

London - Brent Research Ethics Committee

Annual Report

01 April 2017 - 31 March 2018



Part 1 – Committee Membership and Training

| | |
|------------------------------|--|
| Name of REC: | London - Brent Research Ethics Committee |
| Type of REC: | Recognised to review CTIMPS in healthy volunteers – type I Recognised to review CTIMPS in patients – type III |
| Type of Flag: | Phase I studies in Healthy Volunteers Qualitative Research Research involving Children |
| Chair: | Dr Manish Saxena |
| Vice-Chair: | Miss Zainab Yate |
| Alternate Vice-Chair: | Mrs Diana Harvey |
| REC Manager: | Miss Nicole Curtis |
| REC Assistant: | Mr Jake Chambers |
| Committee Address: | 80 London Road Skipton House London SE1 6LH |
| Telephone: | 02071048129 |
| Email: | nrescommittee.london-brent@nhs.net |

Chair's overview of the past year:

The Brent REC had a productive year with in depth ethical review of all applications. This was well supported by sufficient number of lay and expert committee members with diverse backgrounds. During the annual report period, the Committee was pleased to welcome Ms Iona Crawford as a new member and Mr Jake Chambers as REC Assistant but was sad to lose Mrs Sunder Chita and Miss Alice Glaser. The Committee would like to thank these members for their contribution and to wish them every success in their new post.

The committee has adapted to the new HRA review process well.

The Committee continues to provide specialised review in paediatric, qualitative and Phase 1 pharmaceutical research. Members of the Committee attended a variety of courses throughout the year and shared their learning with the committee.

The Committee performed well in terms of delivering on time, safeguarding participants' safety and facilitating research in a safe and ethical way. We look forward to challenges ahead.

London - Brent Research Ethics Committee Membership

| Name | Profession | Expert or Lay | Dates | |
|--------------------------|--|---------------|------------|------------|
| | | | Appointed | Left |
| Mr Suresh Akula | Retired Civil Servant | Lay Plus | 13/02/2009 | |
| Dr Daniel Bradford | Pharmacologist | Expert | 01/07/2013 | |
| Mrs Sunder Chita | Manager | Lay Plus | 31/07/2005 | 20/08/2017 |
| Ms Iona Crawford | Associate Mental Health Worker | Lay | 01/08/2017 | |
| Dr Graham Davison | Pharmaceutical Consultant | Lay | 08/06/2010 | |
| Dr Anke Furck | Consultant in Paediatric Intensive Care | Expert | 10/05/2013 | |
| Miss Alice Glaser | Investigator Initiated Trials Coordinator | Expert | 01/05/2017 | 31/03/2018 |
| Mrs Diana Harvey | Lawyer | Lay Plus | 04/01/2016 | |
| Mr Maurice Hoffman | Retired Teacher | Lay Plus | 23/07/2008 | |
| Dr Dusko Ilic | Reader in Stem Cell Science | Expert | 02/03/2015 | |
| Professor Ramesh Kapadia | Retired Education Consultant | Lay Plus | 01/01/2017 | |
| Dr Prashanth Nandhabalan | Specialist Registrar in Intensive Care and Anaesthesia | Expert | 01/01/2017 | |
| Dr Manish Saxena | Clinical Lecturer | Expert | 30/03/2011 | |
| Ms Sibonginkosi Sibanda | Advanced Nurse Practitioner | Expert | 19/02/2018 | |
| Dr Zdenek Slavik | Consultant Paediatric Cardiologist/Intensivist | Expert | 20/10/2011 | |
| Dr Krishna Soondrum | Consultant Paediatric Gastroenterologist | Expert | 01/09/2014 | |
| Miss Ourania Xeniou | Senior Clinical Research Associate | Lay | 12/10/2008 | |
| Miss Zainab Yate | Bioethics Researcher | Lay | 10/06/2008 | |

London - Brent Research Ethics Committee: Co-opted Members

| Name | Profession | Status | Meeting date attended |
|-------------------|--------------------------|--------|-----------------------|
| Dr Anthony Kaiser | Consultant Neonatologist | Expert | 22/05/2017 |
| Dr Mike Philpot | Retired Psychiatrist | Expert | 22/05/2017 |

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

| Name | Declaration of Interest | Date |
|--------------------------|--|------------|
| Mr Suresh Akula | Imperial BRC PPI Group | 31/03/2018 |
| Dr Daniel Bradford | Director of own limited company Yoshi Poshu Sushi LTD, and its only employee. | 21/03/2018 |
| Ms Iona Crawford | None | 07/08/2017 |
| Dr Graham Davison | Shareholdings in Glaxo Smith Kline | 21/03/2018 |
| Dr Graham Davison | Shareholdings in Oxford Bio Media | 21/03/2018 |
| Dr Anke Furck | None declared | 31/03/2018 |
| Miss Alice Glaser | Currently working in biopharmaceutical (Celgene) managing investigator - initiated clinical trials and research grants. | 16/05/2017 |
| Mrs Diana Harvey | None declared | 20/03/2018 |
| Mr Maurice Hoffman | Admin support, R&D, LNWUHT; Imperial BRC PPI group; NIHR London IVD Cooperative, Lay Advisor; Imperial NIHR STRC Patient Research group; Lay member ACCEA, London North West Sub-committee | 31/03/2018 |
| Dr Dusko Ilic | CSO: Ovid Research, San Francisco CA | 31/03/2018 |
| Dr Dusko Ilic | Review panel member; Horizon 2020 research funding programme, specific CallTopic SC1-BHC-09-2018: Innovation platforms for advanced therapies of the future | 31/03/2018 |
| Professor Ramesh Kapadia | No declared interests | 27/03/2018 |
| Professor Ramesh Kapadia | No declared interests. | 31/03/2018 |
| Dr Prashanth Nandhabalan | Member - Royal College of Anaesthetists, Faculty of Intensive Care Medicine, European Society of Intensive Care Medicine, Intensive Care Society, British Society of Echocardiography. | 31/03/2018 |
| Dr Manish Saxena | Consultancy with The Medicines Company, Esperion Therapeutics/ C5 Research, Baim Institute. Consultancy with KONA Medical, Genentech and Astra Zeneca (completed now). Scientific Advisor BP UK (honorary). Member and Fellow, British and Irish Hypertension Society. Member European Society of Hypertension. Active researcher, Principle Investigator and UK country National Coordinating Investigator/ Chief Investigator on multiple academic and commercial studies as William Harvey Research Institute, Barts Health NHS Trust and QMUL. Helps peer review for studies at Barts Health and QMUL. | 31/03/2018 |
| Ms Sibonginkosi Sibanda | Founder/Director of Clinical Education - ANAM Practice Ltd Healthcare Consultant - Bon Healthcare Ltd Board Member - Africa Interprofessional Education Network (AFriPEN) International Ambassador - American Association of Nurse Practitioners (AANP) Peer Reviewer - Emergency Nurse & Nursing Management Journals (RCNi). | 31/03/2018 |
| Dr Zdenek Slavik | Member of Medical Board, Chain of Hope Charity, London, UK | 21/03/2018 |

| | | |
|---------------------|---|------------|
| Dr Zdenek Slavik | Member of Editorial Board of the following scientific journals: Cor et Vasa Czech-Slovak Paediatric Journal | 21/03/2018 |
| Dr Zdenek Slavik | Member of Medical Board, Chain of Hope Charity, London, UK. | 28/03/2018 |
| Dr Krishna Soondrum | None. | 31/03/2018 |
| Miss Zainab Yate | Committee member Research Governance Kings College London | 31/03/2018 |
| Miss Zainab Yate | Author and owner of www.breastfeedingaversion.com | 31/03/2018 |
| Miss Zainab Yate | Research/PR for World Breastfeeding Initiative UK – WBTi UK | 31/03/2018 |
| Miss Zainab Yate | Breastfeeding Peer supporter for NHS – may conduct research | 31/03/2018 |

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

| Month | Date | Number of Members Present at Meeting |
|-----------|------------|--------------------------------------|
| April | 24/04/2017 | 12 |
| May | 22/05/2017 | 9 |
| July | 31/07/2017 | 10 |
| August | 21/08/2017 | 7 |
| September | 25/09/2017 | 11 |
| October | 30/10/2017 | 8 |
| November | 27/11/2017 | 10 |
| January | 22/01/2018 | 11 |
| February | 26/02/2018 | 10 |
| March | 26/03/2018 | 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 | 13/04/2017 | 3 |
| May | 11/05/2017 | 4 |
| June | 15/06/2017 | 4 |
| July | 14/07/2017 | 3 |
| September | 08/09/2017 | 3 |
| October | 13/10/2017 | 3 |
| February | 09/02/2018 | 3 |
| March | 09/03/2018 | 3 |

8 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 | 01/04/2017 | 3 |
| April | 03/04/2017 | 2 |
| April | 17/04/2017 | 2 |
| April | 21/04/2017 | 3 |
| April | 26/04/2017 | 2 |
| April | 28/04/2017 | 2 |
| May | 08/05/2017 | 12 |
| May | 09/05/2017 | 2 |
| May | 16/05/2017 | 2 |
| May | 24/05/2017 | 2 |
| May | 29/05/2017 | 3 |
| June | 15/06/2017 | 2 |
| June | 21/06/2017 | 3 |

| | | |
|-----------|------------|---|
| June | 29/06/2017 | 3 |
| June | 30/06/2017 | 2 |
| July | 12/07/2017 | 3 |
| July | 28/07/2017 | 2 |
| July | 31/07/2017 | 3 |
| August | 16/08/2017 | 3 |
| August | 31/08/2017 | 2 |
| September | 01/09/2017 | 2 |
| September | 15/09/2017 | 2 |
| September | 29/09/2017 | 2 |
| October | 13/10/2017 | 2 |
| October | 24/10/2017 | 3 |
| October | 31/10/2017 | 2 |
| November | 14/11/2017 | 3 |
| November | 15/11/2017 | 2 |
| November | 30/11/2017 | 2 |
| December | 08/12/2017 | 3 |
| December | 15/12/2017 | 2 |
| December | 31/12/2017 | 2 |
| January | 03/01/2018 | 3 |
| January | 15/01/2018 | 2 |
| January | 31/01/2018 | 2 |
| February | 08/02/2018 | 3 |
| February | 09/02/2018 | 3 |
| February | 14/02/2018 | 3 |
| February | 14/02/2018 | 2 |
| February | 28/02/2018 | 2 |
| March | 01/03/2018 | 2 |
| March | 14/03/2018 | 3 |
| March | 15/03/2018 | 2 |
| March | 16/03/2018 | 3 |
| March | 31/03/2018 | 2 |

45 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 |
|--------------------------|-----------------------------|
| Mr Suresh Akula | 7 |
| Dr Daniel Bradford | 6 |
| Mrs Sunder Chita | 3 |
| Ms Iona Crawford | 5 |
| Dr Graham Davison | 7 |
| Dr Anke Furck | 6 |
| Miss Alice Glaser | 5 |
| Mrs Diana Harvey | 6 |
| Mr Maurice Hoffman | 9 |
| Dr Dusko Ilic | 4 |
| Professor Ramesh Kapadia | 7 |
| Dr Prashanth Nandhabalan | 4 |
| Dr Manish Saxena | 10 |
| Dr Zdenek Slavik | 5 |
| Dr Krishna Soondrum | 5 |
| Miss Zainab Yate | 7 |

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

| Name | Number of Meetings Attended |
|--------------------|-----------------------------|
| Dr Daniel Bradford | 1 |
| Mrs Sunder Chita | 2 |
| Dr Anke Furck | 1 |
| Mrs Diana Harvey | 4 |
| Dr Dusko Ilic | 2 |
| Dr Manish Saxena | 8 |
| Dr Zdenek Slavik | 2 |
| Miss Zainab Yate | 6 |

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

| Name | Number of Meetings Attended |
|--------------------|-----------------------------|
| Mr Suresh Akula | 1 |
| Dr Daniel Bradford | 10 |
| Mrs Sunder Chita | 13 |
| Dr Graham Davison | 5 |
| Dr Anke Furck | 2 |
| Mrs Diana Harvey | 2 |

| | |
|--------------------------|----|
| Mr Maurice Hoffman | 2 |
| Dr Dusko Ilic | 2 |
| Professor Ramesh Kapadia | 2 |
| Dr Prashanth Nandhabalan | 1 |
| Dr Manish Saxena | 45 |
| Dr Zdenek Slavik | 4 |
| Dr Krishna Soondrum | 3 |
| Miss Zainab Yate | 25 |

Training 01 April 2017 - 31 March 2018

| Name of Member | Date | Event(s) attended |
|--------------------------|-------------|--|
| Mr Suresh Akula | 20/07/2017 | NIHR Collaboration for Leadership in Applied Health Research and Care Northwest London Summer Collaborative Learning Event Continuity of Quality Improvement |
| Ms Iona Crawford | 16/11/2017 | Committee Members Induction |
| Dr Graham Davison | 12/12/2017 | National Members Training Day |
| Dr Anke Furck | 08/03/2018 | London REC Members Training Day |
| Miss Alice Glaser | 25/07/2017 | Committee Members Induction |
| Mrs Diana Harvey | 01/08/2017 | Human Tissue Act (Use of Human Samples in Research) An Introductory Level |
| Mrs Diana Harvey | 12/12/2017 | National Members Training Day |
| Mrs Diana Harvey | 07/02/2018 | Introduction to Phase 1 Research - Trials & Regulation |
| Mrs Diana Harvey | 13/02/2018 | The Ethical Issues of Research Involving Children |
| Mr Maurice Hoffman | 18/05/2017 | CPD - The Future NHS Plans Delivering Transformation and Sustainability |
| Mr Maurice Hoffman | 12/12/2017 | National Members Training Day |
| Dr Dusko Ilic | 08/03/2018 | London REC Members Training Day |
| Professor Ramesh Kapadia | 25/07/2017 | Committee Members Induction |
| Professor Ramesh Kapadia | 12/12/2017 | National Members Training Day |
| Dr Prashanth Nandhabalan | 01/08/2017 | Equality & Diversity |
| Dr Manish Saxena | 24/11/2017 | HRA National Chair's Day and Policy Event |
| Dr Zdenek Slavik | 08/03/2018 | London REC Members Training Day |
| Dr Krishna Soondrum | 15/02/2018 | Equality & Diversity |
| Dr Krishna Soondrum | 08/03/2018 | London REC Members Training Day |
| Miss Zainab Yate | 22/03/2018 | Gave a lecture at the Breastfeeding and Feminism on Breastfeeding Aversion and Agitation with regard to Maternal Autonomy and Consent |
| Miss Zainab Yate | 28/03/2018 | Read the book Law and Ethics for an IBCLC (International Board Certified Lactation Consultant) |

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 | 13 | 27.08 |
| Phase 1 | 13 | 27.08 |
| Gene Therapy | 0 | 0.00 |
| Research Tissue Bank (including renewals) | 0 | 0.00 |
| Research Database (including renewals) | 0 | 0.00 |
| Others | 22 | 45.83 |
| Total Applications Reviewed | 48 | 100 |

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

| | |
|---|----|
| Number of applications made invalid by the REC Manager | 0 |
| Number of applications withdrawn prior to the meeting | 11 |
| Number of student applications reviewed | 10 |
| Number of paediatric applications reviewed | 5 |
| Number of device applications reviewed | 1 |
| 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 | 5 |

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 | 5 | 10.42 |
| Favourable Opinion with Additional Conditions | 4 | 8.33 |
| Unfavourable Opinion | 1 | 2.08 |
| Provisional Opinion | 35 | 72.92 |
| Provisional Opinion Pending Consultation with Referee | 3 | 6.25 |
| Total | 48 | 100 |
| Number of studies sent back to full committee meeting for final opinion | 1 | |

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 | 66.67 |
| Further Information Favourable Opinion with Additional Conditions | 4 | 8.33 |
| Further Information Unfavourable Opinion | 1 | 2.08 |
| Favourable Opinion with Standard Conditions | 5 | 10.42 |
| Favourable Opinion with Additional Conditions | 4 | 8.33 |
| Unfavourable Opinion | 1 | 2.08 |
| Provisional Opinion | 1 | 2.08 |
| Provisional Opinion Pending Consultation with Referee | 0 | 0.00 |
| Further Information response not complete | 0 | 0.00 |
| No decision entered on system | 0 | 0.00 |
| Number of studies withdrawn after the meeting | 0 | 0.00 |
| Total | 48 | 100 |

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

| | |
|------------------------------------|-----------|
| Total Applications Reviewed | 22 |
|------------------------------------|-----------|

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

| | |
|--|----|
| Number of applications made invalid by the REC Manager | 3 |
| Number of studies withdrawn prior to the meeting | 2 |
| Number of student applications reviewed | 12 |
| Number of paediatric applications reviewed | 4 |
| Number of device applications reviewed | 1 |
| Number of qualitative applications reviewed | 6 |

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 | 3 | 13.64 |
| Favourable Opinion with Additional Conditions | 1 | 4.55 |
| No Opinion transfer to full committee for review | 2 | 9.09 |
| Provisional Opinion | 16 | 72.73 |
| Unfavourable Opinion | 0 | 0.00 |
| Total | 22 | 100 |

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

| | |
|---|-------|
| Average number of applications reviewed per full meeting | 4.80 |
| Number of completed applications for full ethical review | 48 |
| Number of completed applications for full ethical review over 60 days | 3 |
| Number of completed applications over 60 days as a % of total | 6.25% |
| Number of days taken to final decision – average (mean) | 39 |
| Number of completed proportionate review applications for ethical review | 20 |
| 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 | 1 |
| 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 | 14 |
| 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 | 112 |
| 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 | 79 |
| Number of substantial amendments received for information | 0 |
| Number of substantial amendments received for new sites/PIs | 15 |
| Number of annual progress reports received | 68 |
| Number of safety reports received | 59 |
| Number of Serious Adverse Events received | 0 |
| Number of final reports received | 44 |

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/LO/0416 | AJM347- First in Human SAD and MAD study | 40 |
| 17/LO/0640 | Efficacy & Safety of UX007 in Movement Disorders associated to Glut1DS | 85 |
| 17/LO/0690 | LP0084-1369 | 47 |
| 17/LO/0716 | BLOOD-VALVES | 41 |
| 17/LO/0728 | Long term study of BRV | 57 |
| 17/LO/0862 | The effect of fruit and vegetable types on vascular function | 41 |
| 17/LO/1176 | A Double-Blind, Biosimilar Study of MB02 in Healthy Males | 16 |
| 17/LO/1244 | An Ethnography of Open Dialogue in the UK | 31 |
| 17/LO/1272 | Phase 1 PK study of Tenofovir Exalidex in healthy subjects (QCL118077) | 36 |
| 17/LO/1273 | CheckMate 648 | 30 |
| 17/LO/1287 | V1Palliative care in general practice: cancer patient/carer experience | 44 |
| 17/LO/1359 | Mass Balance of Single Dose [¹⁴ C]KLH-2109 in Healthy Subjects | 29 |
| 17/LO/1361 | Organ donation intervention in primary care: A feasibility study | 60 |
| 17/LO/1364 | CapHTen | 40 |
| 17/LO/1367 | MO29872: Atezolizumab compared with chemotherapy in NSCLC | 41 |
| 17/LO/1510 | Places of birth: a feasibility study on informed decision-making | 40 |
| 17/LO/1669 | Effect of food on fatty acid oxidation | 39 |
| 17/LO/1710 | 255HV101- SAD and MAD study OF BIIB095 | 37 |
| 17/LO/1849 | Birth experiences of women experiencing postpartum mental illness | 39 |
| 17/LO/1893 | Blood levels of inhaled fluticasone and salmeterol; version 1 | 30 |
| 17/LO/1995 | Network biomarkers of idiopathic generalised epilepsies | 47 |
| 18/LO/0068 | NV1205 in Pediatric Male Subjects with CCALD | 66 |
| 18/LO/0079 | LJPC-401 for iron overload in adults with TDT | 57 |
| 18/LO/0083 | Investigating the anti-inflammatory effects of Annexin A1 in humans vA | 58 |
| 18/LO/0101 | Analysis of breath acetone for nutritional assessment | 45 |
| 18/LO/0243 | Effect of GWP42003-P over exposure of clobazam and N-CLB | 27 |
| 18/LO/0246 | A PK study of ND0612, comparing infusion sites and cannula lengths | 23 |
| 18/LO/0324 | Vitrectomy In Diabetic macular Oedema Trial (VIDEO Trial) | 51 |
| 18/LO/0420 | Exploring Pain in Survivors of Torture: A qualitative study (V1) | 42 |
| 18/LO/0498 | 207804 A two-part phase I study of GSK3858279 | 27 |
| 18/LO/0505 | OMAhA - preventing type 2 diabetes with metformin | 44 |
| 18/LO/0506 | PREDICT HF | 27 |

| Further Information Favourable Opinion with Additional Conditions | | |
|---|--|-------------------------|
| REC Reference | Title | Number of Days on Clock |
| 17/LO/0693 | Long-term safety of Everolimus in patients with TSC related seizures | 75 |
| 17/LO/0727 | Phase 2/3 study in neonates with repeated EEG seizures | 58 |
| 17/LO/1345 | Genetic and Epigenetic Changes in AERD | 34 |
| 17/LO/1376 | BPM31510IV-05 - BPM31510 in Advanced Pancreatic Cancer | 38 |

| Further Information Unfavourable Opinion | | |
|--|--|-------------------------|
| REC Reference | Title | Number of Days on Clock |
| 17/LO/1889 | Psilocybin in Participants with Treatment Resistant Depression (P-TRD) | 51 |

| Favourable Opinion with Standard Conditions | | |
|---|--|-------------------------|
| REC Reference | Title | Number of Days on Clock |
| 17/LO/0455 | Blood levels of inhaled fluticasone and salmeterol; v1 | 28 |
| 17/LO/0870 | radioX | 29 |
| 17/LO/1642 | EFFIP online resource for carers: Prototype usability evaluation study | 25 |
| 18/LO/0073 | Effect of MT-8554 on QT/QTc interval in healthy adults | 16 |
| 18/LO/0287 | Psilocybin in Participants with Treatment Resistant Depression (P-TRD) | 22 |

| Favourable Opinion with Additional Conditions | | |
|---|--|-------------------------|
| REC Reference | Title | Number of Days on Clock |
| 17/LO/0877 | An Exploration into Parental Experience of Childhood Cancer | 28 |
| 17/LO/1247 | Rova-T as 2nd Line Therapy (TAHOE) | 24 |
| 17/LO/1749 | AME of MT-8554 after a single oral dose in healthy male subjects | 20 |
| 17/LO/1809 | A PET study to assess brain uptake of SEP-4199; version 1 | 23 |

| Unfavourable Opinion | | |
|----------------------|-------------------------------|-------------------------|
| REC Reference | Title | Number of Days on Clock |
| 17/LO/1450 | Social Cognition in Psychosis | 24 |

| Provisional Opinion | | |
|---------------------|------------|-------------------------|
| REC Reference | Title | Number of Days on Clock |
| 18/LO/0467 | PISA Study | n/a |

| Provisional Opinion Pending Consultation with Referee | | |
|---|-------|-------------------------|
| REC Reference | Title | Number of Days on Clock |

| Further information response not complete | | |
|---|-------|-------------------------|
| REC Reference | Title | Number of Days on Clock |

| Withdrawn after the meeting | | |
|-----------------------------|-------|-------------------------|
| REC Reference | Title | Number of Days on Clock |

Table 9.2: Breakdown of current status of all PRS applications reviewed within the reporting period

| Further Information Favourable Opinion with Standard Conditions | | |
|---|--|-------------------------|
| REC Reference | Title | Number of Days on Clock |
| 17/LO/0620 | Psychological Flexibility in Prostate Cancer | 21 |
| 17/LO/0622 | LifefInfo Survey: What do you think about use of your data? | 14 |
| 17/LO/0623 | MR assessment of hepatic hydatid disease | 18 |
| 17/LO/0822 | Clot Busting with Microbubbles and Ultrasound | 14 |
| 17/LO/0824 | The Experiences and Outcomes of Tooth Auto-Transplantation | 16 |
| 17/LO/0837 | Effect of Apremilast in Psoriatic Arthritis on Work Related Disability | 19 |
| 17/LO/1026 | Taste evaluation of oral nutritional supplements in Crohn's Disease | 11 |
| 17/LO/1506 | Ward soundscapes | 11 |
| 17/LO/1508 | MEDICAL IMAGES AND LOADING DATA COLLECTION ON PATIENTS | 21 |
| 18/LO/0261 | ABC ReCALL UK | 14 |
| 18/LO/0414 | Using Brain Gauge to assess performance in alcohol misusers. | 18 |
| 18/LO/0446 | Hilotherapy for managing epistaxis and nasal fractures version 1 | 16 |

| Further Information Favourable Opinion with Additional Conditions | | |
|---|---|-------------------------|
| REC Reference | Title | Number of Days on Clock |
| 17/LO/1224 | MSK Telephone Assessments | 19 |
| 17/LO/1505 | Evaluation of IFU for Nova Allegro System | 10 |
| 18/LO/0257 | Identifying causes of kidney disease using human cells & tissue | 15 |
| 18/LO/0263 | Psychophysical investigations of vision changes in glaucoma | 19 |

| 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/LO/0817 | YP's experience of decision making for orthognathic surgery in CLP_v1 | 12 |
| 17/LO/0820 | The LACE Study. Version 1 | 7 |
| 17/LO/1228 | DEUCE - Version 1 | 14 |

| Favourable Opinion with Additional Conditions | | |
|---|---|-------------------------|
| REC Reference | Title | Number of Days on Clock |
| 17/LO/1784 | Movement optimality scoring in high risk infants to predict outcome | 17 |

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

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

| Further information response not complete | | |
|---|-------|-------------------------|
| REC Reference | Title | Number of Days on Clock |

| Withdrawn after the meeting | | |
|-----------------------------|-------|-------------------------|
| REC Reference | Title | Number of Days on Clock |

Table 10.1: Breakdown of current status of all substantial amendments reviewed within the reporting period

| Favourable opinion | | | | |
|--------------------------------|---|---|-------------|--------------------------------|
| Amendment REC Reference | Title | Version | Date | Number of Days on Clock |
| 11/LO/1261/AM13 | INOATYON SECOND LINE CHEMOTHERAPY OVARIAN CANCER | Substantial Amendment no.5 | 23/02/2017 | 22 |
| 11/LO/1261/AM17 | INOATYON SECOND LINE CHEMOTHERAPY OVARIAN CANCER | Substantial Amendment No. 8, SmPC 10/2017 | 15/03/2018 | 28 |
| 11/LO/1855/AM05 | 11-023 Blood samples for medicines research; version 1 | Substantial Amendment 4 | 27/06/2017 | 21 |
| 12/LO/0639/AM18 | A-PREDICT | AM18 | 08/03/2018 | 12 |
| 12/LO/0781/AM04 | SIGNIFY Version 1.6 | 7 | 04/01/2017 | 32 |
| 12/LO/1291/AM03 | Detecting Retinal Changes in ARSACS & Other Ataxias Using OCT | 4 | 19/10/2016 | 7 |
| 12/LO/1876/AM16 | GO28141 PhIII Vemurafenib Vs Vemurafenib + GDC-0973 in Melanoma | IB14, ICF V9 | 25/04/2017 | 16 |
| 12/LO/1876/AM17 | GO28141 PhIII Vemurafenib Vs Vemurafenib + GDC-0973 in Melanoma | Zelboraf IB15, Cobimetinib IB1 | 16/01/2018 | 21 |
| 12/LO/1950/AM17 | C25003 Ph3 A+AVD vs ABVD Frontline in Patients with Hodgkin Lymphoma | SA_IBv15 | 08/01/2018 | 17 |
| 13/LO/1618/AM11 | TELEPATH (Expanded Treatment for Carcinoid Syndrome Symptoms) | 11 | 18/07/2017 | 31 |
| 13/LO/1682/AM15 | Study of Maintenance Rucaparib in Relapsed High-grade Ovarian Cancer | SA10 | 18/04/2017 | 23 |
| 13/LO/1682/AM18 | Study of Maintenance Rucaparib in Relapsed High-grade Ovarian Cancer | SA13 | 23/02/2018 | 31 |
| 14/LO/1347/AM06 | The use of guided self-help in Anorexia Nervosa | 4 | 16/01/2018 | 20 |
| 14/LO/1356/AM07 | WO29217 - Neo-adjuvant Pertuzumab in Breast Cancer | N/A | 23/03/2017 | 13 |
| 14/LO/1356/AM08 | WO29217 - Neo-adjuvant Pertuzumab in Breast Cancer | SA07 | 24/01/2018 | 35 |
| 14/LO/1406/AM05 | Open-label study of GDC-0199 in follicular lymphoma patients | IB edition 8 | 15/02/2017 | 16 |
| 14/LO/1406/AM06 | Open-label study of GDC-0199 in follicular lymphoma patients | 8.1 | 03/05/2017 | 2 |
| 15/LO/0099/AM06 | SAATELLITE - Phase 2 study of MEDI4893 in mechanically ventilated pts | Amendment 5 | 23/08/2017 | 12 |
| 15/LO/0099/AM08 | SAATELLITE - Phase 2 study of MEDI4893 in mechanically ventilated pts | GDPR ICF | 28/11/2017 | 25 |

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| 15/LO/0104/AM11 | Albumin To prevenT Infection in chronic liveR failurE (ATTIRE) | SA09 | 26/10/2017 | 35 |
| 15/LO/0104/AM12 | Albumin To prevenT Infection in chronic liveR failurE (ATTIRE) | SA10 | 15/01/2018 | 10 |
| 15/LO/0714/AM04 | PASTIS | V5 | 22/05/2017 | 8 |
| 15/LO/0714/AM05 | PASTIS | Protocol V6.0 | 06/07/2017 | 10 |
| 15/LO/0714/AM06 | PASTIS | SA06 | 26/07/2017 | 21 |
| 15/LO/0853/AM05 | Switch Study of Dolutegravir + Rilpivirine in HIV infected adults-636 | Thank you cards | 02/05/2017 | 10 |
| 15/LO/0854/AM05 | Switch Study of Dolutegravir + Rilpivirine in HIV infected adults-637 | 2 | 10/05/2017 | 7 |
| 15/LO/1453/AM03 | ARIES: App to support Recovery in Early Intervention Services | 3 | 29/05/2017 | 6 |
| 15/LO/1548/AM11 | GLOOCOSE | Protocol Version 4 | 09/05/2017 | 6 |
| 15/LO/1747/AM06 | Riociguat in children with PAH | 4.0 | 09/01/2017 | 9 |
| 15/LO/1747/AM07 | Riociguat in children with PAH | 1 | 29/08/2017 | 28 |
| 15/LO/1761/AM05 | SAMSON trial | 1.1 | 11/12/2015 | 8 |
| 15/LO/1761/AM07 | SAMSON trial | 1.0 | 07/08/2017 | 18 |
| 15/LO/1761/AM08 | SAMSON trial | Amendment 7 (V1.0) | 05/02/2018 | 16 |
| 15/LO/1883/AM01 | Sleep disordered breathing in children with neuromuscular disease | Amendment 1 Date 20/3/17 | 20/03/2017 | 26 |
| 15/LO/1883/AM03 | Sleep disordered breathing in children with neuromuscular disease | 2 | 11/12/2017 | 20 |
| 16/LO/0060/AM03 | Comparing tablets containing ambrisentan and tadalafil; v1 | As per HARP AM03 | 01/02/2017 | 6 |
| 16/LO/0060/AM04 | Comparing tablets containing ambrisentan and tadalafil; v1 | Amendment 03 | 25/05/2017 | 6 |
| 16/LO/0087/AM08 | CATALYST | SA06 | 29/01/2018 | 20 |
| 16/LO/0089/AM05 | MLN0002SC-3027 Vedolizumab SC in Ulcerative Colitis | SA04 | 22/06/2017 | 26 |
| 16/LO/0090/AM07 | MLN0002SC-3031 Vedolizumab SC in Crohn's Disease | SA07 | 22/06/2017 | 12 |
| 16/LO/0090/AM08 | MLN0002SC-3031 Vedolizumab SC in Crohn's Disease | SA08 - updated participant guide | 24/07/2017 | 24 |
| 16/LO/0090/AM09 | MLN0002SC-3031 Vedolizumab SC in Crohn's Disease | 9 | 29/11/2017 | 30 |
| 16/LO/0334/AM06 | GS-US-296-1080, A Study to evaluate the efficacy&safety of GS-5745 | 6.0 | 06/03/2017 | 6 |
| 16/LO/0334/AM07 | GS-US-296-1080, A Study to evaluate the efficacy&safety of GS-5745 | 5.0 | 17/05/2017 | 8 |
| 16/LO/0348/AM05 | OPAL cohort study | Amendment 05 | 18/07/2017 | 5 |
| 16/LO/0348/AM10 | OPAL cohort study | 10 | 01/03/2018 | 25 |

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| 16/LO/0349/AM09 | The BOOST programme (V1.0) | 09 | 13/06/2017 | 10 |
| 16/LO/0349/AM12 | The BOOST programme (V1.0) | 12 01 November 2017 | 01/11/2017 | 19 |
| 16/LO/0472/AM05 | INN-005 protocol | Substantial Amendment 2 | 11/09/2017 | 23 |
| 16/LO/0590/AM06 | Safety PK PD 3part SAD MAD FE study with KVD818 in healthy adult males | Substantial Amendment 5 (Restart) – Protocol v6.0 | 24/03/2017 | 21 |
| 16/LO/0797/AM04 | VX15-770-124 Cystic Fibrosis | As per HARP AM04 | 15/05/2017 | 1 |
| 16/LO/0797/AM05 | VX15-770-124 Cystic Fibrosis | SA05 Study Guide and ICF | 20/07/2017 | 13 |
| 16/LO/0797/AM07 | VX15-770-124 Cystic Fibrosis | SA06 | 05/10/2017 | 34 |
| 16/LO/0797/AM08 | VX15-770-124 Cystic Fibrosis | SA07 | 15/02/2018 | 28 |
| 16/LO/0813/AM05 | Safety, Tolerability, PK and PD of MT-7117 in Healthy Subjects | Substantial Amendment 4 (Protocol v4.0) | 06/03/2017 | 7 |
| 16/LO/0855/AM03 | The Effect of Total Knee Arthroplasty on Patients' Weight | AMD 3 | 22/12/2017 | 35 |
| 16/LO/0897/AM03 | DMT Imaging | Amendment 2 | 25/05/2017 | 14 |
| 16/LO/0913/AM04 | KERALINK | SA03 | 08/11/2017 | 18 |
| 16/LO/0919/AM09 | MEDI4736 with Tremelimumab in advanced solid tumours | SA05 | 29/03/2017 | 14 |
| 16/LO/0919/AM10 | MEDI4736 with Tremelimumab in advanced solid tumours | SA06 | 24/05/2017 | 2 |
| 16/LO/0919/AM11 | MEDI4736 with Tremelimumab in advanced solid tumours | SA07 | 18/12/2017 | 22 |
| 16/LO/1212/AM01 | CARES | SA01 | 14/11/2017 | 23 |
| 16/LO/1212/AM04 | CARES | SA02 New CI | 15/03/2018 | 11 |
| 16/LO/1218/AM03 | Optimizing Vitamin D Status in Children with Wheeze / Asthma (OPTIVIT) | 2nd Amendment_Contact Slip 04_04_17 | 04/04/2017 | 8 |
| 16/LO/1450/AM04 | M14-031: Venetoclax in Relapsed/Refractory Multiple Myeloma | As per HARP AM04 | 26/04/2017 | 15 |
| 16/LO/1450/AM05 | M14-031: Venetoclax in Relapsed/Refractory Multiple Myeloma | Protocol Am 1 & ICF v4 | 17/07/2017 | 30 |
| 16/LO/1450/AM06 | M14-031: Venetoclax in Relapsed/Refractory Multiple Myeloma | SA#5 Protocol Am 2 & ICF v5 | 19/01/2018 | 21 |
| 16/LO/1450/AM07 | M14-031: Venetoclax in Relapsed/Refractory Multiple Myeloma | SA06 | 08/03/2018 | 13 |

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| 16/LO/1493/AM03 | A PET scan study of TAK-041; version 1 | 1 | 06/03/2017 | 27 |
| 16/LO/1507/AM04 | RADAR Trial | 3 | 05/09/2017 | 3 |
| 16/LO/1739/AM01 | Safety-netting in primary care consultations | 1 | 10/06/2017 | 6 |
| 16/LO/1781/AM03 | LUTONIX Global AV Registry | 1 | 22/03/2017 | 20 |
| 16/LO/1825/AM07 | DP13 SAD/MAD in Healthy Volunteers | SA3 PIS Part B v6 (VERSION 5) | 09/08/2017 | 19 |
| 16/LO/1854/AM04 | F/TAF for pre-exposure HIV-1 prophylaxis in men & transgender women | GS-US-412-2055 ICF v7 & Acurian SMS messaging wording v4 | 18/08/2017 | 12 |
| 16/LO/1854/AM05 | F/TAF for pre-exposure HIV-1 prophylaxis in men & transgender women | GS-US-412-2055 | 23/10/2017 | 26 |
| 16/LO/1854/AM07 | F/TAF for pre-exposure HIV-1 prophylaxis in men & transgender women | 3 | 29/11/2017 | 8 |
| 16/LO/1854/AM08 | F/TAF for pre-exposure HIV-1 prophylaxis in men & transgender women | SA06 | 15/02/2018 | 18 |
| 16/LO/1876/AM03 | FIH, Safety & PK Trial Assessing PIN201104 in HVs & Asthmatic Patients | 1.0 | 11/04/2017 | 23 |
| 16/LO/1890/AM04 | Semaglutide effect on Furosemide & Rosuvastatin PK in healthy subjects | Substantial Amendment 2 (IB Edition 8 – Oral Semaglutide) | 06/04/2017 | 9 |
| 16/LO/2026/AM02 | Phase 2 - Sofosbuvir/Velpatasvir for Chronic HCV Infection | 2 | 12/04/2017 | 21 |
| 16/LO/2026/AM03 | Phase 2 - Sofosbuvir/Velpatasvir for Chronic HCV Infection | SA03 | 17/10/2017 | 16 |
| 16/LO/2224/AM01 | PEARL | 1 | 12/04/2017 | 14 |
| 17/LO/0032/AM01 | CFHealthHub Data Observatory | 1 | 13/07/2017 | 29 |
| 17/LO/0032/AM03 | CFHealthHub Data Observatory | SA2 | 19/12/2017 | 21 |
| 17/LO/0035/AM03 | ACtiF - RCT and parallel process evaluation (WP 3.2 and 3.3) | 1 | 27/06/2017 | 14 |
| 17/LO/0156/AM01 | Safety, Tolerability and PK of ASP7713 in Healthy Volunteers | 1 | 27/06/2017 | 13 |
| 17/LO/0156/AM02 | Safety, Tolerability and PK of ASP7713 in Healthy Volunteers | Substantial Amendment 2.0 (Protocol v4.0) | 21/09/2017 | 21 |
| 17/LO/0156/AM03 | Safety, Tolerability and PK of ASP7713 in Healthy Volunteers | Amendment 3 | 13/10/2017 | 1 |
| 17/LO/0303/AM02 | MAPPS: Study of the mediators and predictors of psychosis v.4 | Amendment 1 | 18/07/2017 | 4 |
| 17/LO/0303/AM03 | MAPPS: Study of the mediators and predictors of psychosis v.4 | Amendment 2 | 08/09/2017 | 35 |
| 17/LO/0306/AM01 | REGN3918 Single and Multiple dose study | Amendment 3 | 19/07/2017 | 5 |

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| 17/LO/0306/AM02 | REGN3918 Single and Multiple dose study | 4 | 09/01/2018 | 24 |
| 17/LO/0416/AM01 | AJM347- First in Human SAD and MAD study | 1 | 15/12/2017 | 19 |
| 17/LO/0416/AM02 | AJM347- First in Human SAD and MAD study | SA2 - v4 | 23/02/2018 | 20 |
| 17/LO/0455/AM01 | Blood levels of inhaled fluticasone and salmeterol; v1 | Amendment 1 | 30/05/2017 | 20 |
| 17/LO/0622/AM04 | LifeInfo Survey: What do you think about use of your data? | Number 2 | 30/01/2018 | 10 |
| 17/LO/0640/AM01 | Efficacy & Safety of UX007 in Movement Disorders associated to Glut1DS | 1.0 | 22/01/2018 | 18 |
| 17/LO/0690/AM02 | LP0084-1369 | 2.0 | 25/07/2017 | 4 |
| 17/LO/0693/AM01 | Long-term safety of Everolimus in patients with TSC related seizures | Substantial Amendment 1 – Updated PICFs & IB Ed 16 | 20/03/2018 | 6 |
| 17/LO/0727/AM02 | Phase 2/3 study in neonates with repeated EEG seizures | SA #01 | 02/03/2018 | 24 |
| 17/LO/0728/AM01 | Long term study of BRV | SA01 | 19/02/2018 | 14 |
| 17/LO/1176/AM01 | A Double-Blind, Biosimilar Study of MB02 in Healthy Males | AM01 - MB02-A-02-17 | 09/01/2018 | 7 |
| 17/LO/1247/AM01 | Rova-T as 2nd Line Therapy (TAHOE) | SA01 | 28/12/2017 | 20 |
| 17/LO/1272/AM01 | Phase 1 PK study of Tenofovir Exalidex in healthy subjects (QCL118077) | SA01 | 14/11/2017 | 23 |
| 17/LO/1272/AM02 | Phase 1 PK study of Tenofovir Exalidex in healthy subjects (QCL118077) | SA02 | 05/03/2018 | 9 |
| 17/LO/1273/AM01 | CheckMate 648 | SA01 | 28/11/2017 | 31 |
| 17/LO/1273/AM02 | CheckMate 648 | SA03 | 02/03/2018 | 17 |
| 17/LO/1367/AM01 | MO29872: Atezolizumab compared with chemotherapy in NSCLC | Amendment 1 | 25/09/2017 | 17 |
| 17/LO/1367/AM02 | MO29872: Atezolizumab compared with chemotherapy in NSCLC | 2 | 22/01/2018 | 18 |
| 18/LO/0073/AM01 | Effect of MT-8554 on QT/QTc interval in healthy adults | AM01 - Protocol Am 2.0 | 13/03/2018 | 17 |
| BEC 657/AM06 | Donation of samples of human material for use in assays of potential | Amendment 19 (incorporated into protocol version 16, dated 18 July 2017) | 18/07/2017 | 13 |

Unfavourable opinion

| Amendment REC | Title | Version | Date | Number of Days on |
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| Reference | | | | Clock |
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| 16/LO/2224/AM05 | PEARL | 2 | 22/11/2017 | 29 |

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/LO/2224/AM05/1 | PEARL | Modified 2 | 22/12/2017 | 12 |

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

Table 11: Items exceeding timelines**Full applications for ethical review over 60 day timeline**

| REC Reference | Title | Number of Days on Clock |
|---------------|--|-------------------------|
| 17/LO/0640 | Efficacy & Safety of UX007 in Movement Disorders associated to Glut1DS | 85 |
| 17/LO/0693 | Long-term safety of Everolimus in patients with TSC related seizures | 75 |
| 18/LO/0068 | NV1205 in Pediatric Male Subjects with CCALD | 66 |

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 |
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Modified Amendments over 14 day timeline

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