Health Research Authority

Research Ethics Service

North East - York Research Ethics Committee

Annual Report

01 April 2017 - 31 March 2018

Part 1 – Committee Membership and Training

Name of REC:	North East - York Research Ethics Committee
Type of REC:	Recognised to review CTIMPS in healthy volunteers - type i, Recognised to review CTIMPS in patients - type iii
Type of Flag:	Phase I in CTIMPs involving Healthy Volunteers, Type III CTIMPs, Prison Research, Paediatric Research, Gene Therapy Advisory Committee (Low Risk), Medical Device Studies
Chair:	Mr Chris Turnock
Vice-Chair:	Mr Steve Chandler
Alternate Vice-Chair:	Mrs Janet Hattle
REC Manager:	Miss Kerry Dunbar (from 16 October 2017 – 25 March 2018) Mrs Helen Wilson (from 1 April 2017 – 15 October 2017, 26 March to date)
REC Assistant:	Kerry Dunbar (until 15 October 2017)
Committee Address:	NHSBT Newcastle Blood Donor Centre Holland Drive Newcastle upon Tyne NE2 4NQ
Telephone:	0207 1048091
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Chair's overview of the past year:

This is my third year as chair of the committee, in which membership has been relatively stable with two resignations due to changed work commitments, Chris Colbourn and Lorraine Wright, and one new member joining the committee, Clive Wilson. The contribution made by Chris and Lorraine to the committee's business has been invaluable and I would like to thank them for their input as committee members.

The work of the committee remains busy, predominately consisting of Phase 1 studies, normal range of CTIMPS and prison based studies. Whilst administrative support for the committee has changed during the year, the continued efficiency of administrative support for full committee meetings and the various sub-committee meetings has enabled members to perform their duties effectively.

Committee members have been able to not only undertake normal range of HRA training activities, but also visit an organisation frequently submitting Phase 1 first in human studies to the committee, Covance. These visits have enabled members to gain better insight into Covance's operational functionality to help reassure members about the effectiveness of medical support for study participants provided by Covance. However, the geographical location of any prison study related training has prevented members attending any such events and it would be helpful any relevant events were held in a more central location.

The committee has begun participation in the pilot to work jointly with the MHRA to review CTIMPs. However, the committee's involvement is at an early stage and thus makes it too early to comment on the pilot apart from welcoming the initiative.

North East - York Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Dr David Cairns	Principal Statistician	Expert	08/10/2013	10/04/2017
Ms Linda Chadd	Library assistant and archivist	Lay Plus	01/10/2013	
Mr Steve Chandler	Retired Consultant Medical Physicist	Expert	01/04/2013	
Professor Chris Colbourn	Clinical Psychology	Expert	01/07/2015	15/08/2017
Dr Mary Connor	Coaching & Mentoring Consultant	Lay Plus	05/10/2010	
Mr Michael Davidson	Retired Personnel Manager	Lay Plus	13/03/2017	
Mrs Janet Hattle	Lay Member	Lay	01/05/2008	
Dr James Hobkirk	Lecturer in Physiology & Scientific Director of Cardio-thoracic Surgery	Expert	08/09/2016	
Dr Jocelyn Hudson	General Practitioner	Expert	21/06/2016	
Mrs Fan Hutchison	Principal Teacher	Lay	01/01/2013	
Mr Anthony Lockett	Medical Director	Expert	01/05/2016	
Mrs Biserka Ross	Retired Research Advisor	Lay	08/09/2016	
Dr John Toy	Retired Honorary Professor of Cancer Medicine	Expert	01/07/2016	
Mr Chris Turnock	Head of Technology Enhanced Learning	Expert	01/09/2014	
Mr John Warden	Clinical Trials Data and Information Systems Manager	Lay	15/06/2016	
Mr Clive Wilson	Associate Principal (retired)	Lay Plus	01/06/2017	
Ms Lorraine Wright	Senior Research Nurse	Expert	01/04/2010	22/09/2017

North East - York Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended
Dr Rhona Bratt	Retired Multimedia Project Manager	Lay	07/07/2017

North East - York Research Ethics Committee: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Ms Linda Chadd	None.	07/03/2018
Mr Steve Chandler	None.	01/03/2018
Dr Mary Connor	None.	31/03/2018
Mr Michael Davidson	None.	31/03/2018
Mrs Janet Hattle	None.	31/03/2018
Dr James Hobkirk	None.	27/02/2018
Dr Jocelyn Hudson	None.	27/02/2018
Mrs Fan Hutchison	None.	30/01/2018
Mr Anthony Lockett	Director MEDQP - research into medical imaging in pulmonary diseases, Director Pharmagenix Ltd - research into cancer support services and products, Director AniPoc Ltd - research into diabetes testing devices, Advsior to Immunopharma in immunology research.MEDQP ownership with 3 individuals. Shareholding in all the above companies. Visiting lecturer in pharmaceutical medicine and Kings College London. Member of the Ethics and Professional Practice Committee of the Faculty of Pharmaceutical Medicine.	11/09/2017
Mrs Biserka Ross	Occasionally a peer reviewer of manuscripts submitted to scientific journals. Members of Editorial Advisory Board of Industrial Hygiene and Toxicology.	19/03/2018
Dr John Toy	None.	01/03/2018
Mr Chris Turnock	Member of University of Hull, School of Education and Culture Research Committee.	27/02/2018
Mr John Warden	None.	27/02/2018
Mr Clive Wilson	Patient Participation Group, surgery, N Lincs	14/03/2018

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

Month	Date	Number of Members Present at Meeting
April	07/04/2017	10
May	05/05/2017	13
June	02/06/2017	14
July	07/07/2017	10
August	04/08/2017	11
October	06/10/2017	11
November	03/11/2017	12
December	01/12/2017	10
January	05/01/2018	12
February	02/02/2018	14

10 full committee meetings were held during the reporting period.

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

Month	Date	Number of Members Present at Meeting
April	25/04/2017	3
May	15/05/2017	3
June	16/06/2017	3
July	20/07/2017	3
August	14/08/2017	3
September	15/09/2017	3
October	18/10/2017	3
November	17/11/2017	3
February	08/02/2018	3
March	16/03/2018	3

10 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	13/04/2017	2
April	27/04/2017	2
May	11/05/2017	2
May	19/05/2017	2
June	08/06/2017	2
June	21/06/2017	2
July	03/07/2017	2
July	19/07/2017	2
August	01/08/2017	2
August	11/08/2017	2
August	23/08/2017	2

September	13/09/2017	2
September	27/09/2017	2
October	11/10/2017	2
October	20/10/2017	2
November	08/11/2017	2
November	08/11/2017	2
November	22/11/2017	2
December	06/12/2017	2
December	18/12/2017	2
January	12/01/2018	2
January	24/01/2018	2
February	06/02/2018	3
February	07/02/2018	2
February	16/02/2018	2
March	07/03/2018	2
March	27/03/2018	2

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

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

None.

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

Name	Number of Meetings Attended
Dr David Cairns	1
Ms Linda Chadd	5
Mr Steve Chandler	9
Professor Chris Colbourn	4
Dr Mary Connor	8
Mr Michael Davidson	8
Mrs Janet Hattle	8
Dr James Hobkirk	7
Dr Jocelyn Hudson	8
Mrs Fan Hutchison	7
Mr Anthony Lockett	7
Mrs Biserka Ross	10
Dr John Toy	9
Mr Chris Turnock	9
Mr John Warden	7
Mr Clive Wilson	7
Ms Lorraine Wright	2

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

Name	Number of Meetings Attended
Ms Linda Chadd	1
Mr Steve Chandler	4
Professor Chris Colbourn	1
Dr Mary Connor	3
Mrs Janet Hattle	2
Dr James Hobkirk	2
Dr Jocelyn Hudson	2
Mrs Fan Hutchison	2
Mr Anthony Lockett	2
Mrs Biserka Ross	2
Dr John Toy	2
Mr Chris Turnock	4
Mr John Warden	2
Ms Lorraine Wright	1

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

Name	Number of Meetings Attended
Mr Steve Chandler	25
Mrs Fan Hutchison	1
Mr Anthony Lockett	2
Mr Chris Turnock	27

Training 01 April 2017 - 31 March 2018

Name of Member	Date	Event(s) attended
Ms Linda Chadd	29/11/2017	Members Regional Training Day
Ms Linda Chadd	29/11/2017	Regional Members Training Day
Ms Linda Chadd	09/02/2018	Complex Cases
Mr Steve Chandler	14/09/2017	Handling Health-Related Findings in Research (Joint MRC/HRA)
Mr Steve Chandler	24/11/2017	HRA National Chairs' Day and Policy Event
Mr Steve Chandler	30/11/2017	Genetic and Genomic Research (previously HTA Advanced)
Dr Mary Connor	29/11/2017	Regional Members Training Day
Mr Michael Davidson	21/04/2017	Self-Directed Log - attended regional training event
Mr Michael Davidson	07/02/2018	Phase 1 Trials & Regulations
Mrs Janet Hattle	14/09/2017	Training for new REC Chairs
Mrs Janet Hattle	09/02/2018	Complex cases
Dr James Hobkirk	05/04/2017	Equality and Diversity
Dr James Hobkirk	04/05/2017	Induction Online Training
Dr James Hobkirk	20/02/2018	Human Tissue Act (Use of Human Samples in Research) - An Introductory Level
Dr Jocelyn Hudson	29/11/2017	Regional Members Training Day
Dr Jocelyn Hudson	12/12/2017	National Members Training Day
Dr Jocelyn Hudson	18/01/2018	Quantitative Research Methods and Statistics: A Health Research Authority Workshop
Mrs Fan Hutchison	29/11/2017	Regional Members Training Day
Mr Anthony Lockett	29/11/2017	Regional Members Training Day
Mrs Biserka Ross	05/10/2017	Introduction to Phase 1 Research - Trials & Regulation
Mrs Biserka Ross	19/10/2017	Quantitative Research Methods and Statistics: A Health Research Authority Workshop
Mrs Biserka Ross	29/11/2017	Regional Members Training Day
Mrs Biserka Ross	06/03/2018	Assessing the Consequences (benefits and harms) of Research: a Health Research Authority workshop
Dr John Toy	29/11/2017	Regional Members Training Day
Dr John Toy	12/12/2017	National Members Training Day
Dr John Toy	27/02/2018	Genetic and Genomic Research
Dr John Toy	27/02/2018	Genetic and Genomic Research (previously HTA Advanced)
Mr Chris Turnock	23/11/2017	Ethical Issues in Phase One Research: An Advanced Training Course
Mr John Warden	31/03/2018	SDL - April 17 - March 18 - 8 hours of reading (GDPR)
Mr Clive Wilson	08/08/2017	Equality and Diversity
Mr Clive Wilson	18/09/2017	Online Members Induction

Mr Clive Wilson	21/09/2017	Committee Members Induction
Mr Clive Wilson	29/11/2017	Regional Members Training Day

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	6	13.33
Phase 1	11	24.44
Gene Therapy	7	15.56
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	0	0.00
Others	21	46.67
Total Applications Reviewed	**45**	**100**

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

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

Table 3: Decisions given at meetings held within the reporting period

Decisions taken at meetings following review of applications	Number	%
Favourable Opinion with Standard Conditions	4	8.89
Favourable Opinion with Additional Conditions	7	15.56
Unfavourable Opinion	3	6.67
Provisional Opinion	31	68.89
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	**45**	**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	28	62.22
Further Information Favourable Opinion with Additional Conditions	2	4.44
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	4	8.89
Favourable Opinion with Additional Conditions	7	15.56
Unfavourable Opinion	3	6.67
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	1	2.22
Total	**45**	**100**

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

Total Applications Reviewed	**21**

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

Number of applications made invalid by the REC Manager	5
Number of studies withdrawn prior to the meeting	1
Number of student applications reviewed	9
Number of paediatric applications reviewed	1
Number of device applications reviewed	1
Number of qualitative applications reviewed	3

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	16	76.19
Favourable Opinion with Additional Conditions	2	9.52
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	3	14.29
Unfavourable Opinion	0	0.00
Total	**21**	**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	4.50
Number of completed applications for full ethical review	44
Number of completed applications for full ethical review over 60 days	0
Number of completed applications over 60 days as a % of total	0.00%
Number of days taken to final decision – average (mean)	26

Number of completed proportionate review applications for ethical review	21
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	19
Number of completed applications for SSA review over 25 days	0
Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs	0.00%

Number of SSAs (Phase 1) reviewed	10
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	121
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	101
Number of substantial amendments received for information	1
Number of substantial amendments received for new sites/PIs	19
Number of annual progress reports received	40
Number of safety reports received	28
Number of Serious Adverse Events received	2
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/NE/0073	LY3074828- SC and IV Bioavailability in Healthy Volunteers	14
17/NE/0109	A Phase I study of BGB-3111 in B-Cell Lymphoid Malignancies	25
17/NE/0125	A Phase I, SAD MAD Study of OLX10010 in Healthy Subjects	29
17/NE/0130	Sotagliflozin vs. Placebo added to Sulfonylurea +/- Metformin in T2DM	21
17/NE/0132	How do suicidal or violent prisoners understand and manage emotion?	23
17/NE/0171	Desistance narratives in personality disordered offenders	25
17/NE/0173	NAXOS	24
17/NE/0177	Patient and Dentist Experiences of Referral to Bariatric Dental Care	23
17/NE/0210	Phase1/2 with AT342 in patients with Crigler Najjar syndrome	33
17/NE/0225	SENZA-PVD2 Rev A	22
17/NE/0240	CA2017 NSRBP study Rev A	17
17/NE/0248	Influence of gut microbes on the immune system - version 01	20
17/NE/0261	Bioequivalence study for Lu AF35700 (Study Lu 17481A)	34
17/NE/0265	Population-based study of two year outcomes in very preterm babies	21
17/NE/0309	The WASH Study: Water Assisted Sigmoidoscopy in NHS BSSP	21
17/NE/0311	A Personalised Cancer Vaccine study in Patients with Advanced Tumours.	50
17/NE/0321	ALN-G01-002 Extension study of long-term ALN-G01 in Patients with PH1	28
17/NE/0335	National evaluation of Medication to Manage Sexual Arousal	34
17/NE/0336	Phase 1 study SAD-MAD of ACT-519276 in healthy subjects.	28
17/NE/0345	Relatives needs when a family member is admitted to a dementia ward.	33
17/NE/0366	Stem cell therapy for sepsis or septic shock caused by pneumonia	47
17/NE/0374	GS030_CLIN_001, Phase 1/2a, Open-Label study for Retinitis Pigmentosa	29
18/NE/0004	VAccination in early and ADvanced prostate caNCEr (ADVANCE)	35
18/NE/0005	Registry Study to Evaluate Survival and Safety of T-VEC Subjects	36
18/NE/0006	Repair of ARDS by Stromal Cell Administration (REALIST)	47
18/NE/0030	SYNAPTIC	51
18/NE/0039	PSR_Gastric Electrical Stimulation	30
18/NE/0040	Feeding Late and Moderately Preterm Infants (FLAMINGO)	24

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

17/NE/0262	An Evaluation of Mental Health Triage version 1.0	22
17/NE/0331	Global Fenestrated Anaconda™ Clinical Study	31

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/NE/0281	E6007-CP3 Phase I AME, Single dose in Healthy Adults	24
17/NE/0323	Serosurveillance study of maternally derived anti-pertussis antibody	20
18/NE/0001	CP1050-E101 SAD & MAD in healthy volunteers	28
18/NE/0002	Single Oral Dose of MT-7117 in Healthy Male Subjects	21

Favourable Opinion with Additional Conditions		
REC Reference	**Title**	**Number of Days on Clock**
17/NE/0034	A study to examine LY3015014 in healthy subjects with elevated LDL	14
17/NE/0042	Phase 1 trial to assess the effect of GWP42003-P on healthy adults	20
17/NE/0108	FAP	17
17/NE/0112	Midazolam probe study with CBD in healthy volunteers	13
17/NE/0136	Long term follow-up of DTX101 in adults with Haemophilia B	31
17/NE/0174	Evaluation of the MCM5 ELISA in bladder cancer recurrence	20
17/NE/0296	LCZ696 regional absorption pharmacoscintigraphic study	13

Unfavourable Opinion		
REC Reference	**Title**	**Number of Days on Clock**
17/NE/0111	Adherence to LUM and IVA in CF	20
17/NE/0209	Oral care system and protocol	20
17/NE/0246	National evaluation of Medication to Manage Sexual Arousal	19

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**
17/NE/0364	CR-BD-001	24

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/NE/0133	Unexplained Dizziness in the Elderly: The Role of Small Vessel Disease	20
17/NE/0195	MOLL trial	14
17/NE/0369	Non-pharmacological management of dental anxiety	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/NE/0164	Delivering secondhand smoke interventions in primary care (DeSSIP)	13

17/NE/0168	Labelling and imaging of leukocyte subpopulations 1.0	13
17/NE/0249	Evaluating Pressure Ulceration with Thermography and Ultrasound	14
17/NE/0285	Opal Study CNTO148UCO4001	11
17/NE/0286	EMA post-authorisation safety study of influenza vaccine - Year 3	7
17/NE/0298	Associations between thirst, assessed hydration and plasma osmolality.	16
17/NE/0299	Developing a Household Food Insecurity Questionnaire	16
17/NE/0302	Optimising the CARE Plus Trial	16
17/NE/0340	Development of novel ex vivo models of liver disease.	12
17/NE/0341	Millennium Cohort Study Seventh Sweep	12
17/NE/0371	Patient, pharmacist and GP views on community pharmacy services (v1)	18
18/NE/0067	Validation of the Edinburgh Social Cognition Test (ESCoT) in ABI	7
18/NE/0070	Biomarkers for early detection of PDAC	3
18/NE/0071	Monitoring antipsychotic drugs in fingerprints and dried blood spots	7
18/NE/0099	Erosive tooth wear related to gastroesophageal reflux disease	17
18/NE/0101	Upper limb rehabilitation after stroke: quality of life investigation	20

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
17/NE/0199	HFpEF Patients & Providers	17
17/NE/0370	CAMG334A3301 BECOME - Migraine Impact data collection study	18

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**
01/3/022/AM09	Juvenile Dermatomyositis Cohort & Biomarker Study (UK & Ireland)	Substantial Amendment 12 - April 2017	25/05/2017	23
01/3/057/AM16	Melanoma Follow-up and Case Control Family Study	5.0	31/03/2017	13
04/3/006/AM10	Arterial Revascularisation Trial (ART)	Substantial Amendment 6 (Amendment 3, 10/7/17)	10/07/2017	8
04/3/006/AM11	Arterial Revascularisation Trial (ART)	Substantial Amendment 7 - (SA2b) - 3/10/17	03/10/2017	14
10/H0903/38/AM18	Morphine in simulated haemorrhagic shock V1.0	Substantial Amendment 9	26/01/2017	22
10/H0903/38/AM19	Morphine in simulated haemorrhagic shock V1.0	Substantial Amendment 10 - 1/8/17	01/08/2017	16
10/H0903/38/AM20	Morphine in simulated haemorrhagic shock V1.0	Substantial Amendment 11 - 24/11/17	24/11/2017	22
12/NE/0010/AM08	Study of Brentuximab Vedotin in Pediatric Patients with Lymphoma	SA to IB (Edition 15)	26/10/2017	16
12/NE/0388/AM10	The AMICI trial	Protocol amendment V10.0, 04May 17	02/06/2017	17
12/NE/0388/AM11	The AMICI trial	Substantial Amendment 6 - Updated IB V2.0	01/12/2017	12
13/NE/0104/AM04	Product Surveillance Registry Base Protocol, Version 3.	Substantial Amendment 3 - 13/02/18	13/02/2018	14
13/NE/0201/AM15	Olaparib maintenance monotherapy in ovarian cancer	14	30/03/2017	14
13/NE/0323/AM06	VLA009 Systemic Treatment of Resistant Metastatic Disease	Substantial	15/05/2017	23

	(STORM)	Amendment 05 - 11		
13/NE/0323/AM07	VLA009 Systemic Treatment of Resistant Metastatic Disease (STORM)	Substantial Amendment 6 - 20/9/17	20/09/2017	33
14/NE/0122/AM08	WA29231 - Long term extension study of tocilizumab in children	7, Protocol 5 - 04/09/2017	04/09/2017	11
14/NE/0122/AM09	WA29231 - Long term extension study of tocilizumab in children	Substantial Amendment 8 - 15/1/18	15/01/2018	24
14/NE/1001/AM05	ReActiv8-A	Substantial Amendment 4 - 21/6/17	21/06/2017	19
14/NE/1055/AM02	Circulating DNA in Head and Neck Cancer	Substantial Amendment 1 - v1.5 01/03/2017	25/04/2017	11
14/NE/1169/AM12	Impact of RA characteristics on outcome of study drug dose tapering	Substantial Amendment 7 - 26/7/17	26/07/2017	1
14/NE/1249/AM10	Phase 2 study of Cobimetinib in TNBC	9	26/12/2016	15
14/NE/1249/AM11	Phase 2 study of Cobimetinib in TNBC	Substantial Amendment 10 - 29/9/17 (updated IB & Protocol)	29/09/2017	6
15/NE/0052/AM05	PEDAL: Long-term Outcome of Children Enrolled in Study ROPP-2008-01	Amendment 3, 11 May 2017	17/08/2017	21
15/NE/0104/AM09	MYOPROSP	5	29/03/2017	14
15/NE/0104/AM11	MYOPROSP	Amendment 6 Dated 27/03/2017	16/05/2017	27
15/NE/0104/AM12	MYOPROSP	Substantial Amendment 7 - 7/7/17	07/07/2017	14
15/NE/0109/AM06	TIKA TB	3	30/03/2017	13
15/NE/0167/AM25	MLN9708 in Multiple Myeloma Not Treated with Stem Cell transplantation	Substantial Amendment 17 - 26/2/18	26/02/2018	26
15/NE/0265/AM01	Exploring pain in the CP population: Piloting a big data approach.	Substantial Amendment	20/03/2017	8

		number one Date 9th March, 2017		
15/NE/0293/AM02	Open Label ESL Extension (FROM IMPORT)	Substantial Amendment 1 - 27/10/17	27/10/2017	17
15/NE/0299/AM07	MoRE: Models of Reablement Evaluation (Version 1)	Substantial Amendment 3 (29 March 17)	29/03/2017	15
15/NE/0299/AM08	MoRE: Models of Reablement Evaluation (Version 1)	Substantial Amendment 4 (04 May 17)	05/05/2017	11
15/NE/0299/AM10	MoRE: Models of Reablement Evaluation (Version 1)	Substantial Amendment 5 - 7/7/17	07/07/2017	7
15/NE/0389/AM16	ABY-035 - Phase I study in healthy subjects and psoriasis patients	Substantial Amendment 11 - 10.5.17	15/05/2017	23
15/NE/0398/AM02	Mi-ECMO	Amendment 1 - number 2 dated 27/04/2017	10/05/2017	9
16/NE/0010/AM13	ALN-GO1 in Healthy Adult Subjects and Patients with PH1	Substantial Amendment 12 - 24/7/17	24/07/2017	11
16/NE/0010/AM15	ALN-GO1 in Healthy Adult Subjects and Patients with PH1	Substantial Amendment 13 - 20/09/17	20/09/2017	16
16/NE/0074/AM09	MAD, two period crossover study in type 2 diabetics	Substantial Amendment 4 - 9/5/17	09/05/2017	22
16/NE/0074/AM10	MAD, two period crossover study in type 2 diabetics	Substantial Amendment 5 - 14/6/17	14/06/2017	11
16/NE/0074/AM11	MAD, two period crossover study in type 2 diabetics	Substantial Amendment 6 - 11/07/2017	11/07/2017	8
16/NE/0074/AM12	MAD, two period crossover study in type 2 diabetics	Substantial Amendment 7 -	18/10/2017	2

		5/9/17		
16/NE/0078/AM07	DTX101 in adults with moderate/severe Haemophillia B	Substantial Amendment 3 - 25/5/17	25/05/2017	13
16/NE/0078/AM08	DTX101 in adults with moderate/severe Haemophillia B	Substantial Amendment 4 - 13/9/17	13/09/2017	16
16/NE/0133/AM03	Describing patterns of cardiovascular disease risk profiles in Prisons	Substantial Amendment 2 - 11/1 /17	11/10/2017	9
16/NE/0133/AM04	Describing patterns of cardiovascular disease risk profiles in Prisons	Substantial Amendment 3 - 3/11/17	03/11/2017	15
16/NE/0133/AM05	Describing patterns of cardiovascular disease risk profiles in Prisons	Substantial Amendment 4 - 9/11/17	09/11/2017	14
16/NE/0133/AM06	Describing patterns of cardiovascular disease risk profiles in Prisons	Substantial Amendment 5 - 04/12/17	04/12/2017	15
16/NE/0133/AM07	Describing patterns of cardiovascular disease risk profiles in Prisons	Substantial Amendment 6 - 01/02/18	01/02/2018	15
16/NE/0198/AM03	Fimaporfin-induced Photochemical Internalisation in Healthy Subjects.	Substantial Amendment 2 - 14/6/17	14/06/2017	10
16/NE/0198/AM04	Fimaporfin-induced Photochemical Internalisation in Healthy Subjects.	Substantial Amendment 3 - 18/7/17	18/07/2017	13
16/NE/0198/AM06	Fimaporfin-induced Photochemical Internalisation in Healthy Subjects.	Substantial Amendment 4 - 18/10/17	26/10/2017	13
16/NE/0198/AM07	Fimaporfin-induced Photochemical Internalisation in Healthy Subjects.	Substantial Amendment 5 - 8/11/17	08/11/2017	10
16/NE/0198/AM10	Fimaporfin-induced Photochemical Internalisation in Healthy Subjects.	Substantial Amendment 6 - 28/02/18	28/02/2018	20

16/NE/0201/AM03	CRISP	Substantial Amendment 1 - 11/9/17	11/09/2017	21
16/NE/0223/AM03	Case-control study investigating the psychology of recurrent DKA	Substantial Amendment 1 - 20/7/2017	20/09/2017	19
16/NE/0223/AM04	Case-control study investigating the psychology of recurrent DKA	Substantial Amendment 2 - 6/10/17	06/10/2017	22
16/NE/0227/AM02	A Phase IIb study on the efficacy of FLU-v	Substantial Amendment 2 - 11.5 .17	11/05/2017	8
16/NE/0315/AM02	SENZA SCI	Substantial Amendment 1 - 8/9/17	08/09/2017	19
16/NE/0316/AM03	Phase 1 Study CYP-001 for the Treatment of Acute Graft vs Host Disease	Substantial Amendment 3 - 26/6/17	26/06/2017	6
16/NE/0316/AM05	Phase 1 Study CYP-001 for the Treatment of Acute Graft vs Host Disease	SA4	08/01/2018	16
16/NE/0346/AM02	ReActiv8-B, Revision B	Substantial Amendment #2 dd. 03 May 2017	09/05/2017	12
16/NE/0370/AM03	SIDEROS, V1	1.0	11/04/2017	16
16/NE/0370/AM04	SIDEROS, V1	Substantial Amendment 13 - 4/9/17	04/09/2017	13
16/NE/0370/AM05	SIDEROS, V1	Substantial Amendment 4 - 20/11/17	20/11/2017	6
16/NE/0386/AM06	IIa: VBP15-002	Substantial Amendment 3 - New IMPD v2, 27.2.17 and IB v6 5.5.17	08/05/2017	13
16/NE/0387/AM06	IIa extension: VBP15-003	Substantial Amendment 3 -	05/05/2017	13

		New IMPD v2, 27.2.17 and IB v6 5.5.17		
16/NE/0387/AM07	IIa extension: VBP15-003	Substantial Amendment 4 - Protocol Amendment 2 - 22/2/17	22/02/2017	7
16/NE/0398/AM01	Clinical Study of the BioVentrix Revivent TCâ„¢	1	03/04/2017	10
16/NE/0398/AM03	Clinical Study of the BioVentrix Revivent TCâ„¢	Substantial Amendment 2 26 May 17	31/05/2017	25
16/NE/0424/AM03	I-ACT Study - Improving access to primary care	Substantial amendment - AM2 27/04/17	27/04/2017	17
16/NE/0424/AM04	I-ACT Study - Improving access to primary care	Substantial Amendment 03 12/7 /17	12/07/2017	14
17/NE/0002/AM03	17208A Itraconazole on the PK, Safety and Tolerability of Lu AF35700	1	12/04/2017	15
17/NE/0002/AM06	17208A Itraconazole on the PK, Safety and Tolerability of Lu AF35700	Substantial Amendment 2 - 9/5//17	20/06/2017	14
17/NE/0002/AM09	17208A Itraconazole on the PK, Safety and Tolerability of Lu AF35700	Substantial Amendment 3 - 14/2/17	14/02/2017	14
17/NE/0002/AM10	17208A Itraconazole on the PK, Safety and Tolerability of Lu AF35700	Substantial Amendment 4 - 15/10/17	15/10/2017	3
17/NE/0002/AM11	17208A Itraconazole on the PK, Safety and Tolerability of Lu AF35700	Substantial Amendment 5 - 11/1/18	11/01/2018	17
17/NE/0009/AM01	CAPSTONE 2	Substantial Amendment 1 - 30.5.17	30/05/2017	27
17/NE/0009/AM02	CAPSTONE 2	Substantial Amendment 2 –	26/07/2017	16

		Recruitment materials		
17/NE/0009/AM04	CAPSTONE 2	Substantial Amendment 4 - 11/8/17	11/08/2017	6
17/NE/0009/AM05	CAPSTONE 2	Substantial Amendment 5 - 7/9/17	07/09/2017	19
17/NE/0009/AM07	CAPSTONE 2	Substantial Amendment 7 - 22/12/17	22/12/2017	19
17/NE/0009/AM08	CAPSTONE 2	Substantial Amendment 8 - 15/2/18	15/02/2018	1
17/NE/0012/AM04	Alleviating Specific Phobias Experienced by Children Trial (ASPECT)	Substantial Amendment 2 - 13/7/17	13/07/2017	11
17/NE/0012/AM05	Alleviating Specific Phobias Experienced by Children Trial (ASPECT)	Substantial Amendment 3 - 22/11/17	27/11/2017	11
17/NE/0012/AM06	Alleviating Specific Phobias Experienced by Children Trial (ASPECT)	Substantial Amendment 4 - 19/1/2018	19/01/2018	3
17/NE/0013/AM01	Single-Dose Study to Assess Bioavailability of LY3074828	Substantial Amendment 1 - 18/12/17	18/12/2017	24
17/NE/0036/AM01	SIR-Spheres for the treatment of cholangiocarcinoma	UK Amendment 1 - 10May17	01/06/2017	21
17/NE/0036/AM02	SIR-Spheres for the treatment of cholangiocarcinoma	Substantial amendment 2	06/09/2017	13
17/NE/0042/AM03	Phase 1 trial to assess the effect of GWP42003-P on healthy adults	Substantial Amendment 1 - 1/9/17	01/09/2017	13
17/NE/0073/AM01	LY3074828- SC and IV Bioavailability in Healthy Volunteers	Substantial Amendment 1 - 18/1/18	17/01/2018	22
17/NE/0084/AM02	The ASSESS Study	Substantial	22/11/2017	19

		Amendment 1 - 22/11/17		
17/NE/0109/AM01	A Phase I study of BGB-3111 in B-Cell Lymphoid Malignancies	Substantial Amendment 1 - 11/10/17	11/10/2017	13
17/NE/0109/AM02	A Phase I study of BGB-3111 in B-Cell Lymphoid Malignancies	Substantial Amendment 2 - 20/12/2017	20/12/2017	22
17/NE/0112/AM01	Midazolam probe study with CBD in healthy volunteers	Substantial amendment 1- INR rate change	05/09/2017	10
17/NE/0112/AM02	Midazolam probe study with CBD in healthy volunteers	Substantial Amendment 2 - 10/11/17	10/11/2017	13
17/NE/0130/AM02	Sotagliflozin vs. Placebo added to Sulfonylurea +/- Metformin in T2DM	Substantial Amendment 2 - 14/6/17	14/06/2017	7
17/NE/0130/AM04	Sotagliflozin vs. Placebo added to Sulfonylurea +/- Metformin in T2DM	Substantial Amendment 4 - Updated IB Edition 10	16/06/2017	10
17/NE/0130/AM05	Sotagliflozin vs. Placebo added to Sulfonylurea +/- Metformin in T2DM	Substantial Amendment 5 - 20/12/17	20/12/2017	3
17/NE/0132/AM01	How do suicidal or violent prisoners understand and manage emotion?	Substantial Amendment 2 - 5/9/17	05/09/2017	11
17/NE/0132/AM02	How do suicidal or violent prisoners understand and manage emotion?	Substantial Amendment 3 - 17/11/2017	17/11/2017	11
17/NE/0132/AM03	How do suicidal or violent prisoners understand and manage emotion?	Substantial Amendment 4 - 13/2/18	13/02/2018	26
17/NE/0136/AM01	Long term follow-up of DTX101 in adults with Haemophilia B	Substantial Amendment 1 - 2/6/17	02/06/2017	7
17/NE/0136/AM02	Long term follow-up of DTX101 in adults with Haemophilia B	v2.1, 23/08/17	31/08/2017	15

17/NE/0171/AM01	Desistance narratives in personality disordered offenders	1, 01.09.17	01/09/2017	9
17/NE/0173/AM01	NAXOS	Substantial Amendment 1 - 26/7/17	26/07/2017	16
17/NE/0173/AM02	NAXOS	Substantial Amendment 2 - 26/9/17	26/09/2017	18
17/NE/0173/AM03	NAXOS	Substantial Amendment 3 - 20/10/17	20/10/2017	17
17/NE/0173/AM04	NAXOS	Substantial Amendment 4 - 27/11/17	27/11/2017	18
17/NE/0177/AM01	Patient and Dentist Experiences of Referral to Bariatric Dental Care	Substantial Amendment 1 - 11/12/2017	11/12/2017	32
17/NE/0199/AM01	HFpEF Patients & Providers	Substantial Amendment 1 - 18/1/17	18/10/2017	18
17/NE/0210/AM01	Phase1/2 with AT342 in patients with Crigler Najjar syndrome	Substantial Amendment 1 - 24/10/17	24/10/2017	17
17/NE/0210/AM02	Phase1/2 with AT342 in patients with Crigler Najjar syndrome	Substantial Amendment 2 - 12/11/2017	12/11/2017	14
17/NE/0210/AM03	Phase1/2 with AT342 in patients with Crigler Najjar syndrome	SA3 protocol v6.0	28/11/2017	21
17/NE/0210/AM04	Phase1/2 with AT342 in patients with Crigler Najjar syndrome	Substantial Amendment 4 - 25/1/18	25/01/2018	17
17/NE/0240/AM03	CA2017 NSRBP study Rev A	Substantial Amendment 1 - 26/9/2017	26/09/2017	15
17/NE/0262/AM02	An Evaluation of Mental Health Triage version 1.0	Substantial Amendment 1 - 27/12/2017	27/12/2017	13
17/NE/0265/AM01	Population-based study of two year outcomes in very preterm babies	Substantial Amendment 1 -	05/09/2017	13

		5/9/17		
17/NE/0298/AM01	Associations between thirst, assessed hydration and plasma osmolality.	Substantial Amendment 1 - 18/1/18	18/01/2018	20
17/NE/0302/AM01	Optimising the CARE Plus Trial	Substantial Amendment 1 - 10/1/17	10/10/2017	7
17/NE/0336/AM01	Phase 1 study SAD-MAD of ACT-519276 in healthy subjects.	Substantial Amendment 1 - 14/1/17	14/11/2017	14
17/NE/0374/AM01	GS030_CLIN_001, Phase 1/2a, Open-Label study for Retinitis Pigmentosa	Substantial Amendment 1 - 28/1/17	28/11/2017	27
18/NE/0001/AM01	CP1050-E101 SAD & MAD in healthy volunteers	Substantial Amendment 1 - 23/1/18	23/01/2018	10

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	**Title**	**Version**	**Date**	**Number of Days on**

Reference				**Clock**

Table 11: **Items exceeding timelines**

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

Proportionate review applications for ethical review over 21 day timeline		
REC Reference	**Title**	**Number of Days on Clock**

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

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

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

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