NHS
Health Research Authority

Research Ethics Service

# London - London Bridge Research Ethics Committee

# Annual Report

# 01 April 2017 - 31 March 2018

## Part 1 – Committee Membership and Training

| | |
|---|---|
| **Name of REC:** | London - London Bridge Research Ethics Committee |
| **Type of REC:** | CTIMPS in healthy volunteers - type i<br>CTIMPS in patients - type iii |
| **Type of Flag:** | Phase 1 Studies in Healthy Volunteers |
| **Chair:** | Ms Jane Smith |
| **Vice-Chair:** | Dr Michael Goggin |
| **Alternate Vice-Chair:** | Dr Ralph White |
| **REC Manager:** | Mr Connor  Frost |
| **Committee Address:** | Skipton House<br>80 London Road<br>London<br>SE1 6LH |
| **Telephone:** | 020 7104 8222 |
| **Email:** | nrescommittee.london-londonbridge@nhs.net |

## Chair's overview of the past year:

Our committee had a successful year, with a few changes. Sadly, we said farewell to our chair of 11 years, Professor David Bartlett, and we thank him for his leadership over the years. Other members who left during the year were Karen Sanders, Parastou Donyai, Frances Dockery, and Colleen Hubbard – and we thank them for all their work and wish them well. We have welcomed five new members, who have quickly settled in – Ahmed Al-Nagar, Hilary Crowe, Nicholas Harper, Anna Stockwell, and Shelley Watcham. We also have a new vice chair in Michael Goggin and alternate vice chair in Ralph White, both longstanding members of the committee. We also said goodbye to our previous REC manager, Ryan Erfani-Ghettani, and welcomed Connor Frost, our current manager. We have a high level of attendance by applicants at the meetings, and the committee finds the dialogue with the applicants helpful, and feedback from the applicants suggests they do to.

We were quorate for all 10 meetings with an average of 11 members at each meeting, and 4.2 applications considered. Almost a quarter of the applications were CTIMPs and almost 20% phase I studies. The rest encompassed a wide variety of research designs. No application took more than 60 days to determine, with two taking over 40 days. 95 substantial amendments were dealt with, with two taking longer than 35 days to complete. All proportionate reviews were dealt with within the required timescales.

## London - London Bridge Research Ethics Committee Membership

| Name | Profession | Expert or Lay | Dates | |
|---|---|---|---|---|
| | | | Appointed | Left |
| Dr Ahmed Al-Nagar | Lead Pharmacist | Expert | 01/08/2017 | |
| Professor David Bartlett | Honorary Consultant | Expert | 13/03/2007 | 28/02/2018 |
| Dr Hilary Crowe | Student of Biomedicine at Birkbeck | Lay | 01/06/2017 | |
| Dr Frances Dockery | Consultant Physician | Expert | 23/01/2012 | 28/03/2018 |
| Dr Parastou Donyai | Pharmacist (Academic) | Expert | 01/02/2016 | 01/06/2017 |
| Mr David Gallacher | Consultant Physicist | Expert | 01/08/2010 | |
| Dr Michael Goggin | Consultant Physician | Expert | 26/06/2009 | |
| Mr Nicholas Harper | Project Manager | Lay | 01/04/2017 | |
| Ms Colleen Hubbard | Director of Clinical Marketing | Lay Plus | 01/12/2016 | 28/03/2018 |
| Dr Imran Jawaid | General Practitioner | Expert | 01/09/2016 | |
| Ms Kate Melvin | Freelance Qualitative Researcher | Lay Plus | 01/10/2015 | |
| Mr Barry Moody | Retired solicitor/partner in law firm | Lay Plus | 04/10/2011 | |
| Ms Karen Sanders | Senior Lecturer Nursing, Health Care Ethics & Law | Expert | 06/06/2006 | 06/06/2017 |
| Ms Jane Smith | Retired medical journal editor (BMJ) | Lay Plus | 07/06/2013 | |
| Miss Anna Stockwell | Early Phase Trials Coordinator | Lay | 28/06/2017 | |
| Dr Shelley Watcham | Medical Advisor | Expert | 01/08/2017 | |
| Dr Ralph White | Pharmacist | Expert | 25/03/2011 | |

## London - London Bridge Research Ethics Committee: Co-opted Members

| Name | Profession | Status | Meeting date attended |
|---|---|---|---|
| Dr Urmi Bapat | Pharmaceutical Physician | Expert | Full Meeting 28/06/2017 |
| Dr John Bull | Retired Consultant Physician | Expert | PR meeting 20/09/2018 |

## London - London Bridge Research Ethics Committee: Members' Declarations of Interest:

| Name | Declaration of Interest | Date |
|---|---|---|
| Dr Ahmed Al-Nagar | Holds positions at King Edward VII Hospital, the MHRA and NICE. Is the Director of Medicine Solutions Limited. Has Membership of the United Kingdom Clinical Pharmacy Association, the Royal Pharmaceutical Society and is registered with the GMC. | 26/07/2017 |
| Dr Hilary Crowe | Shares in Glaxo, Shire, Medtronic and Reckitt Benckiser, to be sold in June and proceeds invested in a passive healthcare tracker fund. | 20/04/2017 |
| Dr Frances Dockery | Consultant physician St Thomas' hospital. Not directly involved in clinical research. | 21/03/2018 |
| Mr David Gallacher | On editorial board of the 'Journal of Radiological Protection' scientific journal run by the Institute of Physics | 27/03/2018 |
| Dr Michael Goggin | Trustee at Kidney charity | 28/03/2018 |
| Mr Nicholas Harper | None. | 21/03/2018 |
| Ms Kate Melvin | None in private companies but I am a freelance consultant social researcher and have been since 1994. Most of my work and experience has been in the field of health services research. Clients include the WHO, Department of Health, the National Social Marketing Centre, the NHS Alliance, Cancer Research UK, the General Medical Council (GMC), the National Institute for Clinical Excellence (NICE), the Commission for Health Improvement (CHI), both Primary Care and Hospital Trusts and, more recently, Clinical Commissioning Groups and Public Health Departments. Academic and research bodies such as Newcastle and Durham universities and the King's Fund have also been clients. I am a member of the Social Research Association and previously I sat on the Tower Hamlets LINks and the Tower Hamlets interim Healthwatch Board which included interviewing for the present Board. I am a research associate of three local Healthwatch and additionally two think tanks, all of which are involved in conducting research. | 31/03/2018 |
| Ms Kate Melvin | Only within a working/consultancy capacity | 31/03/2018 |
| Mr Barry Moody | Shares in Glaxo Smith Kline PLC<br><br>Volunteer at Prostate Cancer (UK) | 21/03/2018 |
| Ms Jane Smith | I have some shares in unit trusts, which almost certainly include some organisations involved in the conduct of research. I have no control over composition of the funds or the choice of companies they invest in | 21/03/2018 |
| Miss Anna Stockwell | Study set-up coordinator at the NIHR UCLH Clinical Research Facility. Occasionally supports UCLH Chief Investigators with their REC/HRA submissions. | 26/07/2017 |
| Dr Shelley Watcham | Previous employment in a regulatory consultancy | 27/07/2017 |

| | | |
|---|---|---|
| | preparing regulatory submissions for pharmaceutical companies. | |
| Dr Ralph White | Director, PPMLD Ltd<br><br>Shares held in GlaxoSmithKline | 21/03/2018 |

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

| Month | Date | Number of Members Present at Meeting |
|---|---|---|
| April | 26/04/2017 | 11 |
| May | 24/05/2017 | 8 |
| June | 28/06/2017 | 10 |
| August | 23/08/2017 | 13 |
| September | 27/09/2017 | 11 |
| October | 25/10/2017 | 12 |
| November | 22/11/2017 | 11 |
| January | 24/01/2018 | 13 |
| February | 28/02/2018 | 8 |
| March | 28/03/2018 | 12 |

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 | 07/04/2017 | 3 |
| May | 05/05/2017 | 3 |
| June | 02/06/2017 | 3 |
| July | 03/07/2017 | 3 |
| August | 07/08/2017 | 3 |
| September | 04/09/2017 | 3 |
| September | 20/09/2017 | 3 |
| October | 02/10/2017 | 3 |
| February | 05/02/2018 | 3 |
| March | 05/03/2018 | 4 |

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 | 14/04/2017 | 2 |
| April | 28/04/2017 | 3 |
| May | 15/05/2017 | 2 |
| May | 24/05/2017 | 2 |
| May | 31/05/2017 | 2 |
| June | 15/06/2017 | 2 |
| June | 30/06/2017 | 4 |
| July | 14/07/2017 | 3 |
| July | 31/07/2017 | 2 |
| August | 15/08/2017 | 2 |
| August | 15/08/2017 | 2 |
| August | 31/08/2017 | 2 |

| | | |
|---|---|---|
| September | 15/09/2017 | 2 |
| September | 29/09/2017 | 2 |
| October | 31/10/2017 | 2 |
| November | 02/11/2017 | 2 |
| November | 15/11/2017 | 2 |
| November | 30/11/2017 | 2 |
| December | 15/12/2017 | 2 |
| December | 31/12/2017 | 2 |
| January | 15/01/2018 | 4 |
| January | 31/01/2018 | 2 |
| February | 15/02/2018 | 2 |
| February | 28/02/2018 | 2 |
| March | 15/03/2018 | 2 |
| March | 31/03/2018 | 2 |

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

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

0

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

| Name | Number of Meetings Attended |
|---|---|
| Dr Ahmed Al-Nagar | 5 |
| Professor David Bartlett | 7 |
| Dr Hilary Crowe | 6 |
| Dr Frances Dockery | 8 |
| Dr Parastou Donyai | 2 |
| Mr David Gallacher | 9 |
| Dr Michael Goggin | 8 |
| Mr Nicholas Harper | 8 |
| Ms  Colleen Hubbard | 6 |
| Dr Imran Jawaid | 1 |
| Ms Kate Melvin | 8 |
| Mr Barry Moody | 8 |
| Ms Karen Sanders | 1 |
| Ms Jane Smith | 10 |
| Miss Anna Stockwell | 5 |
| Dr Shelley Watcham | 6 |
| Dr Ralph White | 10 |

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

| Name | Number of Meetings Attended |
|---|---|
| Professor David Bartlett | 5 |
| Dr Frances Dockery | 2 |
| Mr David Gallacher | 4 |
| Dr Michael Goggin | 4 |
| Mr Nicholas Harper | 1 |
| Ms  Colleen Hubbard | 1 |
| Ms Kate Melvin | 5 |
| Mr Barry Moody | 4 |
| Ms Jane Smith | 3 |
| Dr Ralph White | 1 |

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

| Name | Number of Meetings Attended |
|---|---|
| Professor David Bartlett | 8 |
| Dr Hilary Crowe | 1 |
| Dr Frances Dockery | 4 |
| Dr Parastou Donyai | 1 |
| Mr David Gallacher | 4 |
| Dr Michael Goggin | 10 |
| Mr Nicholas Harper | 2 |
| Ms Kate Melvin | 4 |
| Mr Barry Moody | 4 |
| Ms Karen Sanders | 1 |
| Ms Jane Smith | 11 |
| Dr Ralph White | 8 |

## Training 01 April 2017 - 31 March 2018

| Name of Member | Date | Event(s) attended |
|---|---|---|
| Dr Ahmed Al-Nagar | 12/12/2017 | Mandatory Radiation Protection |
| Dr Ahmed Al-Nagar | 20/12/2017 | Information Governance Training |
| Dr Ahmed Al-Nagar | 21/12/2017 | Mental Capacity Act - Deprivation of Liberty |
| Dr Ahmed Al-Nagar | 23/12/2017 | Mental Health with Dementia and Leaning Disabilities |
| Dr Ahmed Al-Nagar | 25/12/2017 | Safeguarding Adults |
| Dr Ahmed Al-Nagar | 25/12/2017 | Safeguarding Children |
| Professor David Bartlett | 03/05/2017 | RES Chairs' Meeting |
| Dr Hilary Crowe | 11/01/2018 | Committee Members Induction |
| Dr Hilary Crowe | 08/03/2018 | Local Training - London REC Members Training Day |
| Dr Michael Goggin | 12/12/2017 | National Members Training Day |
| Mr Nicholas Harper | 24/04/2017 | Induction for new Research Ethics Service committee members |
| Mr Nicholas Harper | 25/07/2017 | Committee Members Induction |
| Ms  Colleen Hubbard | 25/07/2017 | Committee Members Induction |
| Ms Kate Melvin | 05/10/2017 | Induction to Phase I research - trials and regulation |
| Mr Barry Moody | 12/12/2017 | National Members Training Day |
| Ms Karen Sanders | 12/12/2017 | National Members Training Day |
| Ms Jane Smith | 01/08/2017 | Training - Human Tissue Act |
| Ms Jane Smith | 12/09/2017 | Genetic and Genomic Research |
| Ms Jane Smith | 23/11/2017 | Training - Ethical Issues in Phase One Research: An Advanced Training Course |
| Ms Jane Smith | 24/11/2017 | Training - HRA National Chairs' Day and Policy Event |
| Ms Jane Smith | 12/12/2017 | National Members Training Day |
| Ms Jane Smith | 23/01/2018 | Complex Cases |
| Miss Anna Stockwell | 12/12/2017 | National Members Training Day |
| Miss Anna Stockwell | 11/01/2018 | Committee Members Induction |
| Dr Shelley Watcham | 08/08/2017 | Induction for New Research Ethic Service Committee Members |
| Dr Shelley Watcham | 27/01/2018 | Reviewing Research Design of Clinical Trials |
| Dr Ralph White | 11/12/2017 | Ethics and GCP Forum |
| Dr Ralph White | 08/03/2018 | Local Training - London REC 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 | 10 | 23.81 |
| Phase 1 | 8 | 19.05 |
| Gene Therapy | 0 | 0.00 |
| Research Tissue Bank (including renewals) | 0 | 0.00 |
| Research Database (including renewals) | 0 | 0.00 |
| Others | 24 | 57.14 |
| **Total Applications Reviewed** | **42** | **100** |

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

| | |
|---|---|
| Number of applications made invalid by the REC Manager | 1 |
| Number of applications withdrawn prior to the meeting | 9 |
| Number of student applications reviewed | 12 |
| Number of paediatric applications reviewed | 8 |
| Number of device applications reviewed | 0 |
| 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 | 2 |

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

| Decisions taken at meetings following review of applications | Number | % |
|---|---|---|
| Favourable Opinion with Standard Conditions | 4 | 9.52 |
| Favourable Opinion with Additional Conditions | 6 | 14.29 |
| Unfavourable Opinion | 2 | 4.76 |
| Provisional Opinion | 30 | 71.43 |
| Provisional Opinion Pending Consultation with Referee | 0 | 0.00 |
| **Total** | **42** | **100** |
| Number of studies sent back to full committee meeting for final opinion | 0 | |

***Table 4:*** **Summary of current status of applications reviewed during the reporting period**

| Status of applications at date of generation of report | Number | % |
|---|---|---|
| Further Information Favourable Opinion with Standard Conditions | 27 | 64.29 |
| Further Information Favourable Opinion with Additional Conditions | 1 | 2.38 |
| Further Information Unfavourable Opinion | 0 | 0.00 |
| Favourable Opinion with Standard Conditions | 4 | 9.52 |
| Favourable Opinion with Additional Conditions | 6 | 14.29 |
| Unfavourable Opinion | 2 | 4.76 |
| Provisional Opinion | 4 | 9.52 |
| Provisional Opinion Pending Consultation with Referee | 0 | 0.00 |
| Further Information response not complete | 0 | 0.00 |
| No decision entered on system | 0 | 0.00 |
| Number of studies withdrawn after the meeting | 0 | 0.00 |
| **Total** | **42** | **100** |

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

| | |
|---|---|
| ***Total Applications Reviewed*** | **18** |

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

| | |
|---|---|
| Number of applications made invalid by the REC Manager | 2 |
| Number of studies withdrawn prior to the meeting | 3 |
| Number of student applications reviewed | 7 |
| Number of paediatric applications reviewed | 6 |
| Number of device applications reviewed | 3 |
| Number of qualitative applications reviewed | 3 |

***Table 7:*** **Decisions given at proportionate review sub-committee meetings held within the reporting period**

| **Decisions taken at proportionate review sub-committee meetings** | **Number** | **%** |
|---|---|---|
| Favourable Opinion with Standard Conditions | 2 | 11.11 |
| Favourable Opinion with Additional Conditions | 2 | 11.11 |
| No Opinion transfer to full committee for review | 5 | 27.78 |
| Provisional Opinion | 9 | 50.00 |
| Unfavourable Opinion | 0 | 0.00 |
| **Total** | **18** | **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** | 4.20 |
| **Number of completed applications for full ethical review** | 42 |
| **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)** | 28 |

| | |
|---|---|
| **Number of completed proportionate review applications for ethical review** | 13 |
| **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** | 9 |
| **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** | 96 |
| **Number of completed substantial amendments over 35 days** | 2 |
| **Number of completed substantial amendments over 35 days as a % of total substantial amendments** | 2.08% |

| | |
|---|---|
| **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** | 70 |
| **Number of substantial amendments received for information** | 1 |
| **Number of substantial amendments received for new sites/PIs** | 16 |
| **Number of annual progress reports received** | 56 |
| **Number of safety reports received** | 49 |
| **Number of Serious Adverse Events received** | 0 |
| **Number of final reports received** | 22 |

***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/0418 | A Phase II Study of BGBC008 in Combination with Pembrolizumab | 25 |
| 17/LO/0525 | Aerie PG324 Ophthalmic Solution | 28 |
| 17/LO/0860 | Phase 1 safety, tolerability and PK in healthy Japanese male subjects | 31 |
| 17/LO/0867 | The nature and prevalence of substance use in a forensic population v1 | 36 |
| 17/LO/0872 | Care and prevent: skin infections and kidney disease | 27 |
| 17/LO/0883 | Flexible thinking group (CRT): research project | 27 |
| 17/LO/0925 | M15-554- Comparing ABT-494 to Placebo in PsA subjects | 22 |
| 17/LO/0926 | M15-572- Comparing ABT-494 to Placebo and Adalimumab in PsA subjects | 32 |
| 17/LO/1383 | ANITA (EORTC 1506) | 33 |
| 17/LO/1406 | Cognitive Behavioural Therapy for Renal Fatigue (BReF) | 29 |
| 17/LO/1476 | A phase 2a Study in Adult Volunteers with Sickle Cell Anaemia - 001 | 31 |
| 17/LO/1561 | The dietetic consultation: an illuminative evaluation Version 1.4 | 41 |
| 17/LO/1656 | CO39722 - Cobimetinib and atezolizumab v's pembrolizumab in melanoma | 22 |
| 17/LO/1661 | The Validation of the Pica, ARFID and Rumination Disorder Interview | 28 |
| 17/LO/1802 | EQUIPTT (Evaluation of QUIPP app for Triage and Transfer) | 25 |
| 17/LO/1819 | BladderPath version 1 | 26 |
| 17/LO/1864 | Effect of CB-03-01 on QT interval in HV after given in multiple doses | 19 |
| 17/LO/1923 | EORTC 1447 | 27 |
| 18/LO/0062 | Prospective study to predict outcome following anal fistula surgery | 47 |
| 18/LO/0106 | HYPATIA study - Protocol Version 8.0 | 39 |
| 18/LO/0121 | Anxiety fear conditioning and eating disorders | 38 |
| 18/LO/0207 | Rolandic Epilepsy Genomewide Association International Study (REGAIN) | 47 |
| 18/LO/0284 | Patient experience of pregnancy related venous thrombosis | 44 |
| 18/LO/0349 | DRy eye Outcome and Prescription Study (DROPS) Version 1 | 40 |
| 18/LO/0350 | BARIDEP Protocol V.1 17-01-18 | 43 |
| 18/LO/0514 | Translational brain tumour genomics | 30 |
| 18/LO/0526 | What is the Role of Ultrasound in the Diagnosis of TOS? | 24 |

| Further Information Favourable Opinion with Additional Conditions | | |
|---|---|---|
| **REC Reference** | **Title** | **Number of Days on Clock** |
| 17/LO/1913 | Reminders and rewards to aid adherence in adolescents with asthma | 25 |

| 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/0602 | HTL0018318 Single & Multiple dose PK, Safety study in Healthy Subjects | 8 |
| 17/LO/1390 | Targeted education to reduce non-urgent paediatric ED/UCC reattendance | 22 |
| 17/LO/1518 | Severe complications of enterovirus and human parechovirus infections | 21 |
| 18/LO/0125 | Cardiac events and complications following ICD implantation in HCM | 27 |

| Favourable Opinion with Additional Conditions | | |
|---|---|---|
| **REC Reference** | **Title** | **Number of Days on Clock** |
| 17/LO/0307 | PK/PD & safety of ulipristal acetate delivered from intravaginal ring | 21 |
| 17/LO/1792 | 3 period study of activity and safety of SPR741 with 3 antibiotics | 20 |
| 17/LO/1804 | Pharmacokinetics of BMS-986177 in Healthy Volunteers (QCL118141) | 20 |
| 18/LO/0055 | A Pharmacokinetic food effect study with AZD9977 in healthy males | 19 |
| 18/LO/0107 | Evaluating the effect of Community Mental Health services | 26 |
| 18/LO/0307 | Safety,PK, PD and food effect of BMS-986278 given in SAD and MAD in HV | 15 |

| Unfavourable Opinion | | |
|---|---|---|
| **REC Reference** | **Title** | **Number of Days on Clock** |
| 17/LO/1384 | Reminders and rewards to aid adherence in adolescents with asthma | 22 |
| 17/LO/1916 | Patient-reported outcomes of CKD and diabetes treatments (version 1.0) | 22 |

| Provisional Opinion | | |
|---|---|---|
| **REC Reference** | **Title** | **Number of Days on Clock** |
| 18/LO/0472 | Single dose fMRI effects of Guanfacine and Lisdexamfetamine in ADHD | n/a |
| 18/LO/0503 | 1305.12: BI1015550 and nintedanib or pirfenidone in IPF | 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/0588 | ADHEAR Hearing System: Evaluation on experienced paediatric patients | 8 |
| 17/LO/0595 | Evaluation of the Sheffield Primary Care Pharmacy Programme (PCPP) | 12 |
| 17/LO/0784 | Visual crowding in nystagmus and amblyopia | 14 |
| 17/LO/1370 | Understanding patients' experiences of Addison's disease. v1.3 | 19 |
| 17/LO/1480 | Diabetes and Wellbeing (DWELL) | 13 |
| 17/LO/1694 | Shared decision-making in young people with long-term conditions | 21 |
| 18/LO/0232 | LIESL v1 | 20 |
| 18/LO/0236 | Exploring differences in NETosis in systemic lupus erythematosus (SLE) | 21 |

| 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/LO/1625 | Neutrophils in cytotoxic chemotherapy | 6 |
| 17/LO/1630 | SONG-PD | 15 |

| Favourable Opinion with Additional Conditions | | |
|---|---|---|
| **REC Reference** | **Title** | **Number of Days on Clock** |
| 17/LO/1481 | TEG 6 VS standard testing for postoperative bleeding. | 12 |
| 18/LO/0386 | NT-proBNP to improve risk stratification in orthopaedic surgery | 18 |

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

| Provisional Opinion | | |
|---|---|---|
| **REC Reference** | **Title** | **Number of Days on Clock** |
| 18/LO/0385 | Comparison of outcomes across 3 low-intensity psychological treatments | n/a |

| 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/Q0704/18/AM08 | Imunopathogenesis of Psoriasis v1 | 2 | 08/08/2016 | 4 |
| 08/H0804/139/AM05 | Molecular and Immunopathogenesis of Melanoma | Substantial amendment 5 | 01/08/2017 | 17 |
| 08/H0804/79/AM06 | Cone beam computed tomography study 2 | Substantial amendment 5 | 23/10/2017 | 19 |
| 10/H0804/21/AM04 | Erythrocyte aggregation & haemodynamics | Protocol version 5 | 06/09/2017 | 25 |
| 10/H0804/66/AM04 | Pathological changes in airway smooth muscle in asthma | 3.0 | 03/11/2017 | 15 |
| 12/LO/0776/AM06 | Clinical Assessment Study for Pediatric Patients with Achondroplasia | 6 | 27/06/2017 | 26 |
| 12/LO/0776/AM07 | Clinical Assessment Study for Pediatric Patients with Achondroplasia | 07 | 03/07/2017 | 21 |
| 12/LO/0776/AM08 | Clinical Assessment Study for Pediatric Patients with Achondroplasia | 8 | 31/01/2018 | 31 |
| 13/LO/0288/AM07 | Evaluation of website for parents of children with Juvenile Arthritis | 6 | 06/04/2017 | 18 |
| 13/LO/0288/AM09 | Evaluation of website for parents of children with Juvenile Arthritis | Amendment 8 | 17/11/2017 | 15 |
| 13/LO/1522/AM11 | LTS13632 Long-term phase 2 study of rhASM in ASMD patients | 1.0 | 13/07/2017 | 14 |
| 13/LO/1578/AM14 | A longitudinal study of cognition in people over 50 | #10 | 07/04/2017 | 11 |
| 13/LO/1886/AM16 | IPI-145 in subjects with refractory iNHL | SA13 | 30/10/2017 | 11 |
| 13/LO/1886/AM17 | IPI-145 in subjects with refractory iNHL | SA14 | 26/02/2018 | 29 |
| 14/LO/0566/AM16 | Olaparib therapy in high risk HER2 negative BRCA mutated breast cancer | REC - AM16 | 04/04/2017 | 28 |
| 14/LO/0665/AM09 | MK-5172/MK8742 in HCV Subjects on Opiate Substitution Therapy | 6 | 26/06/2017 | 29 |
| 14/LO/0665/AM10 | MK-5172/MK8742 in HCV Subjects on Opiate Substitution Therapy | SA07 | 12/09/2017 | 6 |
| 14/LO/0720/AM03 | CMR augmented exercise testing in paediatric pulmonary hypertension | Amendment 3 | 31/07/2017 | 28 |
| 14/LO/1043/AM08 | LEAVO (Version 1.0) | 4.0 | 26/06/2017 | 14 |
| 14/LO/1107/AM06 | Effect of MD1003 in multiple sclerosis | 06.01 | 18/05/2017 | 6 |

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|---|---|---|---|---|
| 14/LO/1495/AM03 | Pilot RCT of oxytocin for the treatment of opioid dependence | 4 | 23/05/2017 | 4 |
| 14/LO/1806/AM03 | iFIND- 2. Further Imaging | SA4 | 07/10/2017 | 23 |
| 14/LO/1984/AM02 | Flora Colonoscopy Twin Study | 1 | 25/04/2017 | 14 |
| 14/LO/1984/AM03 | Flora Colonoscopy Twin Study | 2.0 | 27/08/2017 | 15 |
| 14/LO/1990/AM20 | SAD and MAD study of ALN-CC5 in Healthy Volunteers and PNH Patients | 1.0 | 14/07/2017 | 10 |
| 14/LO/2153/AM07 | ORCA-2 | 5 | 10/07/2017 | 5 |
| 14/LO/2194/AM03 | White Adipose Tissue in Pregnancy Study (WAT Study) | 2 | 22/02/2018 | 32 |
| 15/LO/0114/AM05 | Phase I study of MOv18 IgE. | CTA Amendment 13, dated 19 December | 19/12/2017 | 21 |
| 15/LO/0689/AM03 | 1423M0634: S-888711 in CLD Undergoing Invasive Procedures (L-PLUS-2) | 2 | 04/04/2017 | 28 |
| 15/LO/0774/AM05 | PK & PD of ALN - AAT in healthy volunteers and liver disease patients | 1 | 05/04/2017 | 15 |
| 15/LO/0774/AM06 | PK & PD of ALN - AAT in healthy volunteers and liver disease patients | 1.0 | 02/01/2018 | 11 |
| 15/LO/0861/AM09 | Safety and effectiveness of SAR156597 in the treatment of IPF | Amendment 9 | 25/09/2017 | 1 |
| 15/LO/1055/AM07 | PARSIFAL I | 7 | 01/06/2017 | 8 |
| 15/LO/1055/AM08 | PARSIFAL I | Amendment 8 | 03/08/2017 | 21 |
| 15/LO/1280/AM05 | PRIDE- version 2.1 | 4.0 | 06/06/2017 | 20 |
| 15/LO/1326/AM01 | GON migraine study | 1 | 27/01/2017 | 25 |
| 15/LO/1417/AM07 | ASCEND | 3 | 08/02/2017 | 5 |
| 15/LO/1417/AM08 | ASCEND | 1 | 08/06/2017 | 13 |
| 15/LO/1417/AM10 | ASCEND | SA005 V1.0 | 17/10/2017 | 21 |
| 15/LO/1417/AM11 | ASCEND | 1.0 | 26/01/2018 | 29 |
| 15/LO/1425/AM13 | Study of sirukumab (anti-IL-6 drug) for active giant cell arteritis | Amendment 2 | 21/08/2017 | 13 |
| 15/LO/1818/AM12 | AZD2014 and Palbociclib w/ Horm.Therapy in Pts with Adv. Breast Cancer | 5 | 06/07/2017 | 15 |
| 15/LO/1818/AM15 | AZD2014 and Palbociclib w/ Horm.Therapy in Pts with Adv. Breast Cancer | Amendment 7 | 08/01/2018 | 35 |
| 15/LO/1835/AM08 | PNET 5 | SA5 | 20/03/2018 | 27 |
| 15/LO/2011/AM01 | Optimising Management of Serial and Diffuse Coronary Artery Disease | 1 | 15/02/2017 | 27 |
| 15/LO/2011/AM02 | Optimising Management of Serial and Diffuse Coronary Artery Disease | 2 | 12/02/2018 | 25 |

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| 16/LO/0360/AM02 | The effectiveness of treating PST; feasibility study (V2) | 2 | 20/05/2017 | 27 |
| 16/LO/0470/AM09 | ENRICH peer worker programme to enhance psychiatric discharge | 7 | 12/12/2017 | 24 |
| 16/LO/0477/AM01 | Peri-implant bone changes in post-menopausal osteoporotic women | 1 | 10/04/2017 | 18 |
| 16/LO/0794/AM03 | RAINBOW extension study | SA2 | 02/11/2017 | 13 |
| 16/LO/0853/AM09 | BI-1206 + anti-CD20 in patients with CD32b positive B-cell malignancy | CTA Amendment 10 | 25/01/2018 | 35 |
| 16/LO/0858/AM04 | BCX7353 in prevention of HAE attacks | UK EC 03 (version 1) | 12/04/2017 | 37 |
| 16/LO/0858/AM05 | BCX7353 in prevention of HAE attacks | 4 | 24/07/2017 | 5 |
| 16/LO/0858/AM06 | BCX7353 in prevention of HAE attacks | Substantial amendment 5 | 09/08/2017 | 23 |
| 16/LO/0908/AM04 | Efficacy and safety of iNO in Pulmonary Arterial Hypertension, v1.0 | 3 | 07/06/2017 | 19 |
| 16/LO/0908/AM05 | Efficacy and safety of iNO in Pulmonary Arterial Hypertension, v1.0 | Protocol amendment 3.1 | 22/08/2017 | 28 |
| 16/LO/1077/AM04 | Understanding Repeat Attenders for Emergency Care Not Continuing Care | 2 | 04/09/2017 | 3 |
| 16/LO/1304/AM04 | LEAP | SA 002 | 19/02/2018 | 17 |
| 16/LO/1442/AM01 | M15-574 SHARPS study, HS and Adalimubab with Surgery | 1 | 30/11/2016 | 6 |
| 16/LO/1677/AM05 | DARWIN2 | Amendment 4 | 08/12/2017 | 22 |
| 16/LO/1696/AM01 | Safe withdrawal of inhaled steroids in mild or moderate COPD (SWAP) | 1 | 06/09/2017 | 13 |
| 16/LO/1697/AM06 | MK-3475 in the treatment of Advanced/Metastatic Urothelial Carcinoma | SA03 | 03/11/2017 | 30 |
| 16/LO/1701/AM03 | Olaratumab plus Gemcitabine and Docetaxel in Soft Tissue Sarcoma -JGDL | 3 | 06/07/2017 | 19 |
| 16/LO/1701/AM04 | Olaratumab plus Gemcitabine and Docetaxel in Soft Tissue Sarcoma -JGDL | Amendment 4 | 15/08/2017 | 18 |
| 16/LO/1701/AM05 | Olaratumab plus Gemcitabine and Docetaxel in Soft Tissue Sarcoma -JGDL | Amendment 5 | 15/11/2017 | 27 |
| 16/LO/2043/AM04 | CA209-649: Nivo/Ipi vs SOC in gastric cancer patients | 2 | 01/06/2017 | 10 |
| 16/LO/2043/AM05 | CA209-649: Nivo/Ipi vs SOC in gastric cancer patients | EC03 | 16/08/2017 | 2 |
| 16/LO/2043/AM06 | CA209-649: Nivo/Ipi vs SOC in gastric cancer patients | SA05 | 31/01/2018 | 35 |
| 16/LO/2190/AM01 | PLUM | 1 | 07/02/2017 | 20 |

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| 16/LO/2195/AM01 | TRITON2: A Multicenter, Open-label Phase 2 Study of Rucaparib in mCRPC | 1 | 01/06/2017 | 14 |
| 16/LO/2195/AM05 | TRITON2: A Multicenter, Open-label Phase 2 Study of Rucaparib in mCRPC | SA#03 Protocol amendment | 12/12/2017 | 19 |
| 16/LO/2195/AM06 | TRITON2: A Multicenter, Open-label Phase 2 Study of Rucaparib in mCRPC | SA4 | 08/03/2018 | 29 |
| 17/LO/0092/AM01 | CHELATE STUDY GMPO-131-002 | AS#01 | 19/10/2017 | 16 |
| 17/LO/0092/AM02 | CHELATE STUDY GMPO-131-002 | SA-CA01/EC02 | 21/12/2017 | 21 |
| 17/LO/0097/AM02 | Precise Study: NG & MG point-of-care test evaluation | 1 | 31/03/2017 | 7 |
| 17/LO/0130/AM01 | STATIN | 1 | 01/06/2017 | 27 |
| 17/LO/0130/AM02 | STATIN | AM02 | 05/09/2017 | 18 |
| 17/LO/0174/AM02 | Safety, Tolerability, PK, Immunogenicity & PD of JNJ-64179375 | 2 | 17/04/2017 | 10 |
| 17/LO/0174/AM04 | Safety, Tolerability, PK, Immunogenicity & PD of JNJ-64179375 | Amendment 3 | 31/07/2017 | 2 |
| 17/LO/0174/AM05 | Safety, Tolerability, PK, Immunogenicity & PD of JNJ-64179375 | SA04 | 26/02/2018 | 31 |
| 17/LO/0307/AM02 | PK/PD & safety of ulipristal acetate delivered from intravaginal ring | Amendment 2 | 10/08/2017 | 24 |
| 17/LO/0307/AM03 | PK/PD & safety of ulipristal acetate delivered from intravaginal ring | 1 | 30/01/2018 | 7 |
| 17/LO/0418/AM01 | A Phase II Study of BGBC008 in Combination with Pembrolizumab | 1 | 05/07/2017 | 20 |
| 17/LO/0418/AM02 | A Phase II Study of BGBC008 in Combination with Pembrolizumab | IB of BGB324 | 11/12/2017 | 18 |
| 17/LO/0442/AM01 | High risk lung health clinic | 1 | 29/08/2017 | 3 |
| 17/LO/0525/AM01 | Aerie PG324 Ophthalmic Solution | Protocol Amendment 3 | 31/07/2017 | 2 |
| 17/LO/0602/AM01 | HTL0018318 Single & Multiple dose PK, Safety study in Healthy Subjects | 1 | 25/05/2017 | 5 |
| 17/LO/0784/AM01 | Visual crowding in nystagmus and amblyopia | 1 | 05/12/2017 | 4 |
| 17/LO/0872/AM01 | Care and prevent: skin infections and kidney disease | 4 | 03/11/2017 | 30 |
| 17/LO/0925/AM01 | M15-554- Comparing ABT-494 to Placebo in PsA subjects | Protocol Amendment 3 | 14/08/2017 | 1 |
| 17/LO/0926/AM01 | M15-572- Comparing ABT-494 to Placebo and Adalimumab in PsA subjects | Protocol Amendment 2 | 18/08/2017 | 6 |

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| 17/LO/1476/AM01 | A phase 2a Study in Adult Volunteers with Sickle Cell Anaemia - 001 | 001 | 03/11/2017 | 8 |
| 17/LO/1476/AM04 | A phase 2a Study in Adult Volunteers with Sickle Cell Anaemia - 001 | Amendment 003 | 04/01/2018 | 23 |
| 17/LO/1656/AM01 | CO39722 - Cobimetinib and atezolizumab v's pembrolizumab in melanoma | Amendment 1 | 13/02/2018 | 23 |
| 17/LO/1694/AM01 | Shared decision-making in young people with long-term conditions | 1 | 12/02/2018 | 23 |

| **Unfavourable opinion** | | | | |
|---|---|---|---|---|
| **Amendment REC Reference** | **Title** | **Version** | **Date** | **Number of Days on Clock** |
| 16/LO/0360/AM03 | The effectiveness of treating PST; feasibility study (V2) | 3 | 08/12/2017 | 45 |

***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/0360/AM03/1 | The effectiveness of treating PST; feasibility study (V2) | Substantial amendment 4 (modification to SA3) | 02/02/2018 | 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** |

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

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

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

| Substantial Amendments over 35 day timeline | | | | |
|---|---|---|---|---|
| **Amendment REC Reference** | **Title** | **Version** | **Date** | **Number of Days on Clock** |
| 16/LO/0360/AM03 | The effectiveness of treating PST; feasibility study (V2) | 3 | 08/12/2017 | 45 |
| 16/LO/0858/AM04 | BCX7353 in prevention of HAE attacks | UK EC 03 (version 1) | 12/04/2017 | 37 |

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