

**Yorkshire & The Humber - Leeds East Research
Ethics Committee**

Annual Report

01 April 2017 - 31 March 2018



Part 1 – Committee Membership and Training

| | |
|------------------------------|---|
| Name of REC: | Yorkshire & The Humber - Leeds East Research Ethics Committee |
| Type of REC: | RECs recognised to review CTIMPS in patients - type iii |
| Type of Flag: | Establishing Research Tissue Banks IRB Registered Phase 1 Studies in Patients Research Involving Adults Lacking Capacity Research Involving Children Establishing Research Databases |
| Chair: | Dr Rhona Bratt |
| Vice-Chair: | Dr Deborah Jane Fox |
| Alternate Vice-Chair: | Dr Alexandros Chatziagorakis |
| REC Manager: | Ms Katy Cassidy |
| REC Assistant: | Miss Sarah Prothero |
| Committee Address: | NHSBT Newcastle Blood Donor Centre Holland Drive Newcastle upon Tyne NE2 4NQ |
| Telephone: | 0207 104 8081 |
| Email: | nrescommittee.yorkandhumber-leedseast@nhs.net |

Chair's overview of the past year:

This is my fourth annual report as Chair of the Leeds East Research Ethics Committee.

In my work as Chair I have been fortunate to have the support of Vice Chairs, Debbie Fox and Alex Chatziagorakis and on behalf of the Chairs I would like to express our appreciation of the work of our REC manager, Katy Cassidy and our REC Assistant, Sarah Prothero.

One member of the committee left in the course of this year and his contribution must not be forgotten or go unappreciated. Karl Ward left because of the demands of his career promotion.

The work of the committee has changed over recent years but the underlying principles remain – the participant and the research matter. It is with this in mind that we work with the researchers. The committee greatly appreciates the work of the researchers in preparing their applications and in particular their attendance at meetings where many questions are resolved in face-to-face discussions.

All the committee members, lay and expert, are volunteers and the great majority work full time in very demanding jobs. They spend many hours preparing for meetings, face to face and in correspondence. The Committee continues to show a balance of professionalism, support of the researcher and research, as well as a great deal of good humour, and I cannot thank them enough for continuing to do such sterling work.

Yorkshire & The Humber - Leeds East Research Ethics Committee Membership

| Name | Profession | Expert or Lay | Dates | |
|------------------------------|---|---------------|------------|------------|
| | | | Appointed | Left |
| Miss Jennifer Blaikie | Senior Research Ethics Administrator | Lay Plus | 01/01/2014 | |
| Dr Rhona Bratt | Retired Multimedia Project Manager | Lay Plus | 01/08/2014 | |
| Professor Kenneth Brodlie | Retired Professor of Visualization | Lay Plus | 13/06/2011 | |
| Dr Alexandros Chatziagorakis | Consultant Psychiatrist | Expert | 01/10/2014 | |
| Dr Deborah Jane Fox | Senior Lecturer in Nursing | Expert | 01/04/2011 | |
| Mrs Ann Kay | Retired Special Needs Coordinator | Lay Plus | 01/03/2014 | |
| Dr Nicky Kime | Senior Research Fellow | Expert | 01/06/2016 | |
| Dr Nicolas Orsi | Senior Research Fellow | Expert | 01/12/2015 | |
| Dr Robert Phillips | Senior Clinical Academic | Expert | 03/10/2016 | |
| Dr Andrew Pollard | Consultant Anaesthetist | Expert | 22/09/2014 | |
| Mr Satti Saggu | Research Project Manager | Lay Plus | 11/02/2015 | |
| Dr Anna Schuberth | Specialty Registrar in Palliative Medicine | Expert | 01/03/2014 | |
| Mr Karl Ward | Senior Research Nurse | Expert | 18/04/2016 | 15/02/2018 |
| Mr Tom Wilson | Consultant ENT Surgeon | Expert | 18/04/2011 | |
| Miss Kate Woodrow | Associate Director of Pharmacy – Patient Care | Expert | 01/12/2012 | |

Yorkshire & The Humber - Leeds East Research Ethics Committee: Co-opted Members

| Name | Profession | Status | Meeting date attended |
|-------------------------|--|--------|-----------------------|
| Dr Sheila E. Fisher | Retired Maxillofacial Surgeon/Clinical Research Fellow | Expert | 04/04/2017 |
| Dr Jane Orton | Consultant Clinical Oncologist | Expert | 04/04/2017 |
| Dr Meiyi Pu | Consultant | Expert | 07/11/2017 |
| Dr Christopher Skidmore | Retired University Lecturer | Lay | 04/04/2017 |

Yorkshire & The Humber - Leeds East Research Ethics Committee: Members' Declarations of Interest:

| Name | Declaration of Interest | Date |
|------------------------------|--|-------------|
| Miss Jennifer Blaikie | Employed by the University of Leeds. | 09/01/2018 |
| Dr Rhona Bratt | None | 05/01/2018 |
| Professor Kenneth Brodlie | Small shareholdings in AstraZeneca and GlaxoSmithKline | 16/01/2018 |
| Dr Alexandros Chatziagorakis | None declared | 06/06/2017 |
| Dr Deborah Jane Fox | None declared | 31/03/2018 |
| Mrs Ann Kay | None | 05/01/2018 |
| Dr Nicky Kime | None declared | 06/02/2018 |
| Dr Nicolas Orsi | Consultancy for Ostara Biomedical. Small shareholding in Ostara Biomedica. I Trustee, Action on Womb Cancer | 05/01/2018 |
| Dr Robert Phillips | Research advisory board, CCLG Clinical Academic, CRD, York | 08/01/2018 |
| Dr Andrew Pollard | None declared. | 06/02/2018 |
| Mr Satti Saggi | Research Project Manager for the Academic Unit of Elderly Care and Rehabilitation at the Bradford Institute for Health Research. Community Champion for diabetes use. | 01/06/2017 |
| Dr Anna Schuberth | I am a specialty registrar in palliative medicine and will be working at St Leonard's hospice, York. As a palliative medicine registrar employed through Leeds Teaching Hospital Trust I am involved in research through our training programme. | 31/03/2018 |
| Mr Karl Ward | LTHT Research Executive Committee - Neuro and Trust Wide | 02/05/2017 |
| Mr Tom Wilson | None declared | 09/04/2017 |
| Miss Kate Woodrow | None declared | 23/01/2018 |

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

| Month | Date | Number of Members Present at Meeting |
|-----------|------------|--------------------------------------|
| April | 04/04/2017 | 9 |
| May | 02/05/2017 | 12 |
| June | 06/06/2017 | 8 |
| August | 01/08/2017 | 8 |
| September | 05/09/2017 | 11 |
| October | 03/10/2017 | 7 |
| November | 07/11/2017 | 8 |
| December | 05/12/2017 | 7 |
| February | 06/02/2018 | 9 |
| March | 06/03/2018 | 8 |

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 | 27/04/2017 | 4 |
| May | 25/05/2017 | 3 |
| June | 29/06/2017 | 3 |
| August | 31/08/2017 | 3 |
| September | 29/09/2017 | 3 |
| October | 27/10/2017 | 3 |
| December | 01/12/2017 | 3 |
| December | 22/12/2017 | 3 |
| February | 23/02/2018 | 3 |
| March | 23/03/2018 | 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 | 03/04/2017 | 2 |
| April | 18/04/2017 | 2 |
| April | 28/04/2017 | 2 |
| May | 02/05/2017 | 2 |
| May | 15/05/2017 | 2 |
| May | 30/05/2017 | 2 |
| June | 12/06/2017 | 2 |
| June | 26/06/2017 | 2 |
| July | 10/07/2017 | 2 |
| July | 24/07/2017 | 2 |
| August | 07/08/2017 | 2 |

| | | |
|-----------|------------|---|
| August | 21/08/2017 | 2 |
| September | 01/09/2017 | 2 |
| September | 18/09/2017 | 3 |
| October | 02/10/2017 | 2 |
| October | 16/10/2017 | 2 |
| October | 30/10/2017 | 2 |
| November | 13/11/2017 | 2 |
| November | 27/11/2017 | 2 |
| December | 11/12/2017 | 2 |
| December | 20/12/2017 | 2 |
| January | 08/01/2018 | 2 |
| January | 22/01/2018 | 2 |
| February | 05/02/2018 | 2 |
| February | 19/02/2018 | 2 |
| February | 21/02/2018 | 2 |
| March | 05/03/2018 | 2 |
| March | 19/03/2018 | 2 |

28 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 |
|------------------------------|------------------------------------|
| Miss Jennifer Blaikie | 3 |
| Dr Rhona Bratt | 8 |
| Professor Kenneth Brodlie | 8 |
| Dr Alexandros Chatziagorakis | 4 |
| Dr Deborah Jane Fox | 9 |
| Mrs Ann Kay | 5 |
| Dr Nicky Kime | 7 |
| Dr Nicolas Orsi | 7 |
| Dr Robert Phillips | 4 |
| Dr Andrew Pollard | 6 |
| Mr Satti Saggu | 3 |
| Dr Anna Schuberth | 2 |
| Mr Karl Ward | 4 |
| Mr Tom Wilson | 8 |
| Miss Kate Woodrow | 5 |

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

| Name | Number of Meetings Attended |
|------------------------------|------------------------------------|
| Miss Jennifer Blaikie | 2 |
| Dr Rhona Bratt | 7 |
| Professor Kenneth Brodlie | 1 |
| Dr Alexandros Chatziagorakis | 2 |
| Dr Deborah Jane Fox | 2 |
| Mrs Ann Kay | 2 |
| Dr Nicky Kime | 2 |
| Dr Nicolas Orsi | 2 |
| Dr Robert Phillips | 2 |
| Dr Andrew Pollard | 1 |
| Mr Satti Saggu | 2 |
| Mr Chris Turnock | 1 |
| Mr Karl Ward | 3 |
| Mr Tom Wilson | 2 |

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

| Name | Number of Meetings Attended |
|------------------------------|------------------------------------|
| Miss Jennifer Blaikie | 3 |
| Dr Rhona Bratt | 22 |
| Professor Kenneth Brodrie | 2 |
| Dr Alexandros Chatziagorakis | 6 |
| Dr Deborah Jane Fox | 5 |
| Mrs Ann Kay | 1 |
| Dr Nicky Kime | 1 |
| Dr Nicolas Orsi | 2 |
| Dr Robert Phillips | 3 |
| Dr Andrew Pollard | 3 |
| Mr Satti Saggi | 2 |
| Mr Karl Ward | 3 |
| Mr Tom Wilson | 3 |
| Miss Kate Woodrow | 1 |

Training 01 April 2017 - 31 March 2018

| Name of Member | Date | Event(s) attended |
|------------------------------|-------------|---|
| Miss Jennifer Blaikie | 24/08/2017 | Confidentiality Advisory Group |
| Dr Rhona Bratt | 24/11/2017 | Training - HRA National Chairs' Day and Policy Event |
| Dr Rhona Bratt | 29/11/2017 | Training - Regional Members Training Day |
| Professor Kenneth Brodlie | 30/11/2017 | Training - Genetic and Genomic Research |
| Dr Alexandros Chatziagorakis | 08/02/2018 | Research involving adults lacking capacity |
| Dr Alexandros Chatziagorakis | 08/02/2018 | Confidentiality and information governance considerations in research |
| Dr Alexandros Chatziagorakis | 06/03/2018 | Reviewing the research design of Clinical Trials |
| Dr Alexandros Chatziagorakis | 06/03/2018 | Medical Devices |
| Dr Deborah Jane Fox | 31/01/2018 | Training - Complex Cases |
| Mrs Ann Kay | 29/11/2017 | Training - Regional Members Training Day |
| Dr Nicky Kime | 29/11/2017 | Training - Regional Members Training Day |
| Dr Nicolas Orsi | 29/11/2017 | Training - Regional Members Training Day |
| Dr Robert Phillips | 29/11/2017 | Training - Regional Members Training Day |
| Dr Andrew Pollard | 19/10/2017 | Training - Quantitative Research Methods and Statistics |
| Mr Satti Saggi | 29/11/2017 | Training - Regional Members Training Day |
| Mr Tom Wilson | 29/11/2017 | Training - Regional Members Training Day |
| Miss Kate Woodrow | 29/11/2017 | Training - 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 | 15 | 28.85 |
| Phase 1 | 0 | 0.00 |
| Gene Therapy | 0 | 0.00 |
| Research Tissue Bank (including renewals) | 3 | 5.77 |
| Research Database (including renewals) | 3 | 5.77 |
| Others | 31 | 59.62 |
| Total Applications Reviewed | 52 | 100 |

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

| | |
|---|----|
| Number of applications made invalid by the REC Manager | 2 |
| Number of applications withdrawn prior to the meeting | 4 |
| Number of student applications reviewed | 13 |
| Number of paediatric applications reviewed | 13 |
| Number of device applications reviewed | 2 |
| 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 | 2 |
| 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 | 6 | 11.54 |
| Favourable Opinion with Additional Conditions | 4 | 7.69 |
| Unfavourable Opinion | 1 | 1.92 |
| Provisional Opinion | 41 | 78.85 |
| Provisional Opinion Pending Consultation with Referee | 0 | 0.00 |
| Total | 52 | 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 | 32 | 61.54 |
| Further Information Favourable Opinion with Additional Conditions | 6 | 11.54 |
| Further Information Unfavourable Opinion | 0 | 0.00 |
| Favourable Opinion with Standard Conditions | 6 | 11.54 |
| Favourable Opinion with Additional Conditions | 4 | 7.69 |
| Unfavourable Opinion | 1 | 1.92 |
| Provisional Opinion | 0 | 0.00 |
| Provisional Opinion Pending Consultation with Referee | 0 | 0.00 |
| Further Information response not complete | 1 | 1.92 |
| No decision entered on system | 0 | 0.00 |
| Number of studies withdrawn after the meeting | 2 | 3.85 |
| Total | 52 | 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 | 4 |
| Number of student applications reviewed | 7 |
| Number of paediatric applications reviewed | 2 |
| Number of device applications reviewed | 2 |
| Number of qualitative applications reviewed | 2 |

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 | 10 | 47.62 |
| Favourable Opinion with Additional Conditions | 3 | 14.29 |
| No Opinion transfer to full committee for review | 4 | 19.05 |
| Provisional Opinion | 4 | 19.05 |
| 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 | 5.20 |
| Number of completed applications for full ethical review | 49 |
| Number of completed applications for full ethical review over 60 days | 0 |
| Number of completed applications over 60 days as a % of total | 0.00% |
| Number of days taken to final decision – average (mean) | 26 |
| Number of completed proportionate review applications for ethical review | 17 |
| 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 | 16 |
| 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 | 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 | 139 |
| 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 | 1 |
| Number of completed modified amendments over 14 days | 0 |
| Number of completed modified amendments over 14 days as a % of total modified amendments | 0.00% |
| Number of non substantial amendments received | 114 |
| Number of substantial amendments received for information | 9 |
| Number of substantial amendments received for new sites/PIs | 40 |
| Number of annual progress reports received | 77 |
| Number of safety reports received | 52 |
| Number of Serious Adverse Events received | 1 |
| Number of final reports received | 19 |

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/YH/0081 | DOncaster MESH Trial | 24 |
| 17/YH/0096 | Penicillin Allergy De-Labeling in Elective Surgical patients (PADLES) | 21 |
| 17/YH/0100 | UCL Eastman Biobank | 23 |
| 17/YH/0106 | Exploring perspectives of sedentary behaviour in stroke survivors | 26 |
| 17/YH/0107 | (duplicate) HealthTracker: Tracking ADHD Cohort-Sheffield v1 | 22 |
| 17/YH/0108 | RJAH Biobank for Studying Health and Disease | 23 |
| 17/YH/0136 | Least restrictive practice its role in patient independence & recovery | 24 |
| 17/YH/0140 | Feasibility and acceptability of orthotic shorts for people with MS | 19 |
| 17/YH/0163 | LIBERATES | 23 |
| 17/YH/0173 | ARCADIA | 23 |
| 17/YH/0177 | CCP - Next Generation | 27 |
| 17/YH/0178 | Mother to infant attachment and body image in the postpartum period. | 27 |
| 17/YH/0186 | Efficacy and safety of oral GKT137831 | 22 |
| 17/YH/0224 | Activity monitoring in paediatric type 1 diabetes v1.0 | 21 |
| 17/YH/0255 | A Phase 1 Study of AZD4785 in Patients with Advanced Solid Tumours | 26 |
| 17/YH/0261 | Leeds Osteoarthritis of the Foot study (LOFT) | 34 |
| 17/YH/0325 | A national surveillance study of inherited white matter disorders | 26 |
| 17/YH/0329 | Generation 1-CAD106 and CNP520 in participants at risk of Alzheimer's | 29 |
| 17/YH/0331 | European Galactosemia Network Patient Registry (GalNET) (Version 1) | 30 |
| 17/YH/0334 | Extracorporeal Shockwave Therapy For Diabetic Foot Wounds - Version 1 | 29 |
| 17/YH/0336 | Comprehensive Geriatric Assessment in Primary Care: A Feasibility RCT | 32 |
| 17/YH/0348 | Blood flow restricted exercise training in CHF | 33 |
| 17/YH/0369 | Phase 3 study of BGB-3111 in CLL or SLL | 30 |
| 17/YH/0383 | Cervical Health: A novel approach to imaging the cervix | 30 |
| 17/YH/0388 | ACT-246475 in Coronary Artery Disease | 32 |
| 17/YH/0390 | SOTA-EMPA | 29 |
| 17/YH/0404 | Morphine or IV Paracetamol in Acutely Injured Neck of Femur Fractures | 30 |
| 17/YH/0412 | Managing long term symptoms with complex causes in primary care | 36 |
| 18/YH/0038 | Clinical comparison study of S-649266 on HABP/VABP/H CABP infections | 30 |
| 18/YH/0042 | STARS4Diabetes | 24 |
| 18/YH/0070 | Investigating the molecular mechanisms of rare genetic disorders v1.4 | 51 |
| 18/YH/0094 | The impact of Singing Speech on Pre-schoolers with speech difficulties | 32 |

| Further Information Favourable Opinion with Additional Conditions | | |
|--|--|--------------------------------|
| REC Reference | Title | Number of Days on Clock |
| 17/YH/0117 | VINDICATE-MI | 29 |
| 17/YH/0118 | Empagliflozin vs metformin in PCOS | 23 |
| 17/YH/0256 | What I Need in School (WINS) | 24 |
| 17/YH/0286 | Microarray for Rapid Pathogen Identification in ventilated pneumonia | 38 |
| 18/YH/0046 | A Phase 1/2 Study of AEB1102 in Patients With Arginase I Deficiency | 42 |
| 18/YH/0047 | OLE study: Safety & efficacy - Azeliragon in mild Alzheimer's patients | 30 |

| 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/YH/0086 | Ethical Tissue, the Research Tissue Bank | 17 |
| 17/YH/0133 | CAREGIVERSPRO-MMD:trial of a website for people with dementia/carers | 17 |
| 17/YH/0250 | UK-SAFE (WP2a - RO-HES) | 21 |
| 17/YH/0396 | Paediatric Cataract Registry (CO2) | 24 |
| 18/YH/0058 | Avoiding Cardiac Toxicity in Lung Cancer Patients | 24 |
| 18/YH/0096 | Atrial function in stroke | 24 |

| Favourable Opinion with Additional Conditions | | |
|--|---|--------------------------------|
| REC Reference | Title | Number of Days on Clock |
| 17/YH/0187 | PRISM | 22 |
| 17/YH/0260 | Parental experiences of neonatal therapies | 21 |
| 17/YH/0301 | HABIT | 19 |
| 17/YH/0313 | A pilot study of efficacy, safety and tolerability of AX-8 in cough | 26 |

| Unfavourable Opinion | | |
|-----------------------------|--------------|--------------------------------|
| REC Reference | Title | Number of Days on Clock |

| | | |
|------------|---|----|
| 17/YH/0285 | Managing long term symptoms with complex causes in primary care | 21 |
|------------|---|----|

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 |
|---------------|---|-------------------------|
| 17/YH/0335 | Place-making between hospital and home. | n/a |

Withdrawn after the meeting

| REC Reference | Title | Number of Days on Clock |
|---------------|--|-------------------------|
| 17/YH/0315 | Study to evaluate effects of GSK3772847 in patients with asthma. | 19 |
| 17/YH/0216 | An evaluation of the Maternity Care Pathway for women with LD | 21 |

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/YH/0141 | Cancer Needs Assessment in Primary Care (CANAssess:PC) | 20 |
| 17/YH/0143 | Identification and Management of Frequent Users of Emergency Services | 10 |
| 17/YH/0145 | Assessment of range of motion in total knee arthroplasty | 17 |
| 17/YH/0446 | faecal calprotectin levels in infants with heart defects Version 3 | 10 |

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/YH/0294 | The gut microbiome in polycystic ovary syndrome? | 18 |
| 17/YH/0342 | Physical activity in youth with chronic kidney disease | 14 |
| 17/YH/0344 | DVT after cardiac procedure | 12 |
| 17/YH/0416 | Active FES - v1 | 20 |
| 17/YH/0418 | A comparison of mycobium of sputum with dust from patients' homes | 20 |
| 17/YH/0444 | Dementia patients living in care homes accessing audiology services -1 | 8 |
| 18/YH/0075 | ACT-FLARE study | 15 |
| 18/YH/0079 | The role of psychological flexibility in appearance anxiety. | 14 |
| 18/YH/0115 | Effect of genetic variants on immune cell function | 21 |
| 18/YH/0118 | Medication Use in Patients Receiving Home Parenteral Nutrition. | 21 |

| Favourable Opinion with Additional Conditions | | |
|--|--|--------------------------------|
| REC Reference | Title | Number of Days on Clock |
| 17/YH/0223 | The APPLAUD Study v.1 08.06.2017 | 9 |
| 17/YH/0296 | Wearable Patch Vital Sign Monitoring Project | 16 |
| 18/YH/0078 | Enzyme Replacement Therapy in Niemann-Pick Disease | 16 |

| 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 |
| 06/Q1206/127/AM08 | Fracture healing and Mesenchymals Stem cells | Substantial Amendment 5, 22/08/16 | 27/07/2017 | 11 |
| 07/Q1206/53/AM32 | Imatinib versus nilotinib in newly diagnosed Ph+ve CML | Protocol Amendment 12, 30/03/17 | 25/05/2017 | 14 |
| 08/H1306/115+5/AM01 | Discovering new cancer biomarkers from patients' serum and DNA | Substantial Amendment 6, 05/04/17 | 05/04/2017 | 21 |
| 08/H1306/147+5/AM05 | Respiratory Tissue Bank | Substantial Amendment 5, 03/04/17 | 07/04/2017 | 13 |
| 09/H1306/64/AM47 | Strategic Timing of AntiRetroviral Treatment (START) | Substantial amendment 31 - 28.08.17 | 28/08/2017 | 18 |
| 09/H1306/97/AM19 | South Yorkshire Cohort | Substantial Amendment 13, 16/06/17 | 21/06/2017 | 25 |
| 10/H1306/61/AM60 | Collaborative care for elders - the CASPER Trial | Substantial Amendment 26, 12/06/17 | 26/06/2017 | 20 |
| 11/H1306/1/AM21 | CC-10004-PSA-005 Apremilast in Active Psoriatic Arthritis | Substantial Amendment - IB v18, 14/03/17 | 01/06/2017 | 11 |
| 11/H1306/1/AM22 | CC-10004-PSA-005 Apremilast in Active Psoriatic Arthritis | Substantial Amendment - IB v19, 12/07/17 | 17/08/2017 | 11 |
| 11/YH/0290/AM14 | STOMP: SCLC Trial of Olaparib (AZD2281) as Maintenance Programme. | Substantial Amendment 10, 06/04/17 | 07/04/2017 | 22 |
| 12/YH/0179/AM32 | 0117 - Phase 3 Extension Study of GS-1101 in CLL | Substantial Amendment 14, | 21/04/2017 | 25 |

| | | | | |
|-----------------|--|------------------------------------|------------|----|
| | | 11/04/17 | | |
| 12/YH/0179/AM34 | 0117 - Phase 3 Extension Study of GS-1101 in CLL | Substantial Amendment 16 - 6/9/17 | 07/02/2018 | 22 |
| 12/YH/0318/AM26 | 0115: Bendamustine, Rituximab and GS-1101 or placebo in CLL | Substantial Amendment 16, 05/04/17 | 20/04/2017 | 13 |
| 12/YH/0318/AM27 | 0115: Bendamustine, Rituximab and GS-1101 or placebo in CLL | Substantial Amendment 17, 21/09/17 | 16/10/2017 | 16 |
| 12/YH/0318/AM28 | 0115: Bendamustine, Rituximab and GS-1101 or placebo in CLL | Substantial Amendment 18, 08/12/17 | 09/01/2018 | 11 |
| 12/YH/0452/AM56 | INCA | Substantial Amendment 47, 18/01/18 | 18/01/2018 | 19 |
| 12/YH/0464/AM01 | Genetic and environmental effects in lymphocytes from various diseases | Substantial Amendment 1, 02/06/17 | 06/06/2017 | 17 |
| 12/YH/0464/AM02 | Genetic and environmental effects in lymphocytes from various diseases | Substantial Amendment 2, 02/06/07 | 02/06/2017 | 17 |
| 12/YH/0475/AM13 | GP28331 - A PHASE Ib study - CHRONIC LYMPHOCYTIC LEUKAEMIA | Substantial Amendment 9, 27/07/17 | 03/08/2017 | 18 |
| 12/YH/0475/AM15 | GP28331 - A PHASE Ib study - CHRONIC LYMPHOCYTIC LEUKAEMIA | Substantial Amendment 10, 05/10/17 | 05/10/2017 | 6 |
| 13/YH/0229/AM25 | GO2, Version 1.0 | Substantial Amendment 19, 22/11/17 | 24/11/2017 | 18 |
| 13/YH/0281/AM07 | Evaluation of [18F]-FET-βAG-TOCA for the imaging of NETs | Substantial Amendment 4, 07/12/16 | 22/02/2017 | 10 |
| 13/YH/0333/AM21 | Long term study for participants completing SIRROUND-D and SIRROUND-T | Substantial Amendment 14, 08/11/17 | 08/11/2017 | 19 |

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| 13/YH/0333/AM22 | Long term study for participants completing SIRROUND-D and SIRROUND-T | Substantial Amendment 15, 13/12/17 | 13/12/2017 | 6 |
| 14/YH/0088/AM10 | Phase I study of KHK2823 in AML or MDS | Substantial Amendment 9, 13/07/17 | 13/07/2017 | 8 |
| 14/YH/0123/AM07 | 1325 - Expanded access study with Idelalisib in patients with CLL | Substantial Amendment 7, 21/11/17 | 22/11/2017 | 20 |
| 14/YH/0131/AM13 | ACP-196 in Subjects with Chronic Lymphocytic Leukemia | Substantial Amendment 9, 17/05/17 | 18/05/2017 | 19 |
| 14/YH/0131/AM17 | ACP-196 in Subjects with Chronic Lymphocytic Leukemia | Substantial Amendment 11, 16/11/17 | 16/11/2017 | 12 |
| 14/YH/0151/AM01 | Gene Therapy in Heart Failure: A Qualitative Interview Study | Substantial Amendment 1, 30/08/17 | 30/08/2017 | 33 |
| 14/YH/1052/AM14 | The MUNROS project: the questionnaires (Work Packages 4,5 and 6) | Substantial Amendment 8, 08/02/17 | 14/02/2017 | 18 |
| 14/YH/1056/AM10 | Phase2/3 of masitinib+dexamethasone & gemcitabine in TCell lymphoma v1 | Substantial Amendment 9, 22/06/17 | 04/07/2017 | 20 |
| 14/YH/1066/AM06 | eRAPID RCT in systemic cancer treatment | Substantial Amendment 1.7, 31/03/17 | 04/04/2017 | 21 |
| 14/YH/1066/AM07 | eRAPID RCT in systemic cancer treatment | Substantial Amendment 1.8, 28/09/17 | 24/10/2017 | 20 |
| 14/YH/1125/AM02 | Vitamin D & PCOS | Substantial Amendment 2, 11/04/17 | 24/04/2017 | 27 |
| 14/YH/1157/AM03 | BONES – BOne (dys)function in donor NephrectomieS | Substantial Amendment 2, 10/04/17 | 17/08/2017 | 14 |
| 14/YH/1282/AM09 | PF-06252616 in Boys with Duchenne Muscular Dystrophy | Substantial | 12/07/2017 | 16 |

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| | | Amendment 8, 12/07/17 | | |
| 14/YH/1282/AM11 | PF-06252616 in Boys with Duchenne Muscular Dystrophy | Substantial Amendment 9, 18/12/2017 | 18/12/2017 | 18 |
| 15/YH/0025/AM01 | Leeds Breast Research Tissue Bank | Substantial Amendment 1, 24/07/17 | 26/07/2017 | 12 |
| 15/YH/0051/AM29 | SCIMITAR Plus (version 1.0) | Substantial Amendment 30, 09/06/17 | 15/06/2017 | 7 |
| 15/YH/0051/AM30 | SCIMITAR Plus (version 1.0) | Substantial Amendment 31, 30/08/17 | 31/08/2017 | 26 |
| 15/YH/0051/AM31 | SCIMITAR Plus (version 1.0) | Substantial Amendment 32, 03/10/17 | 09/10/2017 | 7 |
| 15/YH/0080/AM02 | Leeds Multidisciplinary Research Tissue Bank | Substantial Amendment 2, 28/02/18 | 01/03/2018 | 7 |
| 15/YH/0125/AM09 | Phase 1b/2 Participants with Waldenström Macroglobulinemia ACE-WM-001 | Substantial Amendment 6, 28/03/17 | 28/03/2017 | 21 |
| 15/YH/0125/AM10 | Phase 1b/2 Participants with Waldenström Macroglobulinemia ACE-WM-001 | Substantial Amendment 7, 17/07/17 | 17/07/2017 | 8 |
| 15/YH/0125/AM14 | Phase 1b/2 Participants with Waldenström Macroglobulinemia ACE-WM-001 | Substantial Amendment 8, 23/11/17 | 23/11/2017 | 16 |
| 15/YH/0125/AM15 | Phase 1b/2 Participants with Waldenström Macroglobulinemia ACE-WM-001 | Substantial Amendment 9, 23/02/18 | 23/02/2018 | 20 |
| 15/YH/0252/AM02 | POD study | Substantial Amendment 2, 30/03/17 | 08/05/2017 | 18 |
| 15/YH/0294/AM05 | Pro-Euro-DILI Registry version 1 | Substantial Amendment 3, | 28/03/2017 | 23 |

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|-----------------|---|------------------------------------|------------|----|
| | | 22/03/17 | | |
| 15/YH/0294/AM09 | Pro-Euro-DILI Registry version 1 | Substantial Amendment 4, 02/10/17 | 22/11/2017 | 22 |
| 15/YH/0309/AM11 | Type-2 Diabetes; Adults with inadequate glycemc control on Metformin | Substantial Amendment 6, 09/02/18 | 16/02/2018 | 9 |
| 15/YH/0311/AM01 | UCL/UCLH Biobank for Studying Health and Disease | Substantial Amendment 7, 24/07/17 | 18/07/2017 | 7 |
| 15/YH/0388/AM06 | Ceritinib food effect study in ALK positive NSCLC patients | Substantial Amendment 5, 14/03/17 | 15/03/2017 | 16 |
| 15/YH/0388/AM08 | Ceritinib food effect study in ALK positive NSCLC patients | Substantial Amendment 7, 05/09/17 | 04/09/2017 | 14 |
| 15/YH/0428/AM14 | 4228: DUALâ„¢ VIII – Durability, IDegLira vs IGlar in Type 2 diabetes | Substantial Amendment 7, 30/11/17 | 30/11/2017 | 14 |
| 15/YH/0434/AM10 | Idelalisib Dose Optimisation Study | Substantial Amendment 8, 24/03/17 | 24/03/2017 | 10 |
| 15/YH/0434/AM13 | Idelalisib Dose Optimisation Study | Substantial Amendment 11, 01/11/17 | 01/11/2017 | 10 |
| 15/YH/0434/AM14 | Idelalisib Dose Optimisation Study | Substantial Amendment 12, 14/11/17 | 14/11/2017 | 25 |
| 15/YH/0434/AM15 | Idelalisib Dose Optimisation Study | Substantial Amendment 13, 03/01/18 | 03/01/2018 | 22 |
| 15/YH/0484/AM07 | I1F-MC-RHBF Ixekizumab in patients with active psoriatic arthritis | Substantial Amendment 5, 03/07/17 | 03/07/2017 | 22 |
| 15/YH/0484/AM08 | I1F-MC-RHBF Ixekizumab in patients with active psoriatic arthritis | Substantial Amendment 6, 05/12/17 | 05/12/2017 | 9 |

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| 15/YH/0484/AM10 | I1F-MC-RHBF Ixekizumab in patients with active psoriatic arthritis | Substantial Amendment 7, 09/03/18 | 09/03/2018 | 11 |
| 15/YH/0485/AM05 | GP15-301 Study to compare GP2015 and Enbrel® in Rheumatoid Arthritis | Substantial Amendment 3, 31/3/17 | 31/03/2017 | 20 |
| 15/YH/0489/AM02 | REVAKI-2 | Substantial Amendment 2, 12/06/17 | 13/06/2017 | 20 |
| 15/YH/0490/AM09 | MK-3682B in Hepatitis C (GT1 or GT3) patients who have failed a DAA | Substantial Amendment 8, 14/06/17 | 14/06/2017 | 28 |
| 15/YH/0490/AM13 | MK-3682B in Hepatitis C (GT1 or GT3) patients who have failed a DAA | Substantial Amendment 9, 04/08/17 | 04/08/2017 | 18 |
| 15/YH/0530/AM06 | CLARITY | Substantial Amendment 5, 26/04/17 | 26/04/2017 | 19 |
| 15/YH/0535/AM11 | TRANSITION_LCZ696 pre/ post discharge in acute heart failure | Substantial Amendment 8, 21/09/17 | 21/09/2017 | 15 |
| 15/YH/0535/AM13 | TRANSITION_LCZ696 pre/ post discharge in acute heart failure | Substantial amendment 10 - 17.10.17 | 17/10/2017 | 14 |
| 15/YH/0535/AM16 | TRANSITION_LCZ696 pre/ post discharge in acute heart failure | Substantial Amendment 11, 29/11/17 | 29/11/2017 | 14 |
| 16/YH/0024/AM02 | 233AS101 - Phase 1 Study in ALS | Substantial Amendment 2, 21/03/2017 | 17/03/2017 | 21 |
| 16/YH/0024/AM03 | 233AS101 - Phase 1 Study in ALS | Substantial Amendment 3, 05/05/17 | 12/06/2017 | 15 |
| 16/YH/0024/AM05 | 233AS101 - Phase 1 Study in ALS | Substantial Amendment 4, 30/01/18 | 30/01/2018 | 20 |
| 16/YH/0026/AM01 | Developing clinical outcome assessments for rare diseases | Substantial | 23/08/2017 | 28 |

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| | | Amendment 4, 30/01/18 | | |
| 16/YH/0032/AM03 | Rituximab Objective Outcome measures Trial in SLE (ROOTS) | Substantial Amendment 2, 21/07/17 | 09/08/2017 | 11 |
| 16/YH/0068/AM11 | A longer-term care strategy for stroke – a feasibility study | Substantial Amendment 9, 22/02/18 | 02/03/2018 | 18 |
| 16/YH/0078/AM02 | Detecting transitional cell carcinoma from haematuria | Substantial Amendment 1, 09/02/17 | 13/02/2017 | 22 |
| 16/YH/0078/AM03 | Detecting transitional cell carcinoma from haematuria | Substantial Amendment 2, 25/07/17 | 26/07/2017 | 23 |
| 16/YH/0081/AM04 | TULIP-LN1 | Substantial Amendment 4, 14/03/17 | 14/03/2017 | 24 |
| 16/YH/0081/AM05 | TULIP-LN1 | Substantial Amendment 5, 16/08/17 | 16/08/2017 | 34 |
| 16/YH/0083/AM08 | PEGPH20 in patients with pancreatic cancer with high levels of HA | Substantial Amendment 8, 08/05/17 | 08/05/2017 | 7 |
| 16/YH/0083/AM11 | PEGPH20 in patients with pancreatic cancer with high levels of HA | Substantial Amendment 9, 02/08/17 | 02/08/2017 | 18 |
| 16/YH/0083/AM12 | PEGPH20 in patients with pancreatic cancer with high levels of HA | Substantial amendment 10 - 12.09.17 | 12/09/2017 | 21 |
| 16/YH/0083/AM13 | PEGPH20 in patients with pancreatic cancer with high levels of HA | Substantial Amendment 11, 14/11/17 | 14/11/2017 | 8 |
| 16/YH/0114/AM02 | Posture and Mobility in Care Homes. | Substantial Amendment 2, 06/04/17 | 06/04/2017 | 13 |
| 16/YH/0114/AM03 | Posture and Mobility in Care Homes. | Substantial Amendment 3, | 20/07/2017 | 18 |

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| | | 17/07/17 | | |
| 16/YH/0114/AM04 | Posture and Mobility in Care Homes. | Substantial Amendment 4, 08/08/17 | 17/08/2017 | 20 |
| 16/YH/0114/AM05 | Posture and Mobility in Care Homes. | Substantial Amendment 5, 26/09/17 | 28/09/2017 | 18 |
| 16/YH/0114/AM06 | Posture and Mobility in Care Homes. | Substantial Amendment 6, 10/11/17 | 23/11/2017 | 15 |
| 16/YH/0151/AM01 | The ZOLMENO study | Substantial Amendment 1, 13/04/17 | 16/05/2017 | 14 |
| 16/YH/0224/AM01 | The effect of DHA- & EPA-enriched oils on cognitive function and mood | Substantial amendment 1 - 13.09.17 | 13/09/2017 | 12 |
| 16/YH/0234/AM04 | TOPSAT2 | Substantial Amendment 1, 25/01/18 | 06/02/2018 | 10 |
| 16/YH/0238/AM08 | Journeying through Dementia | Substantial Amendment 3, 14/06/17 | 15/06/2017 | 22 |
| 16/YH/0238/AM09 | Journeying through Dementia | Substantial Amendment 4, 18/08/17 | 21/08/2017 | 13 |
| 16/YH/0238/AM11 | Journeying through Dementia | Substantial Amendment 5, 30/10/17 | 31/10/2017 | 21 |
| 16/YH/0364/AM02 | Understanding asthma phenotypes | Substantial Amendment 2, 24/03/17 | 12/04/2017 | 20 |
| 16/YH/0364/AM03 | Understanding asthma phenotypes | Substantial Amendment 3, 21/10/17 | 16/11/2017 | 11 |
| 16/YH/0371/AM04 | eRAPID feasibility pilot study in pelvic radiotherapy | Substantial Amendment 1, 20/06/17 | 23/06/2017 | 8 |

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| 16/YH/0371/AM05 | eRAPID feasibility pilot study in pelvic radiotherapy | Substantial Amendment 2, 31/07/17 | 09/08/2017 | 22 |
| 16/YH/0396/AM01 | URoBank: Urothelial Research Tissue Bank | Substantial Amendment 1, 07/11/17 | 09/11/2017 | 25 |
| 16/YH/0407/AM01 | LILAC: Effect on Patient Reported Outcomes of Surgery and SABR (V 1.0) | Substantial Amendment 1, 18/04/17 | 28/04/2017 | 13 |
| 16/YH/0420/AM05 | Feasibility of an online rehabilitation program | Substantial amendment 2 - 12.10.17 | 12/10/2017 | 8 |
| 16/YH/0452/AM02 | VINILO | Substantial Amendment 2, 08/03/17 | 24/03/2017 | 23 |
| 16/YH/0452/AM05 | VINILO | Substantial Amendment 5, 18/12/17 | 04/01/2018 | 12 |
| 16/YH/0461/AM02 | THE LONG TERM SAFETY OF PF-06252616 IN BOYS WITH DUCHENNE MUSCULAR DYS | Substantial Amendment 1, 13/07/17 | 13/07/2017 | 19 |
| 16/YH/0461/AM05 | THE LONG TERM SAFETY OF PF-06252616 IN BOYS WITH DUCHENNE MUSCULAR DYS | Substantial Amendment 2, 18/12/2017 | 18/12/2017 | 18 |
| 16/YH/0469/AM04 | 1297.4 - BI695501 versus Humira in patients with active Crohns disease | Substantial Amendment 4, 10/05/17 | 10/05/2017 | 20 |
| 16/YH/0469/AM05 | 1297.4 - BI695501 versus Humira in patients with active Crohns disease | Substantial Amendment 5, 18/01/18 | 18/01/2018 | 21 |
| 16/YH/0489/AM01 | Secukinumab-Phase IV-New Onset plaque Psoriasis-STEPIN Study | Substantial Amendment 1, 16/05/17 | 16/05/2017 | 14 |
| 16/YH/0489/AM02 | Secukinumab-Phase IV-New Onset plaque Psoriasis-STEPIN Study | Substantial Amendment 2, 11/04/17 | 22/08/2017 | 15 |
| 16/YH/0500/AM01 | Phase 1b 2 part study to assess LAM-001 in female subjects | Substantial | 08/03/2017 | 21 |

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| | with LAM | Amendment 1, 08/03/17 | | |
| 17/YH/0024/AM01 | Connected Health Cities: Data linkage of urgent care data | Substantial Amendment 1, 23/05/17 | 13/06/2017 | 11 |
| 17/YH/0071/AM01 | Esperion 1002-050 - Phase 3 Ext Study of ETC-1002 for Hyperlipidaemia | Substantial Amendment 1, 09/05/17 | 09/06/2017 | 18 |
| 17/YH/0071/AM03 | Esperion 1002-050 - Phase 3 Ext Study of ETC-1002 for Hyperlipidaemia | Substantial Amendment 3, 15/01/18 | 06/02/2018 | 10 |
| 17/YH/0078/AM01 | CV markers of stroke | Substantial Amendment 1, 03/08/17 | 03/08/2017 | 18 |
| 17/YH/0096/AM01 | Penicillin Allergy De-Labeling in Elective Surgical patients (PADLES) | Substantial Amendment 1, 31/10/17 | 31/10/2017 | 7 |
| 17/YH/0096/AM02 | Penicillin Allergy De-Labeling in Elective Surgical patients (PADLES) | Substantial Amendment 2, 05/01/18 | 05/01/2018 | 11 |
| 17/YH/0106/AM01 | Exploring perspectives of sedentary behaviour in stroke survivors | Substantial Amendment 1, 30/01/18 | 01/02/2018 | 18 |
| 17/YH/0117/AM01 | VINDICATE-MI | Substantial Amendment 1, 13/10/17 | 31/10/2017 | 21 |
| 17/YH/0118/AM01 | Empagliflozin vs metformin in PCOS | Substantial Amendment 1, 16/08/17 | 17/08/2017 | 16 |
| 17/YH/0141/AM02 | Cancer Needs Assessment in Primary Care (CANAssess:PC) | Substantial amendment 1 - 10.08.17 | 10/08/2017 | 18 |
| 17/YH/0145/AM01 | Assessment of range of motion in total knee arthroplasty | Substantial Amendment 1, 07/08/17 | 17/08/2017 | 20 |
| 17/YH/0186/AM03 | Efficacy and safety of oral GKT137831 | Substantial Amendment 2, | 18/01/2018 | 14 |

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| | | 18/01/18 | | |
| 17/YH/0187/AM01 | PRISM | Substantial amendment 1 - 21.08.17 | 21/08/2017 | 13 |
| 17/YH/0255/AM01 | A Phase 1 Study of AZD4785 in Patients with Advanced Solid Tumours | Substantial Amendment 1, 22/12/17 | 22/12/2017 | 7 |
| 17/YH/0256/AM01 | What I Need in School (WINS) | Substantial Amendment 1, 29/11/17 | 06/12/2017 | 13 |
| 17/YH/0256/AM03 | What I Need in School (WINS) | Substantial Amendment 2, 01/02/18 | 02/02/2018 | 10 |
| 17/YH/0261/AM01 | Leeds Osteoarthritis of the Foot study (LOFT) | Substantial Amendment 1, 21/08/17 | 29/08/2017 | 21 |
| 17/YH/0286/AM01 | Microarray for Rapid Pathogen Identification in ventilated pneumonia | Substantial Amendment 1, 11/01/18 | 12/01/2018 | 15 |
| 17/YH/0313/AM01 | A pilot study of efficacy, safety and tolerability of AX-8 in cough | Substantial Amendment 1, 28/09/17 | 05/10/2017 | 11 |
| 17/YH/0313/AM02 | A pilot study of efficacy, safety and tolerability of AX-8 in cough | Substantial Amendment 2, 21/12/2017 | 29/12/17 | 18 |
| 17/YH/0329/AM04 | Generation 1-CAD106 and CNP520 in participants at risk of Alzheimer's | Substantial Amendment 2, 17/01/18 | 19/01/2018 | 7 |
| 17/YH/0329/AM05 | Generation 1-CAD106 and CNP520 in participants at risk of Alzheimer's | Substantial Amendment 3, 07/02/18 | 07/02/2018 | 11 |
| 17/YH/0336/AM01 | Comprehensive Geriatric Assessment in Primary Care: A Feasibility RCT | Substantial Amendment 1, 03/11/18 | 24/01/2018 | 12 |
| 17/YH/0344/AM02 | DVT after cardiac procedure | Substantial Amendment 1, 10/01/18 | 16/02/2018 | 16 |

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| 17/YH/0369/AM01 | Phase 3 study of BGB-3111 in CLL or SLL | Substantial Amendment 1, 06/12/17 | 06/12/2017 | 12 |
| 17/YH/0369/AM05 | Phase 3 study of BGB-3111 in CLL or SLL | Substantial Amendment 5, 09/03/18 | 09/03/2018 | 7 |
| 17/YH/0390/AM01 | SOTA-EMPA | Substantial Amendment 1, 01/02/18 | 01/02/2018 | 18 |
| 17/YH/0404/AM01 | Morphine or IV Paracetamol in Acutely Injured Neck of Femur Fractures | Substantial Amendment 1, 25/01/18 | 26/01/2018 | 19 |

Unfavourable opinion

| Amendment REC Reference | Title | Version | Date | Number of Days on Clock |
|-------------------------|---|--------------------------------|------------|-------------------------|
| 16/YH/0406/AM08 | Ambulance CPAP: Use, Treatment Effect and Economics feasibility study | Substantial Amendment 3, 21/12 | 21/12/2017 | 21 |

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 |
|-------------------------|---|--------------------------------|------------|-------------------------|
| 16/YH/0406/AM08/1 | Ambulance CPAP: Use, Treatment Effect and Economics feasibility study | Modified Amendment 3, 16/02/18 | 16/02/2018 | 2 |

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 |
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|---------------|-------|-------------------------|

Proportionate review applications for ethical review over 21 day timeline

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

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

Modified Amendments over 14 day timeline

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