	WA21093-Phase III Ocrelizumab Vs Rebif in Relapsing Multiple Sclerosis	E	03/06/2016	21
11/NW/0490/AM12	WA21092-Phase III Ocrelizumab Vs Rebif in Relapsing Multiple Sclerosis	F	03/06/2016	24
11/NW/0548/AM31	RIAltO version 3	22	18/03/2016	28
11/NW/0548/AM33	RIAltO version 3	1	10/05/2016	11
11/NW/0548/AM34	RIAltO version 3	1	25/10/2016	16
11/NW/0597/AM19	PHI/II Study MLN9708 with Melphalan & Prednisone in Multiple Myeloma	10	27/06/2016	16
12/NW/0237/AM49	AMG 785/Alendronate in Postmenopausal women with Osteoporosis	03/11/2016	03/11/2016	28
12/NW/0427/AM17	MEK116513 Dabrafenib plus trametinib vs vemurafinib in melanoma	7.0	06/04/2016	13
12/NW/0427/AM18	MEK116513 Dabrafenib plus trametinib vs vemurafinib in melanoma	04/07/2016	04/07/2016	17
12/NW/0427/AM19	MEK116513 Dabrafenib plus trametinib vs vemurafinib in melanoma	Protocol version 5	11/08/2016	29
12/NW/0427/AM20	MEK116513 Dabrafenib plus trametinib vs vemurafinib in melanoma	01	13/01/2017	24
12/NW/0618/AM17	Phase II PI3K inhibitor in relapsed, indolent or aggressive NHL	13	22/04/2016	26
12/NW/0641/AM25	GO27826 Phase III Adjuvant Therapy in BRAF Mutant Melanoma	v14	01/12/2016	21
13/NW/0134/AM09	NEO-BLADE Version: 2	1.0	24/03/2016	23
13/NW/0134/AM11	NEO-BLADE Version: 2	1.0	23/09/2016	10
13/NW/0347/AM05	Phase 1/2 study of Azacitabine in subjects with AML / MDS after HSCT	Edition 13	17/08/2016	14
13/NW/0353/AM29	CONTACT v1.0	25	24/03/2016	28
13/NW/0363/AM26	Open-label study of long-term evaluation of AMG145 against LDL	20	08/04/2016	14

13/NW/0363/AM28	Open-label study of long-term evaluation of AMG145 against LDL	Substantial Amendment 23	08/06/2016	18
13/NW/0697/AM09	PiSARRO	24/06/2016	24/06/2016	19
13/NW/0697/AM10	PiSARRO	SA REC UK10	08/12/2016	26
13/NW/0842/AM08	FAKTION	7	16/09/2016	21
13/NW/0842/AM11	FAKTION	Substantial Amendment 09	23/02/2017	28
14/NW/0036/AM09	ESPAC-5F: European Study Group for Pancreatic Cancer - Trial 5F	7	23/03/2016	29
14/NW/0036/AM10	ESPAC-5F: European Study Group for Pancreatic Cancer - Trial 5F	ESPAC-5F SUBSTANTIAL AMENDMENT	29/07/2016	31
14/NW/0056/AM02	MIRena for treatment of Endometrial Neoplastic Abnormalities (MIRENA)	2	23/09/2016	8
14/NW/0132/AM01	Scleroderma and Raynaud's Research Bank	Amendment 1.0	16/02/2016	9
14/NW/0132/AM02	Scleroderma and Raynaud's Research Bank	2.0	16/05/2016	26
14/NW/0182/AM05	Identification and remediation of language deficits in TBI	5	09/06/2016	16
14/NW/0296/AM03	The Pain Management Registry Version 1	3	04/02/2016	28
14/NW/0296/AM04	The Pain Management Registry Version 1	Amendment 4	10/11/2016	10
14/NW/0347/AM12	SCAMP - Study of Cognition, Adolescents and Mobile Phones	11	24/05/2016	31
14/NW/0347/AM14	SCAMP - Study of Cognition, Adolescents and Mobile Phones	No. 12	16/12/2016	31
14/NW/0348/AM08	Safety of SBC-103 in MPS IIIB patients	5.0	01/12/2016	10
14/NW/1212/AM02	The LBIH Biobank	Amendment 2	08/11/2016	18
14/NW/1212/AM03	The LBIH Biobank	Amendment 3	12/12/2016	25
14/NW/1215/AM03	Screening for family members of African-Caribbean glaucoma cases	Amendment 2	22/02/2017	21
14/NW/1236/AM02	Metformin for endometrial cancer RCT	2	01/09/2016	21
14/NW/1238/AM11	AZD6738 in combination with other agents in Solid Malignancies	6	22/09/2016	21
14/NW/1238/AM12	AZD6738 in combination with other agents in Solid Malignancies	1	27/10/2016	12
14/NW/1238/AM15	AZD6738 in combination with other agents in Solid Malignancies	Local Amendment 1	08/02/2017	32
14/NW/1238/AM16	AZD6738 in combination with other agents in Solid Malignancies	AZD6738 Revised IB edition 5.0	28/02/2017	23
14/NW/1337/AM12	Long-Term Safety Extension Study to Sirocco (BORA)	7	18/05/2016	33

14/NW/1337/AM13	Long-Term Safety Extension Study to Sirocco (BORA)	1	24/05/2016	23
14/NW/1354/AM06	Romiplostim in Thrombocytopenic Paediatric Patients with ITP	Substantial Amendment 3	31/05/2016	27
14/NW/1354/AM07	Romiplostim in Thrombocytopenic Paediatric Patients with ITP	Substantial amendment 4	22/11/2016	15
14/NW/1398/AM04	Does fidaxomicin therapy reduce spread of Clostridium difficile? V9.9	2	14/07/2016	10
14/NW/1403/AM01	NIMBI feasibility study	SA01	11/04/2016	22
14/NW/1423/AM06	European Long-acting Antipsychotics in Schizophrenia Trial	10/08/2016	10/08/2016	29
14/NW/1423/AM08	European Long-acting Antipsychotics in Schizophrenia Trial	Substantial Amendment No.8	07/12/2016	28
14/NW/1484/AM01	The Wirral Child Health and Development Study 7-9 years - Version 1	Amendment 1	01/02/2016	23
15/NW/0017/AM05	Phase 1b Study of Dexanabinol in Advanced Cancer	20/04/2016	20/04/2016	7
15/NW/0017/AM08	Phase 1b Study of Dexanabinol in Advanced Cancer	6.1	01/05/2016	15
15/NW/0079/AM02	Human Biomaterials Resource Centre	2	09/09/2016	30
15/NW/0098/AM05	A Phase 2 Study of Azacitidine in Children with MDS or JMML	17/08/2016	17/08/2016	17
15/NW/0108/AM04	REMINET	Protocol V3	16/06/2016	13
15/NW/0135/AM02	MYPS I	Protocol V3.0	28/07/2015	22
15/NW/0171/AM06	Dex - CSDH Trial		05/04/2016	23
15/NW/0221/AM02	Profiling memory impairment in people with and without seizures	Amendment 2	02/06/2016	30
15/NW/0221/AM03	Profiling memory impairment in people with and without seizures	Amendment 3.	01/11/2016	21
15/NW/0264/AM01	Imaging biomarkers in lung cancer	2.0	03/03/2016	15
15/NW/0264/AM02	Imaging biomarkers in lung cancer	3.0	27/09/2016	26
15/NW/0319/AM05	Efficacy and safety of LX4211 added to insulin in Type 1 Diabetes	5	21/03/2016	20
15/NW/0409/AM02	Manchester Allergy, Respiratory & Thoracic Surgery Biobank	2	20/05/2016	24
15/NW/0507/AM06	1311.14 BI655066 v placebo in patients with uncontrolled severe asthma	5	23/03/2016	21
15/NW/0507/AM07	1311.14 BI655066 v placebo in patients with uncontrolled severe asthma	6	16/08/2016	28
15/NW/0507/AM10	1311.14 BI655066 v placebo in patients with uncontrolled severe asthma	7	01/12/2016	17
15/NW/0535/AM02	SBC-103 Intravenously in SBC-103 Treatment Na ⁺ ve MPS II	3.0	29/03/2016	24

	(NGLU-CL01-T)			
15/NW/0535/AM03	SBC-103 Intravenously in SBC-103 Treatment Naive MPS II (NGLU-CL01-T)	5.0	01/12/2016	17
15/NW/0535/AM04	SBC-103 Intravenously in SBC-103 Treatment Naive MPS II (NGLU-CL01-T)	Re-consenting Participants (27.	27/02/2017	28
15/NW/0592/AM07	4150: NNC0114-0006 and liraglutide in newly diagnosed type 1 diabetes	2	06/05/2016	28
15/NW/0592/AM09	4150: NNC0114-0006 and liraglutide in newly diagnosed type 1 diabetes	05/07/2016	05/07/2016	8
15/NW/0592/AM14	4150: NNC0114-0006 and liraglutide in newly diagnosed type 1 diabetes	Substantial amendment 4	30/12/2016	14
15/NW/0592/AM15	4150: NNC0114-0006 and liraglutide in newly diagnosed type 1 diabetes	5	28/10/2016	10
15/NW/0614/AM02	17845 Phase 1 dose-escalation study of BAY 1862864 Injection	27 May 2016	27/05/2016	26
15/NW/0614/AM03	17845 Phase 1 dose-escalation study of BAY 1862864 Injection	SA3	27/01/2017	11
15/NW/0626/AM05	Evaluation of Net Clinical Benefit of Sotagliflozin added to Insulin	3	23/03/2016	20
15/NW/0627/AM02	Phase 1B study of Axitinib plus Crizotinib in advanced solid tumours	2	11/03/2016	28
15/NW/0627/AM04	Phase 1B study of Axitinib plus Crizotinib in advanced solid tumours	04/01/2017	04/01/2017	16
15/NW/0677/AM01	ICH-IMAGE	SA1	10/01/2017	14
15/NW/0690/AM04	Immunotherapy with anti-PD in stage III melanoma	v12.0	05/10/2016	28
15/NW/0704/AM01	Attention and Behaviour in Alcohol Dependence (ABAD)	1	01/03/2016	23
15/NW/0780/AM02	Reading, Playing and Talking	Amendment no. 1	10/03/2016	23
15/NW/0780/AM03	Reading, Playing and Talking	Amendment no. 2	27/07/2016	27
15/NW/0786/AM04	MLN0002-3026 Vedolizumab vs Adalimumab in Ulcerative Colitis	additional advertising	25/05/2016	26
15/NW/0786/AM05	MLN0002-3026 Vedolizumab vs Adalimumab in Ulcerative Colitis	4	01/07/2016	28
15/NW/0803/AM04	TDF-Containing Regimen to E/C/F/TAF FDC in HIV-1 Adults Aged ≥ 60 Years	01	30/06/2016	22
15/NW/0826/AM01	Myositis Research Tissue Bank. (Renewal 2015)	1.0	01/09/2016	18
15/NW/0848/AM01	Impact of dental extractions prior to radiotherapy	1	23/04/2016	16

15/NW/0871/AM02	M15-462 (EXPEDITION-4) GT 1 - 6 Chronic HCV with Renal Impairment	Amendment 2	17/03/2016	16
15/NW/0926/AM04	PARTNER	2.0	05/01/2017	17
15/NW/0926/AM05	PARTNER	6	05/01/2017	10
15/NW/0936/AM04	SPIRE	v3.0	08/12/2016	22
16/NW/0054/AM01	MelaTools Apps Study	1	22/03/2016	28
16/NW/0064/AM02	M15-410: ABT-493/530, Hep C patients who are prior DAA failures	Version 5	31/03/2016	28
16/NW/0092/AM01	Magnetic Seed localisation of breast cancers Version 1	1	09/10/2016	21
16/NW/0092/AM02	Magnetic Seed localisation of breast cancers Version 1	2	18/11/2016	13
16/NW/0093/AM01	MEDI0562 in Adults with Selected Advanced Solid Tumours	1	14/06/2016	21
16/NW/0096/AM01	Antenatal Attachment, Mindfulness and Self-compassion Version 1	Version 4	03/10/2016	30
16/NW/0096/AM02	Antenatal Attachment, Mindfulness and Self-compassion Version 1	2	20/02/2017	8
16/NW/0113/AM01	Patient-centred practice within physiotherapy? A qualitative study.	Number 1	06/02/2017	34
16/NW/0134/AM01	Zoster-056 (Cross vaccination study)	01	04/05/2016	22
16/NW/0134/AM03	Zoster-056 (Cross vaccination study)	SA04	23/09/2016	21
16/NW/0134/AM04	Zoster-056 (Cross vaccination study)	Substantial Amendment 05	30/11/2016	19
16/NW/0146/AM01	201190 (Zoster-049)	Protocol Amendment 1	20/05/2016	31
16/NW/0146/AM02	201190 (Zoster-049)	2	14/09/2016	26
16/NW/0146/AM04	201190 (Zoster-049)	Substantial Amendment 3	01/12/2016	19
16/NW/0146/AM06	201190 (Zoster-049)	5	13/03/2017	10
16/NW/0189/AM01	Hp and IL-1 mediated inflammation following intracranial bleeding	SA1	06/10/2016	12
16/NW/0253/AM01	M13-542 Phase 3 ABT-494 study in Mod/Severe RA with Bio-IR	17/06/2016	17/06/2016	9
16/NW/0253/AM05	M13-542 Phase 3 ABT-494 study in Mod/Severe RA with Bio-IR	Protocol Amendment 2	25/10/2016	28
16/NW/0253/AM06	M13-542 Phase 3 ABT-494 study in Mod/Severe RA with Bio-IR	Retention Materials	18/01/2017	35
16/NW/0253/AM08	M13-542 Phase 3 ABT-494 study in Mod/Severe RA with Bio-	SA07	27/01/2017	21

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16/NW/0272/AM04	Phase 1 study of ADCT-301 in Lymphoma patients	SA#2	18/08/2016	26
16/NW/0272/AM05	Phase 1 study of ADCT-301 in Lymphoma patients	SA#3	24/11/2016	20
16/NW/0274/AM01	UK Biobank: a large scale prospective epidemiological resource	1	01/07/2016	12
16/NW/0274/AM02	UK Biobank: a large scale prospective epidemiological resource	Substantial Amendment 2	01/08/2016	10
16/NW/0274/AM03	UK Biobank: a large scale prospective epidemiological resource	Substantial amendment 3	01/10/2016	21
16/NW/0274/AM04	UK Biobank: a large scale prospective epidemiological resource	Substantial Amendment 4	01/12/2016	14
16/NW/0372/AM01	Repeated re-referral: perspectives and experiences	Amendment 1	17/11/2016	24
16/NW/0379/AM01	LY2801653 and LY3009806 - Advanced or Metastatic Biliary Tract Cancer	1	25/07/2016	18
16/NW/0379/AM02	LY2801653 and LY3009806 - Advanced or Metastatic Biliary Tract Cancer	Substantial amendment 2	07/02/2017	31
16/NW/0473/AM01	Smartphone Technology and falls rehabilitation: Version 1.	SA1	07/10/2016	25
16/NW/0519/AM01	Open-Label study of Fragmin in Children with Venous Thromboembolism	1	26/10/2016	15
16/NW/0519/AM02	Open-Label study of Fragmin in Children with Venous Thromboembolism	9	18/10/2016	14
16/NW/0519/AM03	Open-Label study of Fragmin in Children with Venous Thromboembolism	Substantial Amendment 03	01/03/2017	22
16/NW/0557/AM02	CHronic HypERTension and L-citRulline studY (CHERRY)	v1.0	16/02/2017	28
16/NW/0558/AM01	Treatment of Endogenous Cushing's Syndrome Version 4.0	UK_SA01	01/09/2016	20
16/NW/0562/AM02	Pharmacokintetics of cefuroxime in post-operative cardiac infants	SA01	03/02/2017	14
16/NW/0618/AM01	The role of the professions in self-referral physiotherapy	Amendment number 1	21/11/2016	21
16/NW/0671/AM01	AIPAC	1.2	30/09/2016	20
16/NW/0671/AM02	AIPAC	V2.0	07/11/2016	28
16/NW/0671/AM03	AIPAC	SA-03 England	20/02/2017	34
16/NW/0737/AM01	ALXN1210 vs eculizumab study in paroxysmal nocturnal haemoglobinuria	Travel Reimbursement	06/01/2017	24
16/NW/0807/AM01	EMERALD	2.0	27/02/2017	16
99/8/084/AM18	National Repository Study	3E	29/07/2016	19

99/8/084/AM20	National Repository Study	6c	17/10/2016	13
99/8/084/AM21	National Repository Study	Amendment 10a	04/11/2016	13
99/8/084/AM22	National Repository Study	Amendment 11	17/02/2017	23

Unfavourable opinion				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
15/NW/0869/AM02	Measuring neutrophil function in sepsis	SA01	27/04/2016	45
16/NW/0253/AM04	M13-542 Phase 3 ABT-494 study in Mod/Severe RA with Bio-IR	SA04	17/10/2016	20

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
15/NW/0869/AM02/1	Measuring neutrophil function in sepsis	SA02	08/08/2016	8

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
16/NW/0267	UK Early Mitral Surgery Trial	63

Proportionate review applications for ethical review over 21 day timeline

REC Reference	Title	Number of Days on Clock
17/NW/0167	Thermal Imaging of Brown Adipose Tissue in Humans (TIBATH study)	24

SSAs (non Phase 1) over 25 day timeline

REC Reference	Title	Number of Days on Clock
16/NW/0129	A Multicenter, International, Randomized, Double-blind, Alendronate-controlled Study to Determine the Efficacy and Safety of AMG 785 in the Treatment of Postmenopausal Women With Osteoporosis	66
17/NW/0156	A Phase IIIB, non-randomized, open-label, multi-country, multi-centric cross-vaccination study to evaluate the safety of GSK Biologicals' Herpes Zoster subunit (HZ/su) vaccine when administered intramuscularly on a two-dose schedule to subjects who previously received placebo in ZOSTER-006 and ZOSTER-022 studies.	26

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
15/NW/0869/AM02	Measuring neutrophil function in sepsis	SA01	27/04/2016	45

Modified Amendments over 14 day timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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