

London - Hampstead Research Ethics Committee

Annual Report

01 April 2016 - 31 March 2017



Part 1 – Committee Membership and Training

| | |
|------------------------------|--|
| Name of REC: | London - Hampstead Research Ethics Committee |
| Type of REC: | Recognised, Type I and Type III |
| Type of Flag: | Phase I in healthy volunteers, Research involving Children |
| Chair: | Miss Stephanie Ellis, BEM |
| Vice-Chair: | Dr Manish Saxena (but vacant as of 7 April 2017) |
| Alternate Vice-Chair: | Mr Paul Hardiman |
| REC Manager: | Mr Matt Rogerson |
| REC Assistant: | Miss Amber Ecclestone (1 April 2016 to 30 June 2016) Miss Laila Sarwar (REC Admin Assistant; 1 September 2016 to 3 March 2017) Miss Nafeesa Khanam (6 March to date) |
| Committee Address: | Barlow House 3rd Floor 4 Minshull Street Manchester M1 3DZ |
| Telephone: | 02071048127 |
| Email: | nrescommittee.london-hampstead@nhs.net |

Chair's overview of the past year:

This was my fifth year as Chair of Hampstead REC. It has been another enjoyable year. I am grateful to everyone on the committee. I know we enjoy the work but it is hard work and takes a lot of commitment. I am particularly pleased with what a friendly helpful group of people the committee is.

We lost two members this year: Wendy and Jacqueline. I miss their helpful advice. On the other hand we have two new members Guru and Francesca and they have both already shown that they are great assets.

Matt continues to be our very able Manager supporting us and ensuring we get the work done. We lost two members of staff: Amber and Laila. I was sorry to see them both go and wish them well. Nafeesa has joined us and she has already shown she too will be a valuable member of the team.

We passed our three yearly audit with flying colours. No mean feat, as the standards set by the HRA are, quite rightly, very high. The result reflects both the hard work of our management team and that members do an excellent job in keeping up with their conditions of membership and replying to the countless emails we send. Well done everyone.

I am always pleased with how many researchers come back to us - they clearly find us helpful. We have worked hard to achieve this and it is good to know we are helping researchers do good research.

On a slightly selfish and self-promoting note I was delighted to be given a New Year's Honour - a British Empire Medal (BEM). Although I have been given this I would be the first to admit that it is really for the whole Committee (and indeed other RECs). It is good that the work of REC members has been recognised in the honours.

I thank everyone for being such a great, friendly committee.

Stephanie Ellis, BEM

London - Hampstead Research Ethics Committee Membership

| Name | Profession | Expert or Lay | Dates | |
|-------------------------------------|--|---------------|------------|------------|
| | | | Appointed | Left |
| Dr Waheeb Atia | Retired Consultant Physician | Expert | 01/11/2010 | |
| Mrs Jacqueline Birks | Senior Medical Statistician | Expert | 12/10/2008 | 02/08/2016 |
| Dr Rahul Chodhari | Consultant Paediatrician | Expert | 03/04/2008 | |
| Miss Stephanie Ellis, BEM | Former Civil Servant | Lay Plus | 01/04/2012 | |
| Dr Alicia Isabel Etchegoyen Holiday | Psychiatrist | Expert | 12/11/2013 | |
| Dr Kanagasabai Ganeshaguru | Retired Scientist | Lay | 01/10/2016 | |
| Mr Paul Hardiman | Consultant Gynaecologist/Senior Lecturer in Obstetrics and Gynaecology | Expert | 01/09/2010 | |
| Dr Michael Jacobs | Retired Academic Pharmacologist | Lay | 14/05/2013 | |
| Miss Monica Jefford | Retired Midwife | Expert | 31/08/2011 | |
| Miss Mina Karamshi | Specialist Sister in Radiology | Expert | 02/11/2010 | |
| Dr Jane Lees-Millais | General Practitioner | Expert | 01/07/2011 | |
| Ms Anna Osadcow | Clinical Trials Research Pharmacist | Expert | 01/01/2013 | |
| Ms Ann Rosenthal | Literary Consultant (Retired) | Lay Plus | 01/01/2014 | |
| Dr. Manish Saxena | Clinical Lecturer and Clinical Research Fellow | Expert | 01/07/2013 | |
| Mrs Arlene Renee Seaton | Retired Medical Publisher | Lay Plus | 06/02/2013 | |
| Dr Francesca Silverton | Statistics Teacher | Lay | 01/02/2017 | |
| Mrs Wendy Spicer | Pharmacist | Expert | 01/12/2005 | 01/12/2016 |
| Dr Latha Padma Weston | Consultant Psychiatrist | Expert | 14/12/2011 | |

London - Hampstead Research Ethics Committee: Deputy Members

| Name | Profession | Status | Meeting date attended |
|---------------------|--|--------|-----------------------|
| Dr Victoria Chapman | Consultant Child and Adolescent Psychiatrist | Expert | 14/12/2016 |
| Dr Victoria Chapman | Consultant Child and Adolescent Psychiatrist | Expert | 09/11/2016 |
| Dr Victoria Chapman | Consultant Child and Adolescent Psychiatrist | Expert | 14/09/2016 |
| Dr Victoria Chapman | Consultant Child and Adolescent Psychiatrist | Expert | 11/05/2016 |

London - Hampstead Research Ethics Committee: Co-opted Members

London - Hampstead Research Ethics Committee: Members' Declarations of Interest:

| Name | Declaration of Interest | Date |
|-------------------------------------|--|-------------|
| Dr Waheeb Atia | None | 16/03/2017 |
| Dr Victoria Chapman | None | 31/03/2017 |
| Dr Rahul Chodhari | Consultancy work on one occasion with milk formula company. | 12/10/2016 |
| Miss Stephanie Ellis, BEM | None | 01/09/2016 |
| Dr Alicia Isabel Etchegoyen Holiday | None | 31/03/2017 |
| Dr Kanagasabai Ganeshaguru | none | 12/10/2016 |
| Mr Paul Hardiman | None | 14/09/2016 |
| Dr Michael Jacobs | None | 16/03/2017 |
| Miss Monica Jefford | <p>Monica has Shareholdings in:</p> <p>British Telecom; Iberdola; SSE plc</p> <p>Monica has connections with:</p> <p>St Andrew's Church, Coulsdon (member) Coulsdon Churches Together (chair) Croydon Churches Floating Shelter (volunteer) St Andrew's Church Contact Group (Co-ordinator) Croydon Neighbourhood Care Association (affiliation) Croydon Adult Social Services (User Panel member) Croydon Voluntary Action (User Panel member) Bowel Cancer UK (volunteer) The Royal Marsden NHS Foundation Trust: i) Patient and Carer Research Review Panel ii) Clinical Research Facility member and studies co-investigator iii) PPI with the Biomedical Research Centre iv) Patient and Carer Advisory Group member</p> <p>Institute of Cancer Research: Trial Management Group (member) NCRI/N (member) Colorectal Clinical Studies Group (member) SE London Consumer Research Panel (member) NIHR Clinical Research Network - South London (member) Imperial College (PPI sessions with medical students) Guy's and St Thomas' NHS Foundation Trust (Chaplain)</p> | 30/08/2016 |
| Miss Mina Karamshi | None | 09/11/2016 |

| | | |
|-------------------------|---|------------|
| Dr Jane Lees-Millais | None | 22/08/2016 |
| Ms Anna Osadcow | Panel member of CPAS (Chemotherapy & Pharmacy Advisory Service – under NIHR) – the remit of which is to (independently) review draft cancer services trial protocols & provide advice on IMPs & other details of protocols. Primarily employed as a clinical trials pharmacist | 31/03/2017 |
| Ms Ann Rosenthal | Son, Adam Rosenthal, is a Consultant at UCH. If any research study mentions his name an interest would be declared. | 23/08/2016 |
| Mrs Arlene Renee Seaton | Chair of Ethics Committee, IVF Clinic Lister Hospital, Chelsea, London | 25/08/2016 |
| Dr Francesca Silverton | None | 16/03/2017 |
| Dr Latha Padma Weston | Connection: Trustee at Barnet Bereavement Service. Other activities in research: PI in NMDA antibody study BEHMHT | 31/03/2017 |

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

| Month | Date | Number of Members Present at Meeting |
|-----------|------------|--------------------------------------|
| April | 13/04/2016 | 12 |
| May | 11/05/2016 | 9 |
| June | 08/06/2016 | 11 |
| July | 13/07/2016 | 8 |
| September | 14/09/2016 | 11 |
| October | 12/10/2016 | 10 |
| November | 09/11/2016 | 10 |
| December | 14/12/2016 | 12 |
| January | 11/01/2017 | 9 |
| February | 08/02/2017 | 10 |

10 full committee meetings were held during the reporting period.

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

| Month | Date | Number of Members Present at Meeting |
|-----------|------------|--------------------------------------|
| April | 13/04/2016 | 3 |
| May | 25/05/2016 | 3 |
| July | 27/07/2016 | 3 |
| August | 24/08/2016 | 3 |
| September | 28/09/2016 | 3 |
| October | 26/10/2016 | 3 |
| November | 24/11/2016 | 3 |
| December | 21/12/2016 | 3 |
| January | 25/01/2017 | 3 |
| February | 28/02/2017 | 3 |
| March | 22/03/2017 | 3 |

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

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

| Month | Date | Number of Members Present at Meeting |
|-------|------------|--------------------------------------|
| April | 06/04/2016 | 2 |
| April | 20/04/2016 | 3 |
| May | 02/05/2016 | 2 |
| May | 16/05/2016 | 2 |
| May | 30/05/2016 | 2 |
| June | 13/06/2016 | 2 |
| July | 04/07/2016 | 2 |
| July | 18/07/2016 | 2 |

| | | |
|-----------|------------|---|
| August | 01/08/2016 | 2 |
| August | 15/08/2016 | 2 |
| September | 05/09/2016 | 2 |
| September | 19/09/2016 | 2 |
| October | 03/10/2016 | 2 |
| October | 17/10/2016 | 2 |
| November | 01/11/2016 | 2 |
| November | 14/11/2016 | 2 |
| November | 29/11/2016 | 2 |
| December | 19/12/2016 | 2 |
| January | 02/01/2017 | 2 |
| January | 16/01/2017 | 2 |
| January | 30/01/2017 | 2 |
| February | 10/02/2017 | 2 |
| February | 27/02/2017 | 2 |
| March | 13/03/2017 | 2 |
| March | 27/03/2017 | 2 |

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

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

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

| Name | Number of Meetings Attended |
|-------------------------------------|------------------------------------|
| Dr Waheeb Atia | 10 |
| Mrs Jacqueline Birks | 3 |
| Dr Victoria Chapman | 4 |
| Dr Rahul Chodhari | 3 |
| Miss Stephanie Ellis, BEM | 10 |
| Dr Alicia Isabel Etchegoyen Holiday | 6 |
| Dr Kanagasabai Ganeshaguru | 5 |
| Mr Paul Hardiman | 6 |
| Dr Michael Jacobs | 7 |
| Miss Monica Jefford | 6 |
| Miss Mina Karamshi | 7 |
| Dr Jane Lees-Millais | 5 |
| Ms Anna Osadcow | 7 |
| Ms Ann Rosenthal | 5 |
| Dr. Manish Saxena | 1 |
| Mrs Arlene Renee Seaton | 5 |
| Dr Francesca Silverton | 1 |
| Mrs Wendy Spicer | 5 |
| Dr Latha Padma Weston | 6 |

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

| Name | Number of Meetings Attended |
|-------------------------------------|------------------------------------|
| Dr Waheeb Atia | 1 |
| Mrs Jacqueline Birks | 1 |
| Dr Rahul Chodhari | 2 |
| Miss Stephanie Ellis, BEM | 11 |
| Dr Alicia Isabel Etchegoyen Holiday | 1 |
| Dr Kanagasabai Ganeshaguru | 1 |
| Mr Paul Hardiman | 2 |
| Dr Michael Jacobs | 2 |
| Miss Monica Jefford | 3 |
| Dr Jane Lees-Millais | 2 |
| Ms Anna Osadcow | 1 |
| Ms Ann Rosenthal | 2 |
| Mrs Arlene Renee Seaton | 1 |
| Mrs Wendy Spicer | 1 |
| Dr Latha Padma Weston | 2 |

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

| Name | Number of Meetings Attended |
|-------------------------------------|------------------------------------|
| Dr Waheeb Atia | 2 |
| Dr Rahul Chodhari | 1 |
| Miss Stephanie Ellis, BEM | 25 |
| Dr Alicia Isabel Etchegoyen Holiday | 3 |
| Dr Kanagasabai Ganeshaguru | 1 |
| Dr Michael Jacobs | 2 |
| Miss Monica Jefford | 2 |
| Miss Mina Karamshi | 3 |
| Dr Jane Lees-Millais | 2 |
| Ms Anna Osadcow | 1 |
| Ms Ann Rosenthal | 2 |
| Dr. Manish Saxena | 2 |
| Mrs Arlene Renee Seaton | 3 |
| Mrs Wendy Spicer | 1 |
| Dr Latha Padma Weston | 1 |

Training 01 April 2016 - 31 March 2017

| Name of Member | Date | Event(s) attended |
|--|------------|---|
| Dr Waheeb Atia | 23/11/2016 | Equality & Diversity and Human Rights |
| Dr Rahul Chodhari | 31/08/2016 | Information Governance |
| Dr Rahul Chodhari | 13/09/2016 | Safeguarding Children L1, L2, L3 |
| Dr Rahul Chodhari | 21/09/2016 | Mental Capacity Act & DOLS |
| Dr Rahul Chodhari | 23/09/2016 | Safeguarding Adults L1 & L2 |
| Miss Stephanie Ellis, BEM | 18/10/2016 | Royal Marsden DDU visit for Phase I |
| Dr Alicia Isabel Etchegoyen Holiday | 18/10/2016 | Royal Marsden DDU Visit |
| Dr Kanagasabai Ganeshaguru | 16/02/2017 | National Members Training Day |
| Dr Michael Jacobs | 26/11/2016 | Equality Diversity & Human Rights |
| Miss Monica Jefford | 18/10/2016 | Royal Marsden DDU Visit |
| Miss Monica Jefford | 16/11/2016 | London REC Members' Training Day |
| Miss Monica Jefford | 01/12/2016 | Equality & Diversity |
| Miss Mina Karamshi | 03/04/2016 | Safeguarding Adults / Safeguarding Children L1 |
| Miss Mina Karamshi | 09/04/2016 | Information Governance |
| Miss Mina Karamshi | 09/04/2016 | Equality Diversity & Human Rights |
| Miss Mina Karamshi | 13/04/2016 | Safeguarding Adults / Children level 2 |
| Miss Mina Karamshi | 13/04/2016 | Mental Capacity Act & DOLS |
| Miss Mina Karamshi | 18/10/2016 | Royal Marsden DDU Unit |
| Dr Jane Lees-Millais | 29/09/2016 | Course on adoption and adopted children |
| Dr Jane Lees-Millais | 01/12/2016 | Serious case review re death of child in care |
| Ms Anna Osadcow | 11/04/2016 | GCP & Ethics Forum |
| Ms Ann Rosenthal | 16/11/2016 | Local Training Day - London REC Member Day |
| Mrs Arlene Renee Seaton | 16/11/2016 | London REC Members' Training Day |
| Mrs Arlene Renee Seaton | 21/11/2016 | Equality Diversity & Human Rights |
| Dr Francesca Silverton | 08/02/2017 | Induction for new RES Committee Members |
| Dr Latha Padma Weston | 01/09/2016 | Equality & Diversity |
| Dr Latha Padma Weston | 28/10/2016 | Safeguarding Children Level 3 |
| Dr Latha Padma Weston | 31/10/2016 | Information Governance Training |

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 | 19 | 35.19 |
| Phase 1 | 3 | 5.56 |
| Gene Therapy | 0 | 0.00 |
| Research Tissue Bank (including renewals) | 0 | 0.00 |
| Research Database (including renewals) | 0 | 0.00 |
| Others | 32 | 59.26 |
| Total Applications Reviewed | 54 | 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 | 0 |
| Number of student applications reviewed | 14 |
| Number of paediatric applications reviewed | 11 |
| Number of device applications reviewed | 3 |
| Number of prisoner applications reviewed | 0 |
| 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 | 9 | 16.67 |
| Favourable Opinion with Additional Conditions | 10 | 18.52 |
| Unfavourable Opinion | 2 | 3.70 |
| Provisional Opinion | 33 | 61.11 |
| Provisional Opinion Pending Consultation with Referee | 0 | 0.00 |
| Total | 54 | 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 | 59.26 |
| Further Information Favourable Opinion with Additional Conditions | 0 | 0.00 |
| Further Information Unfavourable Opinion | 0 | 0.00 |
| Favourable Opinion with Standard Conditions | 9 | 16.67 |
| Favourable Opinion with Additional Conditions | 10 | 18.52 |
| Unfavourable Opinion | 2 | 3.70 |
| 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 | 1.85 |
| Total | 54 | 100 |

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

| | |
|------------------------------------|-----------|
| Total Applications Reviewed | 23 |
|------------------------------------|-----------|

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

| | |
|--|---|
| Number of applications made invalid by the REC Manager | 1 |
| Number of studies withdrawn prior to the meeting | 1 |
| Number of student applications reviewed | 8 |
| Number of paediatric applications reviewed | 4 |
| Number of device applications reviewed | 2 |
| Number of qualitative applications reviewed | 0 |

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 | 8 | 34.78 |
| Favourable Opinion with Additional Conditions | 8 | 34.78 |
| No Opinion transfer to full committee for review | 2 | 8.70 |
| Provisional Opinion | 5 | 21.74 |
| Unfavourable Opinion | 0 | 0.00 |
| Total | 23 | 100 |

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

| | |
|---|--------|
| Average number of applications reviewed per full meeting | 5.40 |
| Number of completed applications for full ethical review | 53 |
| 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 completed applications for full ethical review over 40 days | 1 |
| Number of completed applications over 40 days as a % of total | 1.85% |
| Number of days taken to final decision – average (mean) | 25 |
| Number of completed proportionate review applications for ethical review | 21 |
| Number of completed proportionate review applications for ethical review over 14 days (<i>Please note, the timeline for the review of PR applications was extended from 14 to 21 calendar days in December 2016</i>) | 5 |
| Number of completed proportionate review applications for ethical review over 21 days | 1 |
| Number of completed proportionate review applications over 14 days as a % of total | 23.81% |
| Number of SSAs (non-Phase 1) reviewed | 9 |
| 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 | 2 |
| 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 | 163 |
| Number of completed substantial amendments over 35 days | 2 |
| Number of completed substantial amendments over 35 days as a % of total substantial amendments | 1.23% |
| Number of completed substantial amendments over 28 days | 18 |
| Number of completed substantial amendments over 28 days as a % of total substantial amendments | 11.04% |
| 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 | 175 |
| Number of substantial amendments received for information | 0 |
| Number of substantial amendments received for new sites/PIs | 44 |
| Number of annual progress reports received | 98 |
| Number of safety reports received | 28 |
| Number of Serious Adverse Events received | 0 |
| Number of final reports received | 17 |

Table 9.1: Breakdown of current status of all full applications reviewed within the reporting period

| Further Information Favourable Opinion with Standard Conditions | | |
|--|--|--------------------------------|
| REC Reference | Title | Number of Days on Clock |
| 16/LO/0637 | The role of I2BS in Huntington's disease | 20 |
| 16/LO/0638 | The role of I2BS in Parkinson's disease | 20 |
| 16/LO/0795 | Theory of Mind questionnaire in ABI | 29 |
| 16/LO/0806 | PPC - Personalised Programmes for Children | 28 |
| 16/LO/0816 | People with ID moving under Transforming Care | 31 |
| 16/LO/0905 | Treating carpal tunnel with a standardised massage protocol - 3.0 | 27 |
| 16/LO/1008 | Phase 2 study in participants with Hepatitis C and liver transplant | 24 |
| 16/LO/1022 | MEDI4736-MM-003 Phase 2 Relapsed and Refractory Multiple Myeloma | 23 |
| 16/LO/1024 | BEAT LUPUS | 27 |
| 16/LO/1035 | Immunodeficiency Patients Attitudes/Experiences of Corticosteroids | 21 |
| 16/LO/1222 | ATLANTIS Trial | 27 |
| 16/LO/1226 | Mainstreamed genetic testing: intentions, decision-making and outcomes | 34 |
| 16/LO/1233 | Endoscopic vidian neurectomy vs turbinoplasty for resistant rhinitis | 32 |
| 16/LO/1436 | Potential Predictors of Disease Progression in aHUS Patients. | 23 |
| 16/LO/1475 | Microparticles and microvascular dysfunction following STEMI | 28 |
| 16/LO/1792 | Endoscopic clot lavage in neonatal post-haemorrhagic hydrocephalus | 22 |
| 16/LO/1798 | Views of Future Care Planning | 22 |
| 16/LO/1809 | An Investigation into Perinatal Psychotherapy as a Treatment Option | 28 |
| 16/LO/1810 | A Phase 3 - Ublituximab in Combination with TGR-1202 | 29 |
| 16/LO/1875 | Safety & Efficacy of VX-440 Combination Therapy for Cystic Fibrosis | 32 |
| 16/LO/1959 | Placebo-Controlled Study of ANB020 in Patient with Atopic Dermatitis | 31 |
| 16/LO/1980 | Evaluation of Fat Grafting to treat Vulvar Lichen Sclerosus | 28 |
| 16/LO/2044 | CL04041023 - Clinical Rheumatoid Arthritis Development for Olokizumab | 33 |
| 16/LO/2138 | Pirates Assessment Tool | 32 |
| 16/LO/2192 | Supporting families when a child needs an amputation due to cancer | 23 |
| 16/LO/2203 | POM study of GSK2330811 in diffuse cutaneous systemic sclerosis 201247 | 23 |
| 17/LO/0014 | Cold therapy (HILOTHERM) in Adnexal surgeries | 17 |
| 17/LO/0040 | PB-102-F30-Open Label Study of PRX-102 in patients with Fabry Disease | 29 |
| 17/LO/0046 | 4345: N8 Given as ITI Treatment | 35 |
| 17/LO/0052 | The OPEN study | 45 |
| 17/LO/0089 | Phase 2 - SOF/VEL in Chronic HCV on Dialysis for Renal Disease | 30 |
| 17/LO/0179 | Safety & Tolerability of MEDI3506 in SAD/MAD Study | 20 |

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

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

| Favourable Opinion with Standard Conditions | | |
|--|--|--------------------------------|
| REC Reference | Title | Number of Days on Clock |
| 16/LO/0574 | MERCK - MS200662_0001 | 20 |
| 16/LO/0592 | IDRIS | 20 |
| 16/LO/1622 | Investigation of a new diet for the treatment of obesity in the NHS | 22 |
| 16/LO/1926 | PINC trial | 27 |
| 16/LO/1974 | Pulmonary Rehabilitation and Cardiovascular Risk in COPD | 27 |
| 16/LO/1978 | Sodium hyaluronate injection for plantaris friction syndrome | 27 |
| 16/LO/2186 | IMAT-Neuroblastoma | 21 |
| 16/LO/2213 | Association between gut permeability and immune function in children | 28 |
| 17/LO/0214 | RaNGO | 22 |

| Favourable Opinion with Additional Conditions | | |
|--|---|--------------------------------|
| REC Reference | Title | Number of Days on Clock |
| 16/LO/1017 | Care for people with Dementia given by Relatives at the End of life | 22 |
| 16/LO/1037 | Salivary pepsin in infant gastro-oesophageal reflux disease | 22 |
| 16/LO/1108 | HPV vaccinee follow up from previous study EUDRACT study 2008-006773-32 | 22 |
| 16/LO/1120 | Domiciliary Monitoring to Predict Exacerbations of COPD | 22 |
| 16/LO/1228 | Quadri meningo follow up of previous study (Eudract 2010-022505-18) | 22 |
| 16/LO/1692 | EORTC SHQ-C22 (Phase IV) | 22 |
| 17/LO/0044 | Medtronic Virgin-Back Study | 27 |
| 17/LO/0207 | RIFT (SSCR101) | 20 |
| 17/LO/0249 | CO39385: Study of Atezolizumab + Enzalutamide vs Enzalutamide in mCRPC | 20 |
| 17/LO/0251 | TGCT Observational Platform | 15 |

| Unfavourable Opinion | | |
|-----------------------------|--|--------------------------------|
| REC Reference | Title | Number of Days on Clock |
| 16/LO/0856 | Improving negative psychological outcomes at breast screening recall | 23 |
| 17/LO/0015 | Understanding unmet needs of family carers (iCARE) version 1.0 | 28 |

| 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 |
| 16/LO/0599 | Phase 2 study of Apremilast in Paediatric Plaque Psoriasis patients | 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 |
| 16/LO/0658 | Earwax metabolites in children with inherited metabolic diseases vs1.0 | 16 |
| 16/LO/0664 | Deceased Organ Donation and Health Literacy | 25 |
| 16/LO/1617 | Patient Experience of SSc-RP | 10 |
| 16/LO/1806 | Analysis of Eicosanoids in EBC from SCD patients. Version 1. | 7 |
| 17/LO/0567 | Crural tension measurement in laparoscopic anti-reflux surgery | 14 |

Further Information Favourable Opinion with Additional Conditions

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

Further Information Unfavourable Opinion

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

Favourable Opinion with Standard Conditions

| REC Reference | Title | Number of Days on Clock |
|---------------|--|-------------------------|
| 16/LO/0674 | Phenotyping in cicatricial conjunctivitis v1.0 | 14 |
| 16/LO/1819 | Retrospective study of remifentanyl analgesia and length of labour v1 | 6 |
| 16/LO/1995 | Biomarker analysis in GEP-NETS | 14 |
| 16/LO/2133 | Short & long-term visual outcomes following Non-Accidental Head Injury | 7 |
| 16/LO/2169 | (1) Comparing FRC in CF patients from two lung function tests | 10 |
| 17/LO/0209 | Analysis of Graves disease using microfluidics (Version 1) | 6 |
| 17/LO/0399 | 3D Simulation for Breast Conserving Therapy | 12 |
| 17/LO/0400 | One-day evaluation of a PEG cast-moulded soft contact lens | 13 |

Favourable Opinion with Additional Conditions

| REC Reference | Title | Number of Days on Clock |
|---------------|---|-------------------------|
| 16/LO/1019 | Effect of lifestyle on secondary prevention of breast cancer | 14 |
| 16/LO/1625 | Assessment of real life care (ARIADNE) | 9 |
| 16/LO/1633 | Microbial behaviour and response to polypropylene mesh | 13 |
| 16/LO/1815 | Optimising screening for the cardiotoxic effects of cancer therapy | 8 |
| 16/LO/2269 | Outcomes following endoscopic resection of complex colorectal lesions | 15 |
| 16/LO/2272 | Role of MitraClip in the treatment of mitral regurgitation | 14 |
| 17/LO/0569 | Clinical characterization of idiopathic sporadic ataxias | 20 |
| 17/LO/0570 | Fibre-optic guided tracheal intubation through SADs | 19 |

Unfavourable Opinion

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

| Further information response not complete | | |
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| 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 |
| 04/Q0501/119/AM05 | The Investigation of the cause and the mechanism of Immunodeficiency di | Amendment 5 | 21/06/2016 | 22 |
| 06/Q0501/45/AM09 | Frequency of follow-up for patients with intermediate adenomas. V.1 | 2 | 14/03/2017 | 25 |
| 07/Q0501/14/AM10 | Action of FASLODEX in progressive precocious puberty | Investigator's Brochure update | 07/12/2016 | 35 |
| 07/Q0501/14/AM11 | Action of FASLODEX in progressive precocious puberty | Substantial Amendment 9 | 27/03/2017 | 14 |
| 09/H0720/132/AM18 | Phase 3 study of Lenalidomide in castrate-resitant prostate cancer | Investigator's Brochure for Lefor Lenalidomide (Revlimid®) version 19.0 | 14/07/2016 | 8 |
| 09/H0720/132/AM19 | Phase 3 study of Lenalidomide in castrate-resitant prostate cancer | Investigator's Brochure for Lenalidomide (Revlimid®) version 20.0 | 21/07/2016 | 21 |
| 10/H0720/28/AM27 | The AIMS Study | 21 | 15/12/2016 | 28 |
| 10/H0720/80/AM05 | The UCH Preterm Development Project v1 | 5 | 01/08/2016 | 5 |
| 10/H0720/80/AM07 | The UCH Preterm Development Project v1 | 5.1 | 17/10/2016 | 28 |
| 10/H0720/82/AM06 | EFFORTLESS S-ICD Registry | 4 | 02/02/2017 | 18 |
| 10/H0720/88/AM14 | LUME-Lung 3. | IB V15, 06 Jun 2016 | 23/06/2016 | 13 |
| 10/H0720/88/AM15 | LUME-Lung 3. | 11 | 18/07/2016 | 36 |
| 10/H0720/88/AM16 | LUME-Lung 3. | 5 | 05/10/2016 | 22 |
| 10/H0720/88/AM17 | LUME-Lung 3. | 16 | 03/11/2016 | 16 |
| 10/H0720/88/AM19 | LUME-Lung 3. | 14 | 09/01/2017 | 12 |
| 11/LO/0425/AM20 | SYCAMORE | 17.0 | 09/09/2016 | 18 |
| 11/LO/0608/AM18 | Phase 2 study of MDV3100 for metastatic prostate cancer | Addendum to IB v8.0 | 08/07/2016 | 14 |

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|-----------------|--|-------------------------------------|------------|----|
| 11/LO/0608/AM19 | Phase 2 study of MDV3100 for metastatic prostate cancer | 5 | 24/06/2016 | 17 |
| 11/LO/1331/AM02 | A pilot qualitative study of severe and enduring eating disorders | Amendment number 4 23 February 2016 | 10/03/2016 | 5 |
| 11/LO/1634/AM05 | MRI assessment of small bowel motility | 5 | 20/12/2016 | 18 |
| 11/LO/2036/AM23 | Phase I/II Safety, PK & Efficacy Study of Oral Rucaparib | Substantial Amendment 14 | 25/08/2016 | 14 |
| 11/LO/2036/AM24 | Phase I/II Safety, PK & Efficacy Study of Oral Rucaparib | 15 | 11/08/2016 | 21 |
| 11/LO/2036/AM25 | Phase I/II Safety, PK & Efficacy Study of Oral Rucaparib | SA16 | 23/03/2017 | 18 |
| 12/LO/0025/AM21 | NN7088-3859 Trial Evaluating Safety and Efficacy of N8-GP in Haem A | Substantial Protocol Amendment | 22/06/2016 | 23 |
| 12/LO/0219/AM06 | A pedometer intervention to increase walking in adults: PACE-UP trial | 5 | 14/02/2017 | 27 |
| 12/LO/0219/AM07 | A pedometer intervention to increase walking in adults: PACE-UP trial | 6 | 21/03/2017 | 20 |
| 12/LO/1411/AM06 | NeSST2: The development of a non-invasive Short Synacthen Test | 5 | 05/12/2016 | 10 |
| 12/LO/1422/AM04 | LuDo | SA03 | 05/07/2016 | 16 |
| 12/LO/1458/AM04 | Long term health effects of women with APS | Amendment 3 | 14/04/2016 | 32 |
| 12/LO/1759/AM19 | OuTSMART | 16 | 01/12/2016 | 13 |
| 13/LO/0032/AM04 | Genetic and environmental risk factors for Acanthamoeba keratitis | 5 | 05/07/2016 | 23 |
| 13/LO/0482/AM08 | Reducing the frequency and severity of voices: AVATAR Clinical Trial | Amendment 08 | 29/04/2016 | 16 |
| 13/LO/0847/AM06 | IPF-PRoM Study | Protocol V6 17th March 2016 | 31/03/2016 | 4 |
| 13/LO/1321/AM13 | GB28547 - Lebrikizumab in patients with idiopathic pulmonary fibrosis | 7 | 23/02/2017 | 19 |
| 13/LO/1520/AM12 | Study Of Diabetic Nephropathy with Atrasentan | 9 | 23/09/2016 | 10 |
| 13/LO/1712/AM02 | MatImms@Imperial: A mother-infant study of immune responses to vaccine | Substantial Amendment Two | 11/05/2016 | 19 |
| 13/LO/1725/AM03 | Randomised comparison of iFR to FFR | FLAIR Version 4.3 13th June 20 | 15/06/2016 | 20 |
| 14/LO/0120/AM05 | Zibotentan better renal scleroderma outcome study (ZEBRA) | SA4 | 07/06/2016 | 28 |
| 14/LO/0120/AM06 | Zibotentan better renal scleroderma outcome study (ZEBRA) | 5 | 10/10/2016 | 21 |

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|-----------------|--|--|------------|----|
| 14/LO/0521/AM08 | Switching to, then stopping treatment with nilotinib for CML patients. | Protocol Amendment 4 | 01/09/2016 | 7 |
| 14/LO/0892/AM06 | Phase 1 study of MEDI4736 in Myelodysplastic Syndrome | Protocol Amendment 4, dated 01 Feb 2016 | 31/03/2016 | 26 |
| 14/LO/0892/AM08 | Phase 1 study of MEDI4736 in Myelodysplastic Syndrome | Updated IB Ed 9 | 29/06/2016 | 23 |
| 14/LO/0892/AM09 | Phase 1 study of MEDI4736 in Myelodysplastic Syndrome | SA7 | 03/08/2016 | 28 |
| 14/LO/1088/AM01 | Molecular Pathology of Glaucoma | 1 | 30/08/2016 | 25 |
| 14/LO/1409/AM01 | Acute Respiratory Tract Illness in an HIV infected population | 1 | 13/10/2016 | 24 |
| 14/LO/1739/AM13 | PRESIDE (9785-MA-1001) | SA3 | 21/07/2016 | 35 |
| 14/LO/2014/AM05 | Phase 3 ALN-TTRSC in Familial Amyloidotic Cardiomyopathy | Substantial Amendment 5 - Protocol Amendment 1 | 22/03/2016 | 5 |
| 14/LO/2014/AM06 | Phase 3 ALN-TTRSC in Familial Amyloidotic Cardiomyopathy | SA6 | 23/03/2016 | 12 |
| 14/LO/2014/AM09 | Phase 3 ALN-TTRSC in Familial Amyloidotic Cardiomyopathy | Substantial Amendment 7 - Updated Patient Alert Card | 02/06/2016 | 5 |
| 14/LO/2014/AM15 | Phase 3 ALN-TTRSC in Familial Amyloidotic Cardiomyopathy | 9 | 13/10/2016 | 11 |
| 14/LO/2014/AM16 | Phase 3 ALN-TTRSC in Familial Amyloidotic Cardiomyopathy | 10 | 14/10/2016 | 7 |
| 14/LO/2033/AM02 | PROVENT | 009339 | 25/05/2016 | 29 |
| 14/LO/2035/AM10 | Alnylam - ALN-TTR02-004 - TTR Mediated Polyneuropathy (FAP) | Updated IB Ed. 9 | 08/06/2016 | 27 |
| 14/LO/2037/AM04 | Riociguat in diffuse cutaneous systemic sclerosis (dcSSc) | Amd 04, Protocol V3.0 | 04/04/2016 | 22 |
| 14/LO/2037/AM05 | Riociguat in diffuse cutaneous systemic sclerosis (dcSSc) | BAY 63-2521 / 16277 | 15/04/2016 | 13 |
| 14/LO/2037/AM06 | Riociguat in diffuse cutaneous systemic sclerosis (dcSSc) | BAY 63-2521 / 16277 | 26/05/2016 | 12 |
| 14/LO/2037/AM08 | Riociguat in diffuse cutaneous systemic sclerosis (dcSSc) | BAY 63-2521 / 16277 PIC Sites | 01/07/2016 | 21 |
| 14/LO/2037/AM09 | Riociguat in diffuse cutaneous systemic sclerosis (dcSSc) | BAY 63-2521 / 16277 - newsletter | 20/07/2016 | 23 |
| 14/LO/2037/AM11 | Riociguat in diffuse cutaneous systemic sclerosis (dcSSc) | IBVAmd1 | 28/07/2016 | 34 |
| 14/LO/2037/AM12 | Riociguat in diffuse cutaneous systemic sclerosis (dcSSc) | 4.0 | 31/08/2016 | 23 |

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|-----------------|--|---|------------|----|
| 14/LO/2086/AM01 | Immune damage and repair after vascular injury | Amendment number 1 01/03/2015 | 04/04/2016 | 19 |
| 14/LO/2166/AM02 | A multimodal investigation of treatment enhancers for eating disorders | Amendment two | 13/04/2016 | 29 |
| 14/LO/2182/AM06 | TheraSphere in Unresectable Hepatocellular Carcinoma (HCC) TS-103 | Amendment 6 | 01/06/2016 | 6 |
| 14/LO/2182/AM12 | TheraSphere in Unresectable Hepatocellular Carcinoma (HCC) TS-103 | 11 | 29/11/2016 | 23 |
| 15/LO/0050/AM03 | Preschool wheeze: Inflammation/Infection Guided Management (PrIGMa) v1 | 1 | 19/09/2016 | 25 |
| 15/LO/0051/AM07 | FI intervention study (FINS) | V6.0 25th May 2016 | 10/06/2016 | 24 |
| 15/LO/0073/AM02 | Sclero XIII | Minor Amendment 1 and Substantial amendment 2 | 23/05/2016 | 15 |
| 15/LO/0075/AM06 | Phase 3 study in treatment-naive HIV-1 infected subjects | SA06 | 11/07/2016 | 11 |
| 15/LO/0075/AM07 | Phase 3 study in treatment-naive HIV-1 infected subjects | 07 | 27/07/2016 | 35 |
| 15/LO/0075/AM08 | Phase 3 study in treatment-naive HIV-1 infected subjects | Protocol V5.0 | 02/11/2016 | 26 |
| 15/LO/0273/AM03 | Randomised, Phase 3 study for subjects with Early Stage TNBC | Updated IB ed 10 dated 23/06/2016 | 11/08/2016 | 6 |
| 15/LO/0273/AM04 | Randomised, Phase 3 study for subjects with Early Stage TNBC | 5 | 31/08/2016 | 20 |
| 15/LO/0278/AM05 | Harvoni in Adolescents and Children with HCV | Protocol Amendment 4, IB v6 and updated PIS-ICF | 29/04/2016 | 21 |
| 15/LO/0278/AM07 | Harvoni in Adolescents and Children with HCV | 5 | 28/02/2017 | 16 |
| 15/LO/0282/AM04 | I1F-MC-RHBE Ixekizumab in patients with active psoriatic arthritis | 3 | 03/08/2016 | 28 |
| 15/LO/0282/AM05 | I1F-MC-RHBE Ixekizumab in patients with active psoriatic arthritis | SA04 | 23/03/2017 | 18 |
| 15/LO/0315/AM01 | Physical Activity Questionnaire for CKD | 01 | 06/05/2016 | 16 |
| 15/LO/0315/AM02 | Physical Activity Questionnaire for CKD | 2 | 31/08/2016 | 10 |
| 15/LO/0424/AM04 | PK of Efavirenz & Lopinavir Nano-Formulations in Healthy Volunteers | SSAT055 SA03 | 09/06/2016 | 28 |

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|-----------------|--|--|------------|----|
| 15/LO/0424/AM05 | PK of Efavirenz & Lopinavir Nano-Formulations in Healthy Volunteers | 04 | 01/11/2016 | 25 |
| 15/LO/0515/AM02 | SPARE: scalp sparing radiotherapy treatment to the whole brain | 1 | 05/05/2016 | 15 |
| 15/LO/0557/AM02 | Hypersexuality in neurological disorders. | Amendment number 2, 22/03/2016 | 30/03/2016 | 32 |
| 15/LO/0833/AM04 | IBIS 3 Feasibility version 1.0 | 3 | 27/04/2016 | 8 |
| 15/LO/0833/AM05 | IBIS 3 Feasibility version 1.0 | SA04 | 17/08/2016 | 6 |
| 15/LO/0844/AM02 | An Open-Label, Phase 2 Study of Neratinib in Patients With Solid Tumor | Amendment 2 | 05/04/2016 | 23 |
| 15/LO/0844/AM04 | An Open-Label, Phase 2 Study of Neratinib in Patients With Solid Tumor | 4 | 06/10/2016 | 23 |
| 15/LO/0984/AM03 | PM01183 - CORAIL Trail | Substantial Amendment #2 Updated ICFs | 05/04/2016 | 21 |
| 15/LO/0997/AM02 | Power Up | 2 | 06/10/2016 | 31 |
| 15/LO/1019/AM01 | Mood mAPPer | 1 | 08/08/2016 | 22 |
| 15/LO/1090/AM01 | Neutrophil defects and tooth loss in children | Amendment 01 | 25/04/2016 | 16 |
| 15/LO/1090/AM02 | Neutrophil defects and tooth loss in children | 2 | 05/09/2016 | 7 |
| 15/LO/1149/AM02 | RACE version 2 | Substantial Amendment 01 | 30/06/2016 | 4 |
| 15/LO/1477/AM04 | PRM-151-202 | Substantial Amendment for PRM-151-202 | 07/04/2016 | 14 |
| 15/LO/1477/AM05 | PRM-151-202 | Protocol v4.0 04/02/2016:PIS/ICF v2.2 06/06/2016 | 07/06/2016 | 30 |
| 15/LO/1585/AM02 | PB102F03: Extension Study of PRX-102 in Fabry Disease | Protocol V4, IB V4, ICF V2 | 07/04/2016 | 19 |
| 15/LO/1592/AM04 | QVA149_Indacaterol maleate/Glycopyrronium bromide_Phase IV_COPD | Amendment 4 | 14/04/2016 | 13 |
| 15/LO/1592/AM05 | QVA149_Indacaterol maleate/Glycopyrronium bromide_Phase IV_COPD | SA05 | 10/05/2016 | 16 |
| 15/LO/1592/AM06 | QVA149_Indacaterol maleate/Glycopyrronium bromide_Phase IV_COPD | 6 | 02/09/2016 | 6 |

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|-----------------|---|---|------------|----|
| 15/LO/1629/AM04 | Quality of life and wellbeing in pregnant women and new mothers V1 | 3: 11/04/2016 | 13/04/2016 | 41 |
| 15/LO/1680/AM01 | BioPolyâ,ç RS Partial Resurfacing Implant | 2.0 | 15/11/2016 | 25 |
| 15/LO/1681/AM03 | 1199.214 Nintedanib vs placebo in scleroderma related lung fibrosis | Substantial Amendment 2 | 24/03/2016 | 11 |
| 15/LO/1681/AM04 | 1199.214 Nintedanib vs placebo in scleroderma related lung fibrosis | Substantial Amendment 3 | 06/04/2016 | 21 |
| 15/LO/1681/AM05 | 1199.214 Nintedanib vs placebo in scleroderma related lung fibrosis | 4 | 04/08/2016 | 27 |
| 15/LO/1681/AM08 | 1199.214 Nintedanib vs placebo in scleroderma related lung fibrosis | 5 | 13/10/2016 | 11 |
| 15/LO/1681/AM09 | 1199.214 Nintedanib vs placebo in scleroderma related lung fibrosis | 6 | 27/01/2017 | 7 |
| 15/LO/1681/AM10 | 1199.214 Nintedanib vs placebo in scleroderma related lung fibrosis | 7 | 16/02/2017 | 19 |
| 15/LO/2027/AM01 | Knowledge mobilisation in critical care | Amendment 1 1/8/16 | 10/08/2016 | 13 |
| 15/LO/2098/AM05 | INTEREST study | 16 | 18/11/2016 | 13 |
| 15/LO/2100/AM02 | TAGS | TO-TAS-102-302 | 24/06/2016 | 13 |
| 15/LO/2100/AM03 | TAGS | 3.0 | 14/12/2016 | 30 |
| 15/LO/2100/AM04 | TAGS | 4.0 | 14/02/2017 | 28 |
| 16/LO/0017/AM01 | Phase I/II study - patients with previously treated solid tumours | SA #1 | 22/04/2016 | 27 |
| 16/LO/0017/AM03 | Phase I/II study - patients with previously treated solid tumours | 2 | 06/12/2016 | 17 |
| 16/LO/0017/AM04 | Phase I/II study - patients with previously treated solid tumours | 3 | 24/02/2017 | 18 |
| 16/LO/0029/AM10 | Phase 3 study with GS-9883/F/TAF in HIV-1, treatment naive subjects | Protocol Amendment 1.1 | 18/04/2016 | 32 |
| 16/LO/0029/AM11 | Phase 3 study with GS-9883/F/TAF in HIV-1, treatment naive subjects | F/TAF Investigator's Brochure Edition 5 | 03/10/2016 | 21 |
| 16/LO/0029/AM12 | Phase 3 study with GS-9883/F/TAF in HIV-1, treatment naive subjects | 2.1 | 03/11/2016 | 21 |
| 16/LO/0029/AM15 | Phase 3 study with GS-9883/F/TAF in HIV-1, treatment naive subjects | Tivicay SmPC, dated 23 February 2017 | 23/02/2017 | 20 |
| 16/LO/0036/AM06 | GS-9883/F/TAF versus ABC/DTG/3TC in HIV-1, treatment-naive subjects | Protocol Amendment 1.1 | 08/04/2016 | 19 |

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|-----------------|--|---|------------|----|
| 16/LO/0036/AM07 | GS-9883/F/TAF versus ABC/DTG/3TC in HIV-1, treatment-naive subjects | Patient Recruitment Materials | 18/04/2016 | 32 |
| 16/LO/0036/AM08 | GS-9883/F/TAF versus ABC/DTG/3TC in HIV-1, treatment-naive subjects | 2.1 | 03/11/2016 | 21 |
| 16/LO/0036/AM10 | GS-9883/F/TAF versus ABC/DTG/3TC in HIV-1, treatment-naive subjects | Triumeq SmPC | 19/01/2017 | 18 |
| 16/LO/0039/AM05 | Phase 3 switch study with GS-9883/F/TAF & ABC/DTG/3TC in HIV-1 subject | Protocol Amendment 1.1 04Apr20 | 18/04/2016 | 32 |
| 16/LO/0039/AM07 | Phase 3 switch study with GS-9883/F/TAF & ABC/DTG/3TC in HIV-1 subject | 2.1 | 03/11/2016 | 21 |
| 16/LO/0039/AM08 | Phase 3 switch study with GS-9883/F/TAF & ABC/DTG/3TC in HIV-1 subject | Change of Chief Investigator t | 18/01/2017 | 28 |
| 16/LO/0039/AM10 | Phase 3 switch study with GS-9883/F/TAF & ABC/DTG/3TC in HIV-1 subject | Triumeq SmPC | 19/01/2017 | 18 |
| 16/LO/0058/AM01 | LAVA- Liver resection surgery versus thermal ablation for CLM | Substantial Amendment 01 | 26/07/2016 | 8 |
| 16/LO/0058/AM03 | LAVA- Liver resection surgery versus thermal ablation for CLM | Substantial Amendment 01 | 06/03/2017 | 15 |
| 16/LO/0129/AM01 | Post Marketing study following long term prophylactic Optivate usage | 8VWF07 | 06/04/2016 | 21 |
| 16/LO/0133/AM02 | Identification and Care of Patients at Risk of Post Stroke Dementia | 1 | 03/11/2016 | 22 |
| 16/LO/0141/AM01 | INCEPTUS: ATX-MTM-009 | 01 21 March 2016 | 24/03/2016 | 11 |
| 16/LO/0141/AM02 | INCEPTUS: ATX-MTM-009 | 2 | 12/08/2016 | 6 |
| 16/LO/0141/AM04 | INCEPTUS: ATX-MTM-009 | 4 | 22/12/2016 | 21 |
| 16/LO/0144/AM01 | SHP-GCB-402-effect of Velaglucerase alfa on Bones in Gaucher Disease | SHP-GCB-402 Protocol Admin Memo, UK ICF Version 3.0_08 Mar 2016_Training Screenshots Jan/Feb 2016 | 29/03/2016 | 35 |
| 16/LO/0144/AM02 | SHP-GCB-402-effect of Velaglucerase alfa on Bones in Gaucher Disease | Amendment 03 | 06/07/2016 | 7 |

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|-----------------|--|--|------------|----|
| 16/LO/0251/AM01 | Fetal Atrial Flutter & Supraventricular Tachycardia Therapy Trial | SA01 | 22/04/2016 | 28 |
| 16/LO/0251/AM05 | Fetal Atrial Flutter & Supraventricular Tachycardia Therapy Trial | 4 | 27/09/2016 | 25 |
| 16/LO/0305/AM01 | Lichen Planus Study | Protocol/PIS amendment/inclusion of validated questionnaires | 04/04/2016 | 25 |
| 16/LO/0318/AM01 | Impact of Loading Pressure on Endothelial Function in Diabetic Foot v1 | SA01 | 07/03/2017 | 17 |
| 16/LO/0574/AM01 | MERCK - MS200662_0001 | Substantial Amendment 01 | 09/05/2016 | 17 |
| 16/LO/0574/AM03 | MERCK - MS200662_0001 | Substantial Amendment 03 | 22/08/2016 | 17 |
| 16/LO/0574/AM06 | MERCK - MS200662_0001 | SA06 | 22/03/2017 | 19 |
| 16/LO/0592/AM01 | IDRIS | 1 | 25/05/2016 | 13 |
| 16/LO/0592/AM03 | IDRIS | 3 | 17/11/2016 | 24 |
| 16/LO/0637/AM01 | The role of I2BS in Huntington's disease | Substantial Amendment 01 | 05/07/2016 | 4 |
| 16/LO/0638/AM01 | The role of I2BS in Parkinson's disease | Substantial Amendment 01 | 05/07/2016 | 4 |
| 16/LO/0806/AM01 | PPC - Personalised Programmes for Children | Amendment one, | 08/08/2016 | 15 |
| 16/LO/1008/AM01 | Phase 2 study in participants with Hepatitis C and liver transplant | SA01 2016/08/11 | 11/08/2016 | 9 |
| 16/LO/1022/AM02 | MEDI4736-MM-003 Phase 2 Relapsed and Refractory Multiple Myeloma | MEDI4736-MM-003 | 07/09/2016 | 14 |
| 16/LO/1022/AM03 | MEDI4736-MM-003 Phase 2 Relapsed and Refractory Multiple Myeloma | 3 | 26/01/2017 | 8 |
| 16/LO/1024/AM01 | BEAT LUPUS | Protocol Amendment version 2.0 | 02/09/2016 | 7 |
| 16/LO/1222/AM01 | ATLANTIS Trial | 1 | 03/10/2016 | 10 |
| 16/LO/1226/AM01 | Mainstreamed genetic testing: intentions, decision-making and outcomes | Amendment 1 - 09/08/2016 | 22/08/2016 | 9 |
| 16/LO/1226/AM03 | Mainstreamed genetic testing: intentions, decision-making and outcomes | 2 | 21/12/2016 | 14 |

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|-----------------|---|---------------------------|------------|----|
| 16/LO/1436/AM01 | Potential Predictors of Disease Progression in aHUS Patients. | 1 | 05/08/2016 | 13 |
| 16/LO/1436/AM02 | Potential Predictors of Disease Progression in aHUS Patients. | 2 | 17/11/2016 | 11 |
| 16/LO/1622/AM02 | Investigation of a new diet for the treatment of obesity in the NHS | 1 | 19/12/2016 | 7 |
| 16/LO/1810/AM01 | A Phase 3 - Ublituximab in Combination with TGR-1202 | 1.0 | 12/01/2017 | 11 |
| 16/LO/1815/AM01 | Optimising screening for the cardiotoxic effects of cancer therapy | 1 | 08/02/2017 | 15 |
| 16/LO/1875/AM01 | Safety & Efficacy of VX-440 Combination Therapy for Cystic Fibrosis | 1 | 12/01/2017 | 11 |
| 16/LO/1926/AM01 | PINC trial | Amendment 1 - Protocol v2 | 02/12/2016 | 35 |
| 16/LO/2044/AM01 | CL04041023 - Clinical Rheumatoid Arthritis Development for Olokizumab | 2 | 23/11/2016 | 14 |

Unfavourable opinion

| Amendment REC Reference | Title | Version | Date | Number of Days on Clock |
|-------------------------|--|--------------------------------|------------|-------------------------|
| 13/LO/0634/AM13 | Late onset depression: Correlates of dopaminergic function | Substantial amendment 3 - 11/0 | 11/01/2017 | 15 |

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 |
|-------------------------|--|----------------------|------------|-------------------------|
| 13/LO/0634/AM13/1 | Late onset depression: Correlates of dopaminergic function | Modified Amendment 3 | 07/03/2017 | 8 |

Unfavourable opinion timeline

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

Table 11: Items exceeding timelines

Full applications for ethical review over 60 day timeline

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

Proportionate review applications for ethical review over 21 day timeline

| REC Reference | Title | Number of Days on Clock |
|---------------|---|-------------------------|
| 16/LO/0664 | Deceased Organ Donation and Health Literacy | 25 |

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 |
|-------------------------|--|---------------|------------|-------------------------|
| 10/H0720/88/AM15 | LUME-Lung 3. | 11 | 18/07/2016 | 36 |
| 15/LO/1629/AM04 | Quality of life and wellbeing in pregnant women and new mothers V1 | 3: 11/04/2016 | 13/04/2016 | 41 |

Modified Amendments over 14 day timeline

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