

North West - Haydock Research Ethics Committee

Annual Report

01 April 2015 - 31 March 2016



Part 1 – Committee Membership and Training

Name of REC:	North West - Haydock Research Ethics Committee
Type of REC:	Type III
Type of Flag:	Research involving Adults Lacking Capacity, Phase 1 Studies in Patients, Research Databases, Research Tissue Banks
Chair:	Dr Tim S Sprosen
Vice-Chair:	Vacant
Alternate Vice-Chair:	Dr Valerie E Siddall
REC Manager:	Ms Rachel Katzenellenbogen
REC Assistant:	Mr Ewan Waters
Committee Address:	3rd Floor - Barlow House 4 Minshull Street Manchester M1 3DZ
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Chair's overview of the past year:

HRA approval is another innovation from the HRA that will genuinely make it much easier to do research. While there is still a way to go until we really have a one-stop-shop to set up a research project in the UK this is an important development along that road. It's really easy to knock ethics committees, but my view is we already have one of the best systems of ethical review in the UK and are well on our way to being the best.

As for the Haydock committee, being a researcher myself I know that the committee is held in very high regard by many in the research community. We look after some of the biggest projects there are, UK Biobank for example, yet give the same time and attention to every project we see. We particularly enjoy seeing the next generation of investigators (and like it even more when their supervisor makes the effort to accompany them to the meeting). The committee always balances the need to protect research participants with the aim of promoting research. The discussions are always lively, frequently punctuated with laughter, and I know that like me the other members genuinely look forward to seeing each other at the racecourse every month.

Being in the chair is both an honour and given the dedication, energy and enthusiasm of my colleagues a rather easy job. The different perspectives that the members bring have made me a better researcher. We filled two difficult to fill slots in the last year, welcoming Simon Hill on board as our pharmacist and Dr Zhe Wang, as our statistician. Both of them are already making a great contribution. We waved goodbye to Chris Haywood, first and foremost a nurse, but also a hospice manager. We need more people in society who are really smart, want to get things done, but also care about other people and have a strong sense of what is right and what is wrong. Chris is the perfect example of this.

Finally, thank you to Rachel and her team. The demands on them to do more, to do things better and with fewer resources are apparent to all. The committee meets all of the targets set for it because of all of the hard work of the team. Thank you.

North West - Haydock Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Mrs Moyra Ann Baldwin	Retired Senior Lecturer - Oncology	Expert	07/11/2013	
Mr Stephen Edgar	Designer	Lay Plus	13/11/2009	
Dr Michael U Eshiett	Consultant Physician in Neurological Rehabilitation	Expert	23/09/2009	
Mrs Chris Haywood	Director of Nursing	Expert	20/08/2010	19/01/2016
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	
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	
Mr Peter Ward	Retired Manufacturing Director	Lay Plus	01/05/2013	31/05/2015

North West - Haydock Research Ethics Committee: Deputy Members

Name	Profession	Status	Meeting date attended
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North West - Haydock Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended
Mr James Burns	Retired	Lay	08/03/2016
Mrs Sue Fitzpatrick	Director	Lay	08/03/2016
Mrs Christine Holly	Retired Librarian	Lay Plus	08/09/2015
Dr Paul Mortimer	Retired Executive Principal of Academy school group	Lay	14/05/2015
Dr Peter Walton	Lay Member	Lay	08/09/2015

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

Name	Declaration of Interest	Date
Mrs Moyra Ann Baldwin	None.	13/01/2016
Dr Michael U Eshiett	None	21/01/2016
Mr Simon Hill	No interests to declare.	09/06/2015
Dr Ben Johnson	None	13/01/2016
Dr Ezzat Kozman	None	13/01/2016
Mr Charles Otim	Employee of NIHR CRN GM	28/05/2015
Dr David Pilling	None	10/02/2016
Miss Anna Sekula	Formerly Drug Safety Nurse for GSK Clinical Trials, working on the Salford Lung Study. Bank Nurse for Pennine Acute Hospitals NHS Trust. Currently employed as R&D Coordinator at the Christie NHS Foundation Trust. Involved in Trust sponsorship decisions for research projects and oversight activities for sponsored clinical trials.	28/01/2016
Dr Valerie E Siddall	Member of Participant Panel at Nuffield Department of Population Health.	18/01/2016
Dr Zhe Wang	None	25/01/2016

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

Month	Date	Number of Members Present at Meeting
April	14/04/2015	7
May	12/05/2015	11
July	14/07/2015	11
August	11/08/2015	9
September	08/09/2015	10
October	13/10/2015	8
November	10/11/2015	8
December	08/12/2015	11
February	09/02/2016	11
March	08/03/2016	7

10 full committee meetings were held during the reporting period.

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

Month	Date	Number of Members Present at Meeting
April	02/04/2015	3
June	11/06/2015	3
July	16/07/2015	3
August	20/08/2015	3
September	24/09/2015	3
October	22/10/2015	3
November	10/11/2015	3
December	08/12/2015	3
January	12/01/2016	3
February	09/02/2016	3
March	02/03/2016	4

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

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

Month	Date	Number of Members Present at Meeting
April	14/04/2015	2
April	28/04/2015	2
May	12/05/2015	2
May	26/05/2015	2
June	09/06/2015	2
June	19/06/2015	2
June	23/06/2015	2
June	30/06/2015	3
July	16/07/2015	2
July	28/07/2015	2

August	11/08/2015	4
August	25/08/2015	2
September	08/09/2015	2
September	22/09/2015	2
September	29/09/2015	2
October	13/10/2015	2
October	27/10/2015	3
November	10/11/2015	3
November	24/11/2015	2
December	08/12/2015	3
December	22/12/2015	2
January	12/01/2016	2
January	18/01/2016	2
January	26/01/2016	3
February	09/02/2016	3
February	23/02/2016	2
March	08/03/2016	2
March	11/03/2016	2
March	22/03/2016	2

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

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

Date	Reason	Action taken

None

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

Name	Number of Meetings Attended
Mrs Moyra Ann Baldwin	8
Mr Stephen Edgar	7
Dr Michael U Eshiett	5
Mrs Chris Haywood	8
Mr Simon Hill	6
Dr Ben Johnson	6
Dr Ezzat Kozman	9
Mr Charles Otim	6
Dr David Pilling	6
Miss Anna Sekula	6
Dr Valerie E Siddall	8
Dr Tim S Sprosen	10
Dr Zhe Wang	2
Mr Peter Ward	1

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

Name	Number of Meetings Attended
Mrs Moyra Ann Baldwin	2
Mr Stephen Edgar	3
Mrs Chris Haywood	4
Dr Ben Johnson	1
Dr Ezzat Kozman	4
Mr Charles Otim	2
Dr David Pilling	1
Dr Valerie E Siddall	6
Dr Tim S Sprosen	11

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

Name	Number of Meetings Attended
Mrs Moyra Ann Baldwin	3
Mr Stephen Edgar	3
Mrs Chris Haywood	7
Dr Ezzat Kozman	6
Dr David Pilling	4
Miss Anna Sekula	1
Dr Valerie E Siddall	18
Dr Tim S Sprosen	24

Training 01 April 2015 - 31 March 2016

Name of Member	Date	Event(s) attended
Mrs Moyra Ann Baldwin	09/06/2015	Qualitative Research
Mr Stephen Edgar	09/06/2015	Qualitative Research
Dr Michael U Eshiett	09/06/2015	Qualitative Research
Mrs Sue Fitzpatrick	08/06/2015	Equality and Diversity
Mrs Sue Fitzpatrick	15/06/2015	Induction
Mrs Chris Haywood	09/06/2015	Qualitative Research
Mr Simon Hill	09/06/2015	Qualitative Research
Mr Simon Hill	24/09/2015	Committee Member's Induction
Mrs Christine Holly	23/04/2015	Equality and Diversity
Mrs Christine Holly	30/06/2015	Human Tissue Act (Use of Human Samples in Research) - An Introductory Level
Dr Ben Johnson	09/06/2015	Qualitative Research
Dr Paul Mortimer	15/06/2015	Members Induction
Mr Charles Otim	09/06/2015	Qualitative Research
Dr David Pilling	09/06/2015	Qualitative Research
Miss Anna Sekula	09/06/2015	Qualitative Research
Dr Tim S Sprosen	09/06/2015	Qualitative Research

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	21	41.18
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	4	7.84
Research Database (including renewals)	1	1.96
Others	25	49.02
Total Applications Reviewed	51	100

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

Number of applications made invalid by the REC Manager	3
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	13
Number of paediatric applications reviewed	4
Number of device applications reviewed	7
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	5
Number of applications reviewed that are funded by the US DHHS	0
Number of qualitative applications reviewed	1

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	11.76
Favourable Opinion with Additional Conditions	19	37.25
Unfavourable Opinion	1	1.96
Provisional Opinion	25	49.02
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	51	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	23	45.10
Further Information Favourable Opinion with Additional Conditions	2	3.92
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	6	11.76
Favourable Opinion with Additional Conditions	19	37.25
Unfavourable Opinion	1	1.96
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	51	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	9
Number of studies withdrawn prior to the meeting	0
Number of student applications reviewed	9
Number of paediatric applications reviewed	6
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	18	78.26
Favourable Opinion with Additional Conditions	3	13.04
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	2	8.70
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	5.10
Number of completed applications for full ethical review	51
Number of completed applications for full ethical review over 60 days	1
Number of completed applications over 60 days as a % of total	1.96%
Number of completed applications for full ethical review over 40 days	8
Number of completed applications over 40 days as a % of total	15.69%
Number of days taken to final decision – average (mean)	30

Number of completed proportionate review applications for ethical review	23
Number of completed proportionate review applications for ethical review over 14 days	1* (0)
Number of completed proportionate review applications over 14 days as a % of total	4.35%* (0%)

**Please note that one of these studies was part of the Proportionate Review Pilot which has been set up to test whether allowing REC staff increased time to work with applicants to ensure that the study documentation is clear, accurate and complete, as well as allowing a minimum number of days for REC members to undertake the ethical review is preferable against set evaluation criteria. One of the objectives of the pilot is to assess the impact of extending the length of review to 21 calendar days rather than 14 calendar days. The numbers in red are the figures excluding any applications which were part of the Proportionate Review pilot.*

Number of SSAs (non-Phase 1) reviewed	12
Number of completed applications for SSA review over 25 days	1
Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs	8.33%

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	167
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 completed substantial amendments over 28 days	10
Number of completed substantial amendments over 28 days as a % of total substantial amendments	5.99%

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 minor amendments received	84
Number of substantial amendments received for information	0
Number of substantial amendments received for new sites/PIs	63
Number of annual progress reports received	138
Number of safety reports received	60
Number of Serious Adverse Events received	1
Number of final reports received	31

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
15/NW/0264	Imaging biomarkers in lung cancer	22
15/NW/0319	Efficacy and safety of LX4211 added to insulin in Type 1 Diabetes	24
15/NW/0326	Attention Training in ADHD	26
15/NW/0351	HLA-G and its ligand KIR2DL4 in renal transplant patients	35
15/NW/0352	Use of H-FABP to confirm NSTEMI for chest pain patients	28
15/NW/0376	ReBeL Phase II (A HOVON 110FL/GLSG/NCRI study)	30
15/NW/0387	PRIME-ICH	28
15/NW/0399	The use CT-perfusion techniques in the evaluation of pseudoprogression	24
15/NW/0409	Manchester Allergy, Respiratory & Thoracic Surgery Biobank	36
15/NW/0467	SAPS	41
15/NW/0626	Evaluation of Net Clinical Benefit of Sotagliflozin added to Insulin	25
15/NW/0677	ICH-IMAGE	37
15/NW/0690	Immunotherapy with anti-PD in stage III melanoma	45
15/NW/0699	M13-590 - HCV Genotype 1 - treatment naive (ENDURANCE-1)	45
15/NW/0700	M13-583 (Endurance-4), ABT-493/ABT-530 in Hep C genotypes 4,5 and 6	45
15/NW/0822	Effective Home Support Dementia Care: Observational Study v.1	36
15/NW/0869	Measuring neutrophil function in sepsis	35
15/NW/0871	M15-462 (EXPEDITION-4) GT 1 - 6 Chronic HCV with Renal Impairment	25
15/NW/0926	PARTNER	36
15/NW/0936	SPIRE	28
16/NW/0064	M15-410: ABT-493/530, Hep C patients who are prior DAA failures	20
16/NW/0093	MEDI0562 in Adults with Selected Advanced Solid Tumours	56
16/NW/0095	A&E BBV Screening Study	29

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
15/NW/0803	TDF-Containing Regimen to E/C/F/TAF FDC in HIV-1 Adults Aged ≥60 Years	40
16/NW/0079	Mental Health Inpatient Staff-Patient Alliance Study (MISPA)	44

Further Information Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
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Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
15/NW/0592	4150: NNC0114-0006 and liraglutide in newly diagnosed type 1 diabetes	23
15/NW/0826	Myositis Research Tissue Bank. (Renewal 2015)	33
16/NW/0092	Magnetic Seed localisation of breast cancers Version 1	25
16/NW/0096	Antenatal Attachment, Mindfulness and Self-compassion Version 1	20
16/NW/0134	Zoster-056 (Cross vaccination study)	28
16/NW/0172	An exploration of sleep disturbance and symptoms in psychosis	28

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
15/NW/0403	Mothers' experiences of bonding with children in context of street sex work	21
15/NW/0449	The UK National Registry of Chronic Myeloid Leukaemia (CML)	61
15/NW/0507	1311.14 BI655066 v placebo in patients with uncontrolled severe asthma	20
15/NW/0535	SBC-103 Intravenously in SBC-103 Treatment Na ⁺ ve MPS II (NGLU-CL01-T)	20
15/NW/0554	Oral and Dental Tolerance and Efficacy on Dental Hypersensitivity	20
15/NW/0603	Flow-cycled ventilation in preterm infants (FLIPI)	23
15/NW/0614	17845 Phase 1 dose-escalation study of BAY 1862864 Injection	23
15/NW/0627	Phase 1B study of Axitinib plus Crizotinib in advanced solid tumours	29
15/NW/0657	Lung Research Tissue Bank (Version 2.1)	43
15/NW/0704	Attention and Behaviour in Alcohol Dependence (ABAD)	24
15/NW/0786	MLN0002-3026 Vedolizumab vs Adalimumab in Ulcerative Colitis	22
15/NW/0787	INCA; investigating neuronal responses by assessing cough in asthma	22
15/NW/0837	Imaging Hypoxia in Cerebral Tumours (version 1)	24
15/NW/0914	Pathway CH S&E Registry	21
15/NW/0929	Investigation of sensory symptoms associated with TMS	21
15/NW/0937	Self-reported needs after subarachnoid haemorrhage (SAH)	21
16/NW/0066	BLUEBELL	27
16/NW/0146	201190 (Zoster-049)	28
16/NW/0167	Extension of lead mortality study to include cancer incidence data v1	28

Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock
15/NW/0723	hVIVO Research Tissue Bank	22

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
15/NW/0311	Recovery and engagement with services in first episode psychosis (V.1)	11
15/NW/0609	Outcomes important to patients with Psoriatic Arthritis	13

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
15/NW/0502	Exploring how online information affects adolescents with CFS/ME	6
15/NW/0506	Adipocytes and breast cancer	6
15/NW/0608	Breast lymphoedema validation study	13
15/NW/0613	Analysis of brush cytology in colorectal cancer diagnosis	12
15/NW/0681	Cellular entry and neutralization mechanisms of quasi-enveloped HEV	6
15/NW/0770	ThermOI	9
15/NW/0777	NMR urine analysis in recurrent urinary stones patients	7
15/NW/0780	Reading, Playing and Talking	7
15/NW/0847	Prevalence of microsporidian in patients from the UK/ version 2	8
15/NW/0848	Impact of dental extractions prior to radiotherapy	8
15/NW/0898	Predicting neonatal outcomes using heart rate variability (HeRO score)	7
15/NW/0900	Fetal and neonatal features of Prader-Willi syndrome	8
15/NW/0968	Respiratory Viruses in Allergy (ResViAL) version 1.2	11
15/NW/0973	Peoples experience of COPD self management v1	10
16/NW/0109	How Fresnel prisms effect binocular visual functions in patients	14
16/NW/0113	Patient-centred practice within physiotherapy? A qualitative study.	14
16/NW/0188	Validation Exercise of a Bleeding Assessment Tool (BAT).	9
16/NW/0189	Hp and IL-1 mediated inflammation following intracranial bleeding	16

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
15/NW/0316	Effects of Agent Formulations on Oral Malodour	6
15/NW/0972	Oxford Peripheral Vascular Disease Study (OxPVD)	10
16/NW/0054	MelaTools Apps Study	13

Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock

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

Favourable opinion				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
00/8/053/AM25	Prospective observational study of the long-term hazards of anti-TNF therapy in rheumatoid arthritis	21	12/10/2015	15
01/8/090/AM11	Trust-based survey on inpatients in acute NHS hospitals	10	06/07/2015	14
02/8/071/AM48	IBIS-II (DCIS)	44	17/11/2015	9
02/8/104/AM14	A prospective study of childhood onset inflammatory arthritis	7	16/06/2015	17
03/8/087/AM09	ASCEND: A randomised 2x2 factorial study of aspirin versus placebo, and	9	15/06/2015	12
03/8/087/AM10	ASCEND: A randomised 2x2 factorial study of aspirin versus placebo, and	10	10/11/2015	9
05/MRE08/74/AM13	Hunter Outcome Survey	Protocol amendment 7	17/11/2015	9
07/MRE08/9/AM11	BAD Biological Interventions Register	8	01/07/2015	26
07/MRE08/9/AM12	BAD Biological Interventions Register	9	01/12/2015	24
09/H1010/19+5/AM02	United Kingdom Primary Sjogren's Syndrome Registry	2.0	23/07/2015	15
09/H1010/2/AM03	Risk modelling for aneurysm surgery 1.0	3	21/10/2015	21
09/H1010/2+5/AM03	Vascular Governance North West Database (VGNW)	2	17/04/2015	24
09/H1010/59/AM04	Icatibant Outcome Survey (IOS). (Firazyr® Patient Registry)	1	25/01/2016	18
09/H1010/59/AM05	Icatibant Outcome Survey (IOS). (Firazyr® Patient Registry)	3	12/06/2015	8
09/H1010/64/AM05	Prospective Registry of Inflammatory Bowel Disease	4	15/03/2015	17
10/H1010/31/AM08	HPV-062 EXT:015	04	30/07/2015	14
10/H1010/46/AM19	110390 (Zoster 006) Herpes Zoster Vaccine Study	Letters regarding early halt	23/04/2015	13
10/H1010/47/AM20	Zoster 022 (113077) Herpes Zoster Vaccine Study in adults 70 yrs+	Letters regarding early halt	23/04/2015	13
10/H1010/58/AM12	efficacy & safety of pazopanib as adjuvant therapy in renal cancer	4	06/08/2015	14
10/H1010/70/AM09	ALSPAC Study Young Adults: Enrolment and Consent for Record Linkage	7	30/04/2015	9

10/H1010/70/AM11	ALSPAC Study Young Adults: Enrolment and Consent for Record Linkage	8	02/07/2015	28
10/H1010/70/AM12	ALSPAC Study Young Adults: Enrolment and Consent for Record Linkage	9	23/10/2015	20
11/H1010/4/AM11	Identifying genes and autoantibodies associated with ILD.	6	11/05/2015	15
11/H1010/4/AM12	Identifying genes and autoantibodies associated with ILD.	7	11/05/2015	10
11/H1010/4/AM13	Identifying genes and autoantibodies associated with ILD.	8	03/06/2015	20
11/NW/0036/AM23	A8081014 - NON-SQUAMOUS CARCINOMA Final Amendment-2 20 December 2010	Updated radiology assessment a	28/07/2015	21
11/NW/0036/AM25	A8081014 - NON-SQUAMOUS CARCINOMA Final Amendment-2 20 December 2010	9	20/07/2015	35
11/NW/0036/AM26	A8081014 - NON-SQUAMOUS CARCINOMA Final Amendment-2 20 December 2010	Addendum 2.0	02/12/2015	14
11/NW/0036/AM27	A8081014 - NON-SQUAMOUS CARCINOMA Final Amendment-2 20 December 2010	Participant Information Sheet and Consent Form part II V12 14-Jan-2016, GP letter Version 5.0 14-Jan-2016, Investigator Brochure Oct 2015	15/02/2016	27
11/NW/0298/AM28	Phase III GA101 or rituximab plus chemo in 1st line indolent NHL	11	02/11/2015	11
11/NW/0382/AM08	UK Biobank: a large scale prospective epidemiological resource	Addendum -TIME study recontact	27/10/2015	21
11/NW/0382/AM09	UK Biobank: a large scale prospective epidemiological resource	9	04/01/2016	26
11/NW/0548/AM24	RIAltO version 3	16	21/04/2015	16
11/NW/0548/AM26	RIAltO version 3	Amendment 17	17/07/2015	14
11/NW/0548/AM27	RIAltO version 3	18	11/08/2015	15
11/NW/0548/AM28	RIAltO version 3	19	21/12/2015	10
11/NW/0548/AM30	RIAltO version 3	21	03/03/2016	8
11/NW/0597/AM17	PHI/II Study MLN9708 with Melphalan & Prednisone in Multiple Myeloma	8.0	31/03/2015	15
11/NW/0606/AM11	Phase 1 Dose Escalation Study of Dexanabinol in Advanced Cancer	008	01/05/2015	17
11/NW/0614/AM04	Homicide by patients with schizophrenia: a case-control study	3	11/12/2015	13
12/NW/0237/AM34	AMG 785/Alendronate in Postmenopausal women with Osteoporosis	26	09/10/2015	32

12/NW/0251/AM13	AAA-III-01	6	05/06/2014	15
12/NW/0262/AM01	Non-invasive brain stimulation for dysphagia after acute stroke	1	20/01/2016	19
12/NW/0427/AM16	MEK116513 Dabrafenib plus trametinib vs vemurafinib in melanoma	2	18/12/2015	27
12/NW/0511/AM01	Ten year analysis of oesophageal cancer resections	1	11/05/2015	20
12/NW/0618/AM12	Phase II PI3K inhibitor in relapsed, indolent or aggressive NHL	9	23/04/2015	8
12/NW/0618/AM13	Phase II PI3K inhibitor in relapsed, indolent or aggressive NHL	11	20/10/2015	18
12/NW/0618/AM14	Phase II PI3K inhibitor in relapsed, indolent or aggressive NHL	11	06/01/2016	18
12/NW/0641/AM20	GO27826 Phase III Adjuvant Therapy in BRAF Mutant Melanoma	Protocol GO27826, Version 8	14/04/2015	16
12/NW/0641/AM24	GO27826 Phase III Adjuvant Therapy in BRAF Mutant Melanoma	13	11/03/2016	11
12/NW/0711/AM26	A Trial of LMTM in Patients with Alzheimer's Disease (TRx-237-015)	16	20/02/2015	21
12/NW/0711/AM27	A Trial of LMTM in Patients with Alzheimer's Disease (TRx-237-015)	6.0	07/07/2015	14
13/NW/0134/AM04	NEO-BLADE Version: 2	3	25/02/2015	15
13/NW/0134/AM06	NEO-BLADE Version: 2	1.0	23/07/2015	9
13/NW/0170/AM02	Imperial Population BioResource Research Tissue Bank	3	29/02/2016	6
13/NW/0319/AM03	Registry biomarker study in RASopathy patients	2	26/08/2015	10
13/NW/0319/AM04	Registry biomarker study in RASopathy patients	3	17/12/2015	24
13/NW/0347/AM03	Phase 1/2 study of Azacitabine in subjects with AML / MDS after HSCT	1	02/03/2015	23
13/NW/0347/AM04	Phase 1/2 study of Azacitabine in subjects with AML / MDS after HSCT	12	06/08/2015	32
13/NW/0363/AM17	Open-label study of long-term evaluation of AMG145 against LDL	12	18/06/2015	15
13/NW/0363/AM18	Open-label study of long-term evaluation of AMG145 against LDL	12	18/06/2015	25
13/NW/0560/AM12	H8A-MC-LZAX: Progression of Mild Alzheimer's Disease	7	21/09/2015	16
13/NW/0560/AM13	H8A-MC-LZAX: Progression of Mild Alzheimer's Disease	7	02/03/2016	7
13/NW/0588/AM03	Airwave Health Monitoring Study Tissue Bank	4	04/09/2015	24
13/NW/0614/AM01	Risk stratification of children with transient loss of consciousness	1	03/03/2016	12
13/NW/0634/AM08	GSK2256098 + Trametinib dose escalation study	4	05/11/2014	13

13/NW/0637/AM06	Phase 2/3 study of nab-paclitaxel in metastatic breast cancer	5	11/08/2015	16
13/NW/0641/AM06	Selumetinib or Placebo + Docetaxel for KRAS positive NSCLC	1	27/05/2015	17
13/NW/0641/AM07	Selumetinib or Placebo + Docetaxel for KRAS positive NSCLC	2	02/12/2015	18
13/NW/0641/AM08	Selumetinib or Placebo + Docetaxel for KRAS positive NSCLC	5	28/01/2016	25
13/NW/0697/AM06	PiSARRO	06	16/06/2015	9
13/NW/0697/AM07	PiSARRO	7	27/11/2015	14
13/NW/0697/AM08	PiSARRO	8	09/03/2016	7
13/NW/0702/AM06	ABC06: ASC alone or with mFOLFOX for advanced biliary tract cancer	5	28/10/2015	22
13/NW/0718/AM06	Targeted Ultrasound in Rheumatoid Arthritis (TURA)	4.1	29/05/2015	8
13/NW/0718/AM10	Targeted Ultrasound in Rheumatoid Arthritis (TURA)	6.0	01/10/2015	8
13/NW/0842/AM04	FAKTION	SA4	02/06/2015	14
13/NW/0844/AM02	Transcranial Direct Current Stimulation: Impact on therapy for aphasia	2	17/08/2015	21
13/NW/0844/AM03	Transcranial Direct Current Stimulation: Impact on therapy for aphasia	3	05/10/2015	34
14/NW/0036/AM05	ESPAC-5F: European Study Group for Pancreatic Cancer - Trial 5F	4	13/05/2015	10
14/NW/0056/AM01	MIRena for treatment of Endometrial Neoplastic Abnormalities (MIRENA)	1	05/03/2015	13
14/NW/0065/AM08	ROP Phase-II	7	09/07/2015	19
14/NW/0065/AM09	ROP Phase-II	Substantial Amendment 8	20/11/2015	14
14/NW/0068/AM01	Global Registry of Bronchial Thermoplasty (BT) Version 4.2	01	21/05/2015	27
14/NW/0119/AM06	Study of PL37 in Peripheral Neuropathic Pain of Diabetic Origin	5	13/04/2015	24
14/NW/0119/AM08	Study of PL37 in Peripheral Neuropathic Pain of Diabetic Origin	SA#7 – Diabetes posters	08/05/2015	18
14/NW/0119/AM09	Study of PL37 in Peripheral Neuropathic Pain of Diabetic Origin	Recruitment methods	12/06/2015	13
14/NW/0119/AM10	Study of PL37 in Peripheral Neuropathic Pain of Diabetic Origin	9	17/07/2015	28
14/NW/0119/AM11	Study of PL37 in Peripheral Neuropathic Pain of Diabetic Origin	6	12/10/2015	29
14/NW/0119/AM12	Study of PL37 in Peripheral Neuropathic Pain of Diabetic Origin	11	21/12/2015	24
14/NW/0182/AM04	Identification and remediation of language deficits in TBI	4	03/09/2015	21
14/NW/0185/AM01	Manchester Skin Health Biobank Renewal	2	25/06/2015	18
14/NW/0185/AM02	Manchester Skin Health Biobank Renewal	03	07/10/2015	26
14/NW/0266/AM01	Why do stroke patients not receive the recommended amount	1	29/06/2015	15

	of therapy?			
14/NW/0290/AM02	Vercise DBS Registry / version AB	AC	14/08/2015	22
14/NW/0347/AM08	SCAMP - Study of Cognition, Adolescents and Mobile Phones	4	30/04/2015	27
14/NW/0347/AM09	SCAMP - Study of Cognition, Adolescents and Mobile Phones	8	22/06/2015	14
14/NW/0347/AM10	SCAMP - Study of Cognition, Adolescents and Mobile Phones	9	27/08/2015	28
14/NW/0347/AM11	SCAMP - Study of Cognition, Adolescents and Mobile Phones	10	28/09/2015	15
14/NW/0348/AM07	Safety of SBC-103 in MPS IIIB patients	4	17/02/2016	26
14/NW/1031/AM01	The perspective of the ISP service user	3.3	29/07/2015	14
14/NW/1076/AM03	RESCUE-ASDH trial. Version 1.0	1	08/06/2015	9
14/NW/1115/AM02	Canine Olfaction Detection of Human Breast Cancer by Breath Samples V1	2	27/01/2016	13
14/NW/1143/AM04	MLN0264 in Adenocarcinoma of the Stomach or Gastroesophageal Junction	3	17/06/2015	8
14/NW/1144/AM06	MLN0264 in Pancreatic Adenocarcinoma	3	17/06/2015	8
14/NW/1212/AM01	The LBIH Biobank	1	08/06/2015	11
14/NW/1221/AM02	The Influence of VNS on blood markers of inflammation	2	07/04/2015	9
14/NW/1221/AM03	The Influence of VNS on blood markers of inflammation	Amendment number 3	11/05/2015	17
14/NW/1221/AM05	The Influence of VNS on blood markers of inflammation	5	30/10/2015	18
14/NW/1238/AM06	AZD6738 in combination with other agents in Solid Malignancies	Global CSP Amendment 3	25/02/2015	9
14/NW/1238/AM07	AZD6738 in combination with other agents in Solid Malignancies	4	05/06/2015	18
14/NW/1238/AM08	AZD6738 in combination with other agents in Solid Malignancies	1	18/11/2015	18
14/NW/1260/AM01	Manchester Biomedical Research Centre (BRC) Biobank	1	01/12/2015	14
14/NW/1310/AM01	Time-lapse imaging: Incubation and annotation (v1.0)	1	07/09/2015	15
14/NW/1337/AM07	Long-Term Safety Extension Study to Sirocco (BORA)	5	22/09/2015	14
14/NW/1337/AM08	Long-Term Safety Extension Study to Sirocco (BORA)	1	22/09/2015	13
14/NW/1337/AM10	Long-Term Safety Extension Study to Sirocco (BORA)	1	22/10/2015	32
14/NW/1354/AM05	Romiplostim in Thrombocytopenic Paediatric Patients with ITP	2	08/12/2015	29
14/NW/1376/AM01	Rhinoconjunctivitis Quality of Life Questionnaire 12+	1	08/04/2015	9
14/NW/1376/AM02	Rhinoconjunctivitis Quality of Life Questionnaire 12+	2	29/04/2015	15
14/NW/1398/AM01	Does fidaxomicin therapy reduce spread of Clostridium difficile? V9.9	1	22/04/2015	25
14/NW/1423/AM03	European Long-acting Antipsychotics in Schizophrenia Trial	2	09/06/2015	8

14/NW/1423/AM04	European Long-acting Antipsychotics in Schizophrenia Trial	4	16/09/2015	14
14/NW/1423/AM05	European Long-acting Antipsychotics in Schizophrenia Trial	5	17/02/2016	23
14/NW/1486/AM01	The Manchester Short Splint in the Rehab of Zone II Flexor Tendon	1	26/01/2016	21
14/NW/1490/AM01	iMAgery focused therapy for PSychosis: iMAPS	1	30/06/2015	13
15/NW/0017/AM01	Phase 1b Study of Dexanabinol in Advanced Cancer	5.0	22/05/2015	20
15/NW/0079/AM01	Human Biomaterials Resource Centre	1	29/11/2015	15
15/NW/0098/AM01	A Phase 2 Study of Azacitidine in Children with MDS or JMML	2	13/05/2015	34
15/NW/0098/AM02	A Phase 2 Study of Azacitidine in Children with MDS or JMML	12	06/08/2015	32
15/NW/0108/AM02	REMINET	2	06/10/2015	25
15/NW/0116/AM01	Complexity and NHS Dementia Inpatient Care. Version 1	1	23/04/2015	18
15/NW/0135/AM01	MYPS I	1	28/07/2015	13
15/NW/0205/AM01	PACE: Palliative Care for Older People	1	22/05/2015	16
15/NW/0205/AM02	PACE: Palliative Care for Older People	2	15/10/2015	9
15/NW/0221/AM01	Profiling memory impairment in people with and without seizures	1	30/06/2015	20
15/NW/0311/AM01	Recovery and engagement with services in first episode psychosis (V.1)	1	12/11/2015	9
15/NW/0311/AM02	Recovery and engagement with services in first episode psychosis (V.1)	2	20/01/2016	15
15/NW/0319/AM01	Efficacy and safety of LX4211 added to insulin in Type 1 Diabetes	1	26/06/2015	22
15/NW/0319/AM02	Efficacy and safety of LX4211 added to insulin in Type 1 Diabetes	2	24/08/2015	18
15/NW/0319/AM03	Efficacy and safety of LX4211 added to insulin in Type 1 Diabetes	3	01/09/2015	13
15/NW/0319/AM04	Efficacy and safety of LX4211 added to insulin in Type 1 Diabetes	4	21/01/2016	21
15/NW/0326/AM01	Attention Training in ADHD	1	29/09/2015	23
15/NW/0326/AM02	Attention Training in ADHD	2	06/12/2015	10
15/NW/0403/AM01	Mothers' experiences of bonding with children in context of street sex work	1	15/07/2015	20
15/NW/0403/AM03	Mothers' experiences of bonding with children in context of street sex work	2	27/10/2015	8
15/NW/0403/AM04	Mothers' experiences of bonding with children in context of street sex work	3	04/11/2015	13

15/NW/0403/AM05	Mothers' experiences of bonding with children in context of street sex work	4	21/01/2016	18
15/NW/0409/AM01	Manchester Allergy, Respiratory & Thoracic Surgery Biobank	1	18/12/2015	24
15/NW/0507/AM01	1311.14 BI655066 v placebo in patients with uncontrolled severe asthma	1	20/08/2015	21
15/NW/0507/AM03	1311.14 BI655066 v placebo in patients with uncontrolled severe asthma	3	01/02/2016	15
15/NW/0535/AM01	SBC-103 Intravenously in SBC-103 Treatment Na ⁺ ve MPS II (NGLU-CL01-T)	1	27/07/2015	22
15/NW/0554/AM01	Oral and Dental Tolerance and Efficacy on Dental Hypersensitivity	1	27/07/2015	22
15/NW/0592/AM02	4150: NNC0114-0006 and liraglutide in newly diagnosed type 1 diabetes	1	21/09/2015	16
15/NW/0609/AM01	Outcomes important to patients with Psoriatic Arthritis	1	30/10/2015	13
15/NW/0626/AM01	Evaluation of Net Clinical Benefit of Sotagliflozin added to Insulin	1	06/10/2015	28
15/NW/0626/AM03	Evaluation of Net Clinical Benefit of Sotagliflozin added to Insulin	2	09/12/2015	9
15/NW/0627/AM01	Phase 1B study of Axitinib plus Crizotinib in advanced solid tumours	1	16/09/2015	12
15/NW/0690/AM01	Immunotherapy with anti-PD in stage III melanoma	1	04/01/2016	15
15/NW/0699/AM02	M13-590 - HCV Genotype 1 - treatment naive (ENDURANCE-1)	Protocol Amendment 1	02/10/2015	13
15/NW/0700/AM02	M13-583 (Endurance-4), ABT-493/ABT-530 in Hep C genotypes 4,5 and 6	1	15/10/2015	12
15/NW/0786/AM01	MLN0002-3026 Vedolizumab vs Adalimumab in Ulcerative Colitis	3	06/10/2015	16
15/NW/0803/AM03	TDF-Containing Regimen to E/C/F/TAF FDC in HIV-1 Adults Aged >60 Years	2	22/07/2015	7
15/NW/0926/AM01	PARTNER	1	08/02/2016	15
15/NW/0936/AM01	SPIRE	1	24/02/2016	9

Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
	United Kingdom Primary Sjogren's Syndrome Registry	3.0	01/10/2015	34

09/H1010/19+5/AM03				
11/NW/0279/AM02	HLA Antibodies and correlation with graft function in Renal Transplant	1	22/04/2015	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
09/H1010/19+5/AM03/1	United Kingdom Primary Sjogren's Syndrome Registry	4.0	09/12/2015	13
11/NW/0279/AM02/1	HLA Antibodies and correlation with graft function in Renal Transplant	Modified SubAm 1	17/06/2015	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
15/NW/0449	The UK National Registry of Chronic Myeloid Leukaemia (CML)	61

Proportionate review applications for ethical review over 14 day timeline

REC Reference	Title	Number of Days on Clock
16/NW/0189	Hp and IL-1 mediated inflammation following intracranial bleeding	16 *

**Please note, that this study was part of the Proportionate Review Pilot (please refer to explanation at table 8)*

SSAs (non Phase 1) over 25 day timeline

REC Reference	Title	Number of Days on Clock
16/NW/0171	1311.14 BI655066 v placebo in patients with uncontrolled severe asthma	27

SSAs (Phase 1) over 14 day timeline

REC Reference	Title	Number of Days on Clock
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Substantial Amendments over 35 day timeline

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

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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