

North West - Haydock Research Ethics Committee

Annual Report

01 April 2017 - 31 March 2018



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:	Establishing Research Databases Establishing Research Tissue Banks Phase 1 Studies in Patients Research Involving Adults Lacking Capacity
Chair:	Dr Tim S Sprosen
Vice-Chair:	Dr Ben Johnson
Alternate Vice-Chair:	Dr Valerie E Siddall
REC Manager:	Ms Rachel Katzenellenbogen
REC Assistant:	Ms Laila Sarwar
Committee Address:	3rd Floor - Barlow House 4 Minshull Street Manchester M1 3DZ
Telephone:	0207 104 8012
Email:	nrescommittee.northwest-haydock@nhs.net

Chair's overview of the past year:

The annual report shows the diversity and volume of work undertaken by the REC over the previous year. My thanks go out to both the volunteers who serve on the committee and the team led by Rachel who provide the link between the committee and the research community.

This year has seen a diverse range of studies coming forward for ethical review. Ranging from large CTIMPs and cohorts, biobanks, research databases through to small student led research the work of the committee is always challenging intellectually combined with the need to be efficient because of the time demands and deadlines for new approvals. Outside of the monthly meetings, Proportionate Review has placed new demands on the system, but so far it appears to be working for the research community for those studies that don't pose major ethical issues. Another area of development has been the pilot work for reviewing CTIMPs as part of the new EU Clinical Trials Regulation. The pilot has shown how useful for ethical review the IRAS form is and without it in the pilot committees initially struggled to get to grips with the new approach to review. The pilot has been invaluable to get used to this new way of working and over the next few months it will transition into a live pilot phase. The committee benefits from being part of these new innovations.

Finally, attracting new members, particularly clinicians, remains a challenge. As an active researcher, membership of a REC provides the perfect learning environment to better understand how to be a better researcher and I hope that more institutions see the benefits of having staff who are also REC members.

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	
Mr Stephen Edgar	Designer	Lay Plus	13/11/2009	
Dr Michael U Eshiett	Consultant Physician in Neurological Rehabilitation	Expert	23/09/2009	
Mrs Lesley France	Retired Statistician	Lay	16/10/2017	
Mr Simon Hill	Pharmacist	Expert	01/06/2015	
Dr Ben Johnson	Vice-Chair - 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	31/07/2017
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	11/07/2017

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

Name	Profession	Status	Meeting date attended
Dr Peter Owen	Retired Mathematics Lecturer	Lay Plus	10/10/2017

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

Name	Declaration of Interest	Date
Mrs Moyra Ann Baldwin	None	14/11/2017
Mr Stephen Edgar	Member of NIHR I4I product awards panel Member of EME board	13/03/2018
Mrs Lesley France	AstraZeneca Shareholder, Honorary Member: Statisticians in Pharmaceutical Industry. Chartered Statistician: Royal Statistical Society. AstraZeneca Pensioner.	14/11/2017
Mr Simon Hill	None	14/11/2017
Dr Ben Johnson	None	14/11/2017
Dr Ezzat Kozman	None	14/11/2017
Mr Charles Otim	Employee of Alder Hey Children's Hospital R&D Department	12/12/2017
Dr David Pilling	None	14/11/2017
Miss Anna Sekula	Position with GMMH R&I office	14/11/2017
Dr Valerie E Siddall	None	14/11/2017
Dr Tim S Sprosen	Employed by University of Oxford, Nuffield Dept of Population Health. Chief Scientific Officer UK Biobank.	14/11/2017

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

Month	Date	Number of Members Present at Meeting
April	11/04/2017	8
May	09/05/2017	8
June	13/06/2017	7
July	11/07/2017	9
October	10/10/2017	7
November	14/11/2017	11
December	12/12/2017	8
February	13/02/2018	8
March	13/03/2018	7

9 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
April	04/04/2017	3
May	02/05/2017	3
June	06/06/2017	3
July	04/07/2017	3
August	01/08/2017	3
September	05/09/2017	3
September	20/09/2017	3
October	03/10/2017	3
November	07/11/2017	3
December	05/12/2017	3
February	06/02/2018	3
March	06/03/2018	3

12 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	04/04/2017	2
April	18/04/2017	2
May	02/05/2017	2
May	16/05/2017	2
May	30/05/2017	2
June	13/06/2017	2
June	27/06/2017	2
July	11/07/2017	2
July	25/07/2017	2
August	07/08/2017	2

August	08/08/2017	2
August	22/08/2017	2
September	05/09/2017	2
September	14/09/2017	2
September	19/09/2017	2
October	03/10/2017	2
October	17/10/2017	2
October	26/10/2017	2
October	31/10/2017	2
November	14/11/2017	2
November	28/11/2017	2
December	12/12/2017	2
January	02/01/2018	2
January	16/01/2018	2
January	30/01/2018	2
February	13/02/2018	2
February	27/02/2018	2
March	13/03/2018	2
March	27/03/2018	2

29 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
Mrs Moyra Ann Baldwin	7
Mr Stephen Edgar	7
Mrs Lesley France	3
Mr Simon Hill	6
Dr Ben Johnson	6
Dr Ezzat Kozman	9
Dr Lorraine Lighton	1
Mr Charles Otim	9
Dr David Pilling	5
Miss Anna Sekula	6
Dr Valerie E Siddall	6
Dr Tim S Sprosen	5
Dr Zhe Wang	2

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

Name	Number of Meetings Attended
Mrs Moyra Ann Baldwin	3
Mr Stephen Edgar	4
Dr Michael U Eshiett	2
Mr Simon Hill	2
Dr Ben Johnson	5
Dr Ezzat Kozman	1
Mr Charles Otim	3
Dr David Pilling	3
Dr Valerie E Siddall	3
Dr Tim S Sprosen	10

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

Name	Number of Meetings Attended
Mrs Moyra Ann Baldwin	1
Mr Stephen Edgar	5
Mr Simon Hill	2
Dr Ben Johnson	7
Dr Ezzat Kozman	3
Mr Charles Otim	4
Dr David Pilling	6

Miss Anna Sekula	2
Dr Valerie E Siddall	9
Dr Tim S Sprosen	18
Dr Zhe Wang	1

Training 01 April 2017 - 31 March 2018

Name of Member	Date	Event(s) attended
Mrs Moyra Ann Baldwin	11/07/2017	ShED 23 report
Mr Stephen Edgar	11/07/2017	ShED 23 report
Mrs Lesley France	01/03/2018	North West Member Training Day
Dr Ben Johnson	23/11/2017	Ethical Issues in Phase One Research: An Advanced Training Course
Dr Ben Johnson	24/11/2017	HRA National Chairs' Day and Policy Event
Dr Ezzat Kozman	11/07/2017	ShED 23 report
Mr Charles Otim	11/07/2017	ShED 23 report
Dr David Pilling	11/07/2017	ShED 23 report
Miss Anna Sekula	11/07/2017	ShED 23 report
Miss Anna Sekula	12/11/2017	Equality and Diversity
Dr Valerie E Siddall	11/07/2017	ShED 23 report
Dr Valerie E Siddall	16/01/2018	Training for new REC Chairs
Dr Valerie E Siddall	31/01/2018	Complex Cases
Dr Tim S Sprosen	24/11/2017	HRA National Chairs' Day and Policy Event
Dr Zhe Wang	11/07/2017	ShED 23 report

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	10	23.81
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	6	14.29
Research Database (including renewals)	6	14.29
Others	20	47.62
Total Applications Reviewed	42	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	2
Number of student applications reviewed	7
Number of paediatric applications reviewed	6
Number of device applications reviewed	5
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	6
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	3	7.14
Favourable Opinion with Additional Conditions	13	30.95
Unfavourable Opinion	2	4.76
Provisional Opinion	23	54.76
Provisional Opinion Pending Consultation with Referee	1	2.38
Total	42	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	21	50.00
Further Information Favourable Opinion with Additional Conditions	1	2.38
Further Information Unfavourable Opinion	1	2.38
Favourable Opinion with Standard Conditions	3	7.14
Favourable Opinion with Additional Conditions	13	30.95
Unfavourable Opinion	2	4.76
Provisional Opinion	1	2.38
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	42	100

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

Total Applications Reviewed	25
------------------------------------	-----------

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	3
Number of student applications reviewed	11
Number of paediatric applications reviewed	5
Number of device applications reviewed	0
Number of qualitative applications reviewed	4

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	17	68.00
Favourable Opinion with Additional Conditions	6	24.00
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	2	8.00
Unfavourable Opinion	0	0.00
Total	25	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	4.67
Number of completed applications for full ethical review	42
Number of completed applications for full ethical review over 60 days	1
Number of completed applications over 60 days as a % of total	2.38%
Number of days taken to final decision – average (mean)	31
Number of completed proportionate review applications for ethical review	25
Number of completed proportionate review applications for ethical review over 21 days	0
Number of completed proportionate review applications over 21 days as a % of total	0.00%
Number of SSAs (non-Phase 1) reviewed	15
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	6.67%
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	134
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	0
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	122
Number of substantial amendments received for information	6
Number of substantial amendments received for new sites/PIs	50
Number of annual progress reports received	110
Number of safety reports received	60
Number of Serious Adverse Events received	0
Number of final reports received	23

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/0185	BSET GLOBALSTAR v2.0	44
17/NW/0208	Tommys Net Database	27
17/NW/0256	Improving Methods of Detecting Tooth Decay	38
17/NW/0275	A dose-ranging trial in patients with post-herpetic neuralgia	28
17/NW/0330	ClarIDHy	37
17/NW/0335	STOP TOOLKIT	24
17/NW/0355	M16-135, Glecaprevir/Pibrentasvir in HCV GTs 1,2,4,5,6 with Cirrhosis	27
17/NW/0403	Surgeon versus anaesthetist inserted rectus sheath catheters: an RCT	34
17/NW/0405	Shared decision making for people living with dementia in care homes	32
17/NW/0507	INTREPID Study	61
17/NW/0572	Free-Cog	35
17/NW/0581	SC IL-1Ra in SAH - phase III trial	34
17/NW/0645	Safety and Effectiveness of Outpatient Based Acute Heart Failure Care	41
17/NW/0651	Cyanoacrylate occlusion of lower limb veins in venous leg ulcer	49
17/NW/0699	Using telemetry to monitor the fetal heart in labour	26
17/NW/0703	Characterisation of subretinal hyper-reflective material in nAMD	49
18/NW/0080	SCY-078-031	48
18/NW/0083	Little Reed Cannula Study	29
18/NW/0104	Recommendations on the diagnostic process from those with EUPD	42
18/NW/0105	LOCALIZE	32
18/NW/0149	Patients with T2DM Inadequately Controlled with Diet and Exercise	40

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
17/NW/0261	Newcastle Epilepsy Surgery Database	35

Further Information Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock
17/NW/0197	Nottingham Chondrocalcinosis Collection	44

Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
17/NW/0207	AstraZeneca Alderley Park Biobank Renewal	24
17/NW/0232	CIPCA database v1.0	24
17/NW/0377	Outcomes following treatment for oesophago-gastric cancer	25

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
17/NW/0311	Digital IAPT (Berkshire)	19
17/NW/0312	CaboGIST (EORTC 1317)	19
17/NW/0380	Behaviour and Expression of Pain in Autism Spectrum Disorders 1.1	24
17/NW/0427	Stroke rehabilitation and dementia	24
17/NW/0590	LOWER: Lomitapide Observational Worldwide Evaluation Registry (v6.0)	21
17/NW/0648	Well-being after stroke: how General Practice can help	23
17/NW/0698	IMMU-132 in Breast Cancer	23
17/NW/0702	The SENSE-Cog Randomised Controlled Trial: version 1	23
17/NW/0704	The Role of neuroinflammation in Gaucher Disease	23
18/NW/0075	Study of the safety & effectiveness of JNJ-56136379 in hepatitis B	21
18/NW/0096	Early Pregnancy Tissue Collection (renewal of 13/NW/0205)	27
18/NW/0110	NEO21-RS Study	27
18/NW/0136	Liverpool Eye Donation Centre and Liverpool Research Eye Bank	34

Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock
17/NW/0225	Research Tissue Bank Application	23
17/NW/0654	Effectiveness of Early Intervention service interventions	24

Provisional Opinion		
REC Reference	Title	Number of Days on Clock
18/NW/0120	Outcomes after investigation for benign upper GI conditions	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
17/NW/0528	An exploration of knowledge and skills of Youth Support Coordinators	13
17/NW/0557	Service Users Experience of a Facial Pain Management Programme	17

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
17/NW/0210	Biphasic CPAP vs N-CPAP on gas exchange in preterm infants	16
17/NW/0212	In vivo imaging of the human zonular apparatus after vitrectomy	21
17/NW/0274	Molecular and Genetic Profiling of Serrated Colorectal Tumours	9
17/NW/0276	POSCAN (GP-patient communication about POSSible CANcer) Study 1	9
17/NW/0278	DCBNORWICH	10
17/NW/0416	Secondary analysis of the DOSS study data: reducing noise	14

17/NW/0417	The HepCare Study	13
17/NW/0469	Towards UK poSt Arthroplasty Follow-up rEcommendations• UK SAFE (WP2b)	8
17/NW/0470	SNACC Survey (symptoms and nutrition after critical care)	9
17/NW/0526	A prognostic model for abdominal wall reconstruction	14
17/NW/0577	The prevalence of Pollen Food Syndrome in patients with IBS	15
17/NW/0642	Cognition and learning in ADHD	19
17/NW/0643	Service users and students' lived experiences of their time together	15
17/NW/0691	Investigating speed-accuracy tradeoff in children with dysgraphia	15
18/NW/0163	Assessing The Impact Of A Carer Support Group	17
18/NW/0164	Expectant fathers' perspectives on place of birth decisions	14
18/NW/0165	Gait Analysis after Lower Limb Functional Reconstruction	5

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
17/NW/0213	Patient outcomes following Spinal Cord Stimulator procedure	21
17/NW/0363	Rheumatology team care: A patient survey	7
17/NW/0475	The First Consultation for Low Mood in General Practice (Revised)	20
17/NW/0644	Validation of a dietary questionnaire	15
17/NW/0692	Superior markers of kidney dysfunction at liver transplant assessment	17
18/NW/0095	iMAP3	17

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
---------------	-------	-------------------------

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/AM30	Prospective observational study of the long-term hazards of anti-TNF therapy in rheumatoid arthritis	25	17/07/2017	21
01/8/090/AM14	Trust-based survey on inpatients in acute NHS hospitals	May 2017	01/05/2017	9
02/8/070/AM65	IBIS-II (Prevention)	52	13/04/2017	8
02/8/070/AM67	IBIS-II (Prevention)	53	31/07/2017	26
02/8/071/AM58	IBIS-II (DCIS)	52	13/04/2017	8
02/8/104/AM20	A prospective study of childhood onset inflammatory arthritis	11	14/11/2017	20
03/8/087/AM14	ASCEND: A randomised 2x2 factorial study of aspirin versus placebo, and	14	12/12/2010	8
07/MRE08/1/AM09	Survey of women's experience of NHS maternity services	7	12/02/2018	11
07/MRE08/9/AM22	BAD Biological Interventions Register	10	01/08/2017	19
08/H1010/70/AM15	COMPARing the efficacy sAfety & toleRability of paZopanib vs sunitinib	12	14/03/2016	24
08/H1010/90/AM17	COSMOS Mobile Phone and Health Study (version 1)	17	08/08/2017	32
09/H1010/59/AM13	Icatibant Outcome Survey (IOS). (Firazyr® Patient Registry)	7	21/08/2017	21
11/NW/0298/AM38	Phase III GA101 or rituximab plus chemo in 1st line indolent NHL	19	19/09/2017	15
11/NW/0548/AM37	RIAltO version 3	26	13/06/2017	16
12/NW/0237/AM53	AMG 785/Alendronate in Postmenopausal women with Osteoporosis	44	05/06/2017	9
12/NW/0427/AM21	MEK116513 Dabrafenib plus trametinib vs vemurafinib in melanoma	6	15/07/2016	8
12/NW/0427/AM26	MEK116513 Dabrafenib plus trametinib vs vemurafinib in melanoma	7	07/11/2017	10
12/NW/0641/AM26	GO27826 Phase III Adjuvant Therapy in BRAF Mutant Melanoma	15	14/03/2017	13
12/NW/0641/AM27	GO27826 Phase III Adjuvant Therapy in BRAF Mutant Melanoma	10	30/11/2017	8
12/NW/0641/AM28	GO27826 Phase III Adjuvant Therapy in BRAF Mutant Melanoma	IB v15	09/01/2018	9
13/NW/0134/AM12	NEO-BLADE Version: 2	10	20/03/2017	15

13/NW/0134/AM14	NEO-BLADE Version: 2	12	18/04/2017	10
13/NW/0560/AM16	H8A-MC-LZAX: Progression of Mild Alzheimer's Disease	8	21/03/2017	20
13/NW/0563/AM01	Exercise Testing	1	28/06/2017	7
13/NW/0697/AM12	PiSARRO	12	19/09/2017	13
13/NW/0702/AM08	ABC06: ASC alone or with mFOLFOX for advanced biliary tract cancer	7	26/06/2017	8
13/NW/0718/AM11	Targeted Ultrasound in Rheumatoid Arthritis (TURA)	7	05/05/2017	8
13/NW/0842/AM15	FAKTION	12	12/03/2018	7
14/NW/0036/AM11	ESPAC-5F: European Study Group for Pancreatic Cancer - Trial 5F	9	02/05/2017	21
14/NW/0182/AM06	Identification and remediation of language deficits in TBI	8	30/05/2017	20
14/NW/0185/AM03	Manchester Skin Health Biobank Renewal	4	18/07/2017	22
14/NW/0347/AM15	SCAMP - Study of Cognition, Adolescents and Mobile Phones	13	12/12/2017	22
14/NW/0347/AM16	SCAMP - Study of Cognition, Adolescents and Mobile Phones	14	26/02/2018	7
14/NW/0348/AM09	Safety of SBC-103 in MPS IIIB patients	Study halt	09/08/2017	15
14/NW/1014/AM02	UK CLL Trials Biobank	2	08/02/2017	18
14/NW/1076/AM07	RESCUE-ASDH trial. Version 1.0	2	26/06/2017	8
14/NW/1238/AM17	AZD6738 in combination with other agents in Solid Malignancies	7	22/06/2016	9
14/NW/1238/AM19	AZD6738 in combination with other agents in Solid Malignancies	11	06/09/2017	14
14/NW/1238/AM21	AZD6738 in combination with other agents in Solid Malignancies	13	17/01/2018	7
14/NW/1354/AM08	Romiplostim in Thrombocytopenic Paediatric Patients with ITP	5	28/04/2017	21
14/NW/1484/AM02	The Wirral Child Health and Development Study 7-9 years - Version 1	2	13/03/2017	20
14/NW/1484/AM03	The Wirral Child Health and Development Study 7-9 years - Version 1	5	23/05/2017	14
15/NW/0171/AM12	Dex - CSDH Trial	11	12/05/2017	25
15/NW/0319/AM09	Efficacy and safety of LX4211 added to insulin in Type 1 Diabetes	7	03/04/2017	11
15/NW/0376/AM04	ReBeL Phase II (A HOVON 110FL/GLSG/NCRI study)	4	26/07/2017	21
15/NW/0409/AM03	Manchester Allergy, Respiratory & Thoracic Surgery Biobank	3	06/12/2017	9
15/NW/0507/AM12	1311.14 BI655066 v placebo in patients with uncontrolled severe asthma	8	20/03/2017	21
15/NW/0507/AM13	1311.14 BI655066 v placebo in patients with uncontrolled	9	22/08/2017	27

	severe asthma			
15/NW/0535/AM05	SBC-103 Intravenously in SBC-103 Treatment Na ⁺ ve MPS II (NGLU-CL01-T)	Halt of trial dosing	09/08/2017	15
15/NW/0592/AM17	4150: NNC0114-0006 and liraglutide in newly diagnosed type 1 diabetes	5	02/05/2017	9
15/NW/0592/AM19	4150: NNC0114-0006 and liraglutide in newly diagnosed type 1 diabetes	7	22/12/2017	12
15/NW/0614/AM05	17845 Phase 1 dose-escalation study of BAY 1862864 Injection	5	20/06/2017	13
15/NW/0614/AM07	17845 Phase 1 dose-escalation study of BAY 1862864 Injection	7	21/11/2017	21
15/NW/0614/AM08	17845 Phase 1 dose-escalation study of BAY 1862864 Injection	8	07/02/2018	8
15/NW/0626/AM08	Evaluation of Net Clinical Benefit of Sotagliflozin added to Insulin	5	03/04/2017	11
15/NW/0627/AM05	Phase 1B study of Axitinib plus Crizotinib in advanced solid tumours	4	20/09/2017	17
15/NW/0627/AM06	Phase 1B study of Axitinib plus Crizotinib in advanced solid tumours	5	12/02/2018	11
15/NW/0677/AM03	ICH-IMAGE	2	09/10/2017	19
15/NW/0690/AM08	Immunotherapy with anti-PD in stage III melanoma	6	24/07/2017	8
15/NW/0690/AM11	Immunotherapy with anti-PD in stage III melanoma	8	11/10/2017	8
15/NW/0690/AM12	Immunotherapy with anti-PD in stage III melanoma	9	19/12/2017	17
15/NW/0786/AM06	MLN0002-3026 Vedolizumab vs Adalimumab in Ulcerative Colitis	5	29/03/2017	27
15/NW/0803/AM09	TDF-Containing Regimen to E/C/F/TAF FDC in HIV-1 Adults Aged ≥60 Years	4	28/09/2017	20
15/NW/0926/AM08	PARTNER	9	06/07/2017	9
15/NW/0926/AM09	PARTNER	10	24/08/2017	30
16/NW/0096/AM03	Antenatal Attachment, Mindfulness and Self-compassion Version 1	3	01/06/2017	16
16/NW/0134/AM09	Zoster-056 (Cross vaccination study)	7	16/08/2017	29
16/NW/0134/AM12	Zoster-056 (Cross vaccination study)	8	19/10/2017	12
16/NW/0146/AM08	201190 (Zoster-049)	6	13/09/2017	13
16/NW/0146/AM11	201190 (Zoster-049)	7	02/11/2017	14
16/NW/0146/AM14	201190 (Zoster-049)	8	15/01/2018	16

16/NW/0253/AM10	M13-542 Phase 3 ABT-494 study in Mod/Severe RA with Bio-IR	9	09/08/2017	13
16/NW/0253/AM11	M13-542 Phase 3 ABT-494 study in Mod/Severe RA with Bio-IR	10	15/08/2017	21
16/NW/0253/AM12	M13-542 Phase 3 ABT-494 study in Mod/Severe RA with Bio-IR	11	23/11/2017	18
16/NW/0272/AM06	Phase 1 study of ADCT-301 in Lymphoma patients	4	15/05/2017	16
16/NW/0272/AM08	Phase 1 study of ADCT-301 in Lymphoma patients	6	10/08/2017	24
16/NW/0272/AM09	Phase 1 study of ADCT-301 in Lymphoma patients	7	10/11/2017	24
16/NW/0272/AM10	Phase 1 study of ADCT-301 in Lymphoma patients	8	01/02/2018	14
16/NW/0274/AM05	UK Biobank: a large scale prospective epidemiological resource	5	13/07/2017	29
16/NW/0274/AM06	UK Biobank: a large scale prospective epidemiological resource	6	01/01/2018	13
16/NW/0274/AM07	UK Biobank: a large scale prospective epidemiological resource	7	01/03/2018	21
16/NW/0379/AM03	LY2801653 and LY3009806 - Advanced or Metastatic Biliary Tract Cancer	3	24/04/2017	19
16/NW/0380/AM01	Ocular Oncology Biobank	1	18/07/2017	8
16/NW/0388/AM01	What matters to frail older people (and their carers) in primary care	1	18/04/2017	20
16/NW/0389/AM06	Effective Home Support Dementia Care: DESCANT v.1	4	19/09/2017	15
16/NW/0455/AM01	Mental health student nurse communication (V1)	1	06/03/2017	15
16/NW/0455/AM02	Mental health student nurse communication (V1)	2	03/08/2017	20
16/NW/0536/AM01	Double Icodextrin Dose in PD patients the Dido study	1	01/09/2017	26
16/NW/0557/AM03	CHronic HypERTension and L-citRulline studY (CHERRY)	3	01/06/2017	13
16/NW/0557/AM05	CHronic HypERTension and L-citRulline studY (CHERRY)	4	23/06/2017	10
16/NW/0557/AM06	CHronic HypERTension and L-citRulline studY (CHERRY)	5.0	23/10/2017	10
16/NW/0558/AM06	Treatment of Endogenous Cushing's Syndrome Version 4.0	2	06/12/2017	12
16/NW/0558/AM07	Treatment of Endogenous Cushing's Syndrome Version 4.0	2	21/03/2018	7
16/NW/0618/AM02	The role of the professions in self-referral physiotherapy	2	08/06/2017	15
16/NW/0671/AM04	AIPAC	04	04/07/2017	8
16/NW/0671/AM06	AIPAC	05	15/03/2018	13
16/NW/0674/AM02	Effectiveness of the Incredible Years parent training programme (V1)	1	06/06/2017	14
16/NW/0674/AM03	Effectiveness of the Incredible Years parent training	2	12/01/2018	19

	programme (V1)			
16/NW/0675/AM01	Investigating the Locus Coeruleus in Alzheimer's Disease using MRI	1	06/06/2017	26
16/NW/0737/AM02	ALXN1210 vs eculizumab study in paroxysmal nocturnal haemoglobinuria	2.0	18/04/2017	27
16/NW/0737/AM04	ALXN1210 vs eculizumab study in paroxysmal nocturnal haemoglobinuria	3	12/12/2017	24
16/NW/0803/AM02	(HOMEWARD (Phase 2 - Case Studies)	1	20/03/2017	20
16/NW/0806/AM01	The PBRU Liverpool Pancreatic Diseases Control Biobank	Amended PIS and consent forms	07/06/2016	22
16/NW/0807/AM03	EMERALD	3	28/09/2017	21
16/NW/0807/AM04	EMERALD	4	08/02/2018	18
16/NW/0877/AM01	A Safety and Tolerability Study of LY3303560 in Alzheimer's Disease	1	31/03/2017	25
16/NW/0877/AM03	A Safety and Tolerability Study of LY3303560 in Alzheimer's Disease	2	07/06/2017	23
16/NW/0877/AM04	A Safety and Tolerability Study of LY3303560 in Alzheimer's Disease	3	19/07/2017	7
16/NW/0877/AM07	A Safety and Tolerability Study of LY3303560 in Alzheimer's Disease	5	26/02/2018	7
16/NW/0880/AM03	Evaluation of a childhood obesity intervention in Manchester, Version 1	1	23/05/2017	16
17/NW/0060/AM01	UK Computer Aided Theragnostics (ukCAT)	01	15/05/2017	9
17/NW/0105/AM01	PREM-SBC	1	25/10/2017	13
17/NW/0164/AM02	EUROSTAD	1	13/07/2017	21
17/NW/0180/AM02	INCYTE, Efficacy and Safety of INCB054828 in Cholangiocarcinoma	2	19/06/2017	11
17/NW/0180/AM03	INCYTE, Efficacy and Safety of INCB054828 in Cholangiocarcinoma	3	13/10/2017	19
17/NW/0207/AM01	AstraZeneca Alderley Park Biobank Renewal	1	05/10/2017	14
17/NW/0275/AM02	A dose-ranging trial in patients with post-herpetic neuralgia	2	26/06/2017	15
17/NW/0275/AM03	A dose-ranging trial in patients with post-herpetic neuralgia	3	07/11/2017	10
17/NW/0275/AM04	A dose-ranging trial in patients with post-herpetic neuralgia	4	12/12/2017	30
17/NW/0278/AM01	DCBNORWICH	1	28/11/2017	11
17/NW/0311/AM01	Digital IAPT (Berkshire)	1	06/06/2017	9
17/NW/0311/AM02	Digital IAPT (Berkshire)	2	24/08/2017	16

17/NW/0330/AM01	ClarIDHy	1	01/09/2017	14
17/NW/0335/AM01	STOP TOOLKIT	1	19/12/2017	14
17/NW/0355/AM02	M16-135, Glecaprevir/Pibrentasvir in HCV GTs 1,2,4,5,6 with Cirrhosis	2	06/09/2017	20
17/NW/0475/AM01	The First Consultation for Low Mood in General Practice (Revised)	1	06/10/2017	13
17/NW/0507/AM01	INTREPID Study	1	05/01/2018	9
17/NW/0577/AM01	The prevalence of Pollen Food Syndrome in patients with IBS	1.8	13/11/2017	30
17/NW/0581/AM01	SC IL-1Ra in SAH - phase III trial	1	16/02/2018	10
17/NW/0642/AM01	Cognition and learning in ADHD	1	13/02/2018	17
17/NW/0692/AM01	Superior markers of kidney dysfunction at liver transplant assessment	1	19/12/2017	22
99/8/084/AM24	National Repository Study	12	21/03/2017	23
99/8/084/AM25	National Repository Study	8c	10/05/2017	13
99/8/084/AM26	National Repository Study	3F	24/10/2017	34

Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
-------------------------	-------	---------	------	-------------------------

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
-------------------------	-------	---------	------	-------------------------

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
17/NW/0507	INTREPID Study	61

Proportionate review applications for ethical review over 21 day timeline

REC Reference	Title	Number of Days on Clock
---------------	-------	-------------------------

SSAs (non Phase 1) over 25 day timeline

REC Reference	Title	Number of Days on Clock
18/NW/0235	A Modular Phase I, Open-Label,	44

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
-------------------------	-------	---------	------	-------------------------