Health Research Authority

Research Ethics Service

# RES Committee London - Brent

# Annual Report

# 01 April 2014 - 31 March 2015

## Part 1 – Committee Membership and Training

| | |
|---|---|
| **Name of REC:** | RES Committee London – Brent |
| **Type of REC:** | REC recognised to review CTIMPS in healthy volunteers - type i<br>REC recognised to review CTIMPS in patients - type iii |
| **Type of Flag:** | Qualitative, Research involving Children |
| **Chair:** | Dr Manish Saxena |
| **Vice-Chair:** | Mrs Sunder Chita |
| **Alternate Vice-Chair:** | Miss Zainab Yate |
| **REC Manager:** | Ms Julie Kidd |
| **REC Assistant:** | Amy Spruce (until December 2014), Hayley Fraser (until June 2014) |
| **Committee Address:** | 80 London Road<br>Skipton House<br>London<br>SE1 6LH |
| **Telephone:** | 020 7972 2554 |
| **Email:** | nrescommittee.london-brent@nhs.net |

## Chair's overview of the past year:

Brent REC enjoyed another successful and stimulating year. The committee lost some old members and some new members joined in but committee is now settled in membership and continues to provide specialized 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 aims to facilitate research in a timely manner.

## RES Committee London - Brent Membership

| Name | Profession | Expert or Lay | Dates | |
|---|---|---|---|---|
| | | | Appointed | Left |
| Mr Suresh Akula | Retired Civil Servant | Lay Plus | 13/02/2009 | |
| Mr Babak Babakinejad | Research Postgraduate | Expert | 07/10/2011 | |
| Dr Daniel Bradford | Pharmacologist | Expert | 01/07/2013 | |
| Mrs Sunder Chita | Manager | Lay Plus | 31/07/2005 | |
| Dr Graham Davison | Pharmaceutical Consultant | Expert | 08/06/2010 | |
| Dr Anke Furck | Consultant in Paediatric Intensive Care | Expert | 10/05/2013 | |
| Mr Maurice Hoffman | Retired | Lay Plus | 23/07/2008 | |
| Dr Dusko Ilic | Reader in Stem Cell Science | Expert | 02/03/2015 | |
| Dr John Keen | GP | Expert | 01/11/2014 | 31/03/2015 |
| Mrs Alison Lee | Specialist in Special Care Dentistry | Expert | 28/11/2011 | 25/08/2014 |
| Mr Adeyemi Olagbegi | Clinical Pharmacology Study Data Manager | Expert | 18/05/2007 | |
| Dr Alexander Rakow | Consultant Neonatologist | Expert | 04/06/2014 | |
| Dr Manish Saxena | Clinical Lecturer | Expert | 30/03/2011 | |
| 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 | 30/06/2008 | |
| Miss Zainab Yate | Bioethics Researcher | Lay | 10/06/2008 | |

## RES Committee London - Brent: Members' Declarations of Interest:

| Name | Declaration of Interest | Date |
|---|---|---|
| Mr Suresh Akula | None | 29/01/2015 |
| Dr Daniel Bradford | Director of his own company (Yoshi Poshi Sushi LTD. which employs him. 70% shareholder | 29/01/2015 |
| Mrs Sunder Chita | Trustee for Tasha foundation - unpaid | 29/01/2015 |
| Dr Graham Davison | Shareholder of GSK | 26/11/2014 |
| Dr Anke Furck | Consultant Paediatric Intensive Care and Paediatric Cardiology | 29/01/2015 |
| Mr Maurice Hoffman | Admin Support LNWHT R+D | 29/01/2015 |
| Dr Dusko Ilic | I am occasionally reviewing grants or manuscript; not a member of committees of peer review bodies on a regular basis. | 02/03/2015 |
| Dr John Keen | No Declarations of interest | 07/11/2014 |
| Mr Adeyemi Olagbegi | Director of clinical data supplies | 25/02/2015 |
| Dr Manish Saxena | Principle investigator in many academic studies and member of the British hypertension society | 25/02/2015 |
| Dr Zdenek Slavik | Member of Medical Board of Chain of Hope Charity, UKMember of Editorial Board: Cos et Vasal, Czech - Slovak Paediatric Journal | 29/01/2015 |
| Dr Alexander Rakow | None | 31/03/2015 |
| Dr Krishna Soondrum | None | 25/02/2015 |
| Miss Ourania Xeniou | None | 27/11/2014 |
| Miss Zainab Yate | None | 02/05/2014 |

## Meetings for Full Ethical Review 01 April 2014 - 31 March 2015:

| Month | Date | Number of Members Present at Meeting |
|---|---|---|
| April | 28/04/2014 | 13 |
| May | 19/05/2014 | 10 |
| June | 30/06/2014 | 9 |
| July | 28/07/2014 | 12 |
| August | 18/08/2014 | 10 |
| September | 29/09/2014 | 9 |
| September | 29/09/2014 | 9 |
| October | 27/10/2014 | 11 |
| November | 24/11/2014 | 8 |
| January | 26/01/2015 | 10 |
| February | 23/02/2015 | 11 |
| March | 30/03/2015 | 9 |

12 full committee meetings were held during the reporting period.

## Proportionate Review Sub-Committee Meetings held during 01 April 2014 - 31 March 2015:

| Month | Date | Number of Members Present at Meeting |
|---|---|---|
| June | 18/06/2014 | 3 |
| July | 11/07/2014 | 3 |
| July | 14/07/2014 | 3 |
| September | 15/09/2014 | 3 |
| October | 13/10/2014 | 4 |
| October | 15/10/2014 | 3 |
| November | 14/11/2014 | 3 |
| January | 28/01/2015 | 3 |
| February | 20/02/2015 | 3 |

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

## Sub-Committee Meetings held during 01 April 2014 - 31 March 2015:

| Month | Date | Number of Members Present at Meeting |
|---|---|---|
| April | 15/04/2014 | 3 |
| April | 30/04/2014 | 2 |
| May | 16/05/2014 | 2 |
| May | 30/05/2014 | 2 |
| June | 15/06/2014 | 2 |
| June | 23/06/2014 | 2 |
| June | 27/06/2014 | 2 |
| July | 17/07/2014 | 2 |
| July | 21/07/2014 | 2 |
| August | 07/08/2014 | 2 |

| | | |
|---|---|---|
| August | 21/08/2014 | 2 |
| September | 04/09/2014 | 2 |
| September | 10/09/2014 | 2 |
| September | 15/09/2014 | 2 |
| September | 30/09/2014 | 2 |
| October | 07/10/2014 | 2 |
| October | 15/10/2014 | 3 |
| October | 30/10/2014 | 2 |
| November | 13/11/2014 | 2 |
| November | 21/11/2014 | 2 |
| November | 27/11/2014 | 2 |
| December | 01/12/2014 | 2 |
| December | 10/12/2014 | 2 |
| December | 17/12/2014 | 3 |
| January | 06/01/2015 | 2 |
| January | 14/01/2015 | 2 |
| January | 26/01/2015 | 2 |
| February | 10/02/2015 | 2 |
| February | 25/02/2015 | 2 |
| March | 06/03/2015 | 2 |
| March | 10/03/2015 | 2 |
| March | 25/03/2015 | 2 |

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

**Details of inquorate meeting held:01 April 2014 - 31 March 2015**

None

## Attendance of Members at full committee meetings:01 April 2014 - 31 March 2015

| Name | Number of Meetings Attended |
|---|---|
| Mr Suresh Akula | 9 |
| Mr Babak Babakinejad | 3 |
| Dr Daniel Bradford | 8 |
| Mrs Sunder Chita | 11 |
| Dr Graham Davison | 11 |
| Dr Anke Furck | 10 |
| Mr Maurice Hoffman | 12 |
| Dr Dusko Ilic | 1 |
| Dr John Keen | 5 |
| Mrs Alison Lee | 1 |
| Mr Adeyemi Olagbegi | 5 |
| Dr  Alexander Rakow | 7 |
| Dr Manish Saxena | 10 |
| Dr Zdenek Slavik | 9 |
| Dr Krishna Soondrum | 6 |
| Miss Ourania Xeniou | 7 |
| Miss Zainab Yate | 6 |

## Attendance of Members at proportionate review sub-committee meetings: 01 April 2014 - 31 March 2015

| Name | Number of Meetings Attended |
|---|---|
| Mr Babak Babakinejad | 1 |
| Mrs Sunder Chita | 8 |
| Dr Anke Furck | 1 |
| Dr John Keen | 4 |
| Mr Adeyemi Olagbegi | 1 |
| Dr Manish Saxena | 8 |
| Dr Zdenek Slavik | 2 |
| Dr Krishna Soondrum | 1 |
| Miss Ourania Xeniou | 1 |
| Miss Zainab Yate | 1 |

## Attendance of Members at sub-committee meetings: 01 April 2014 - 31 March 2015

| Name | Number of Meetings Attended |
|---|---|
| Dr Daniel Bradford | 1 |
| Mrs Sunder Chita | 29 |
| Dr Anke Furck | 2 |

| | |
|---|---|
| Dr John Keen | 14 |
| Mr Adeyemi Olagbegi | 3 |
| Dr Manish Saxena | 17 |
| Miss Ourania Xeniou | 1 |

## Training 01 April 2014 - 31 March 2015

| Name of Member | Date | Event(s) attended |
|---|---|---|
| Dr Graham Davison | 31/07/2014 | Ethical Issues in Phase One Research: An Advanced Training Course |
| Dr Graham Davison | 06/10/2014 | Research Involving the disadvantaged and Vulnerable |
| Dr Anke Furck | 31/07/2014 | Ethical issues Phase 1 training |
| Mr Maurice Hoffman | 10/11/2014 | Qualitative Research & Ethical Review |
| Dr John Keen | 08/09/2014 | NREA/Chairs meeting |
| Dr John Keen | 20/11/2014 | NREAP Training |
| Dr Alexander Rakow | 02/05/2014 | European Neonatal Ethics Conference |
| Dr Alexander Rakow | 06/11/2014 | Research Training |
| Dr Manish Saxena | 10/12/2014 | National Training Day for Chairs |
| Dr Manish Saxena | 08/01/2015 | Training of New REC Chairs |
| Dr Zdenek Slavik | 03/07/2014 | Training for New REC Chairs |
| Dr Zdenek Slavik | 21/07/2014 | The Ethical issues of Research Involving Children |
| Dr Zdenek Slavik | 31/07/2014 | Ethical issues in phase 1 |

## 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 | 12 | 22.22 |
| Phase 1 | 24 | 44.44 |
| Gene Therapy | 0 | 0.00 |
| Research Tissue Bank (including renewals) | 0 | 0.00 |
| Research Database (including renewals) | 0 | 0.00 |
| Others | 18 | 33.33 |
| **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 | 1 |
| Number of applications withdrawn prior to the meeting | 1 |
| Number of student applications reviewed | 8 |
| Number of paediatric applications reviewed | 6 |
| 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 | 1 |

### *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 | 13 | 24.07 |
| Favourable Opinion with Additional Conditions | 17 | 31.48 |
| Unfavourable Opinion | 0 | 0.00 |
| Provisional Opinion | 24 | 44.44 |
| 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 | 23 | 42.59 |
| Further Information Favourable Opinion with Additional Conditions | 0 | 0.00 |
| Further Information Unfavourable Opinion | 0 | 0.00 |
| Favourable Opinion with Standard Conditions | 13 | 24.07 |
| Favourable Opinion with Additional Conditions | 17 | 31.48 |
| Unfavourable Opinion | 0 | 0.00 |
| 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*** | **15** |

***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 | 1 |
| Number of student applications reviewed | 10 |
| Number of paediatric applications reviewed | 1 |
| Number of device applications reviewed | 0 |
| Number of qualitative applications reviewed | 2 |

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

| **Decisions taken at proportionate review sub-committee meetings** | **Number** | **%** |
|---|---|---|
| Favourable Opinion with Standard Conditions | 6 | 40.00 |
| Favourable Opinion with Additional Conditions | 4 | 26.67 |
| No Opinion transfer to full committee for review | 2 | 13.33 |
| Provisional Opinion | 3 | 20.00 |
| Unfavourable Opinion | 0 | 0.00 |
| **Total** | **15** | **100** |

***Table 8:*** **Other Management Information for the reporting period:**

| | |
|---|---|
| **Average number of applications reviewed per full meeting** | 4.50 |
| **Number of applications for full ethical review** | 54 |
| **Number of applications for full ethical review over 60 days** | 1 |
| **Number of applications over 60 days as a % of total** | 1.85% |
| **Number of applications for full ethical review over 40 days** | 9 |
| **Number of applications over 40 days as a % of total** | 16.67% |
| **Number of days taken to final decision – average (mean)** | 31 |

| | |
|---|---|
| **Number of proportionate review applications for ethical review** | 13 |
| **Number of proportionate review applications for ethical review over 14 days** | 1 |
| **Number of proportionate review applications over 14 days as a % of total** | 7.69% |

| | |
|---|---|
| **Number of SSAs (non-Phase 1) reviewed** | 6 |
| **Number of applications for SSA review over 25 days** | 2 |
| **Number of applications for SSA review over 25 days as % of all non- Phase 1 SSAs** | 33.33% |

| | |
|---|---|
| **Number of SSAs (Phase 1) reviewed** | 21 |
| **Number of applications for SSA review over 14 days** | 0 |
| **Number of applications for SSA review over 14 days as % of all Phase 1 SSAs** | 4.76% |

| | |
|---|---|
| **Number of substantial amendments reviewed** | 105 |
| **Number of substantial amendments over 35 days** | 4 |
| **Number of substantial amendments over 35 days as a % of total substantial amendments** | 3.81% |
| **Number of substantial amendments over 28 days** | 9 |
| **Number of substantial amendments over 28 days as a % of total substantial amendments** | 8.57% |

| | |
|---|---|
| **Number of modified amendments reviewed** | 2 |
| **Number of modified amendments over 14 days** | 0 |
| **Number of modified amendments over 14 days as a % of total modified amendments** | 0.00% |

| | |
|---|---|
| **Number of minor amendments received** | 39 |
| **Number of substantial amendments received for information** | 2 |
| **Number of substantial amendments received for new sites/PIs** | 10 |
| **Number of annual progress reports received** | 65 |
| **Number of safety reports received** | 23 |
| **Number of Serious Adverse Events received** | 5 |
| **Number of final reports received** | 18 |

***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** |
| 14/LO/0617 | Long-term Outcomes of Parent-Infant Psychotherapy | 47 |
| 14/LO/0622 | Genetics of trigeminal neuralgia | 37 |
| 14/LO/0644 | Vascular dysfunction in Paediatric IBD (V1) | 28 |
| 14/LO/0645 | Colonic Propionate, Appetite and Glucose Homeostasis | 37 |
| 14/LO/0776 | The adaptive immune response in Hepatitis B vaccination | 34 |
| 14/LO/0785 | Illness perceptions of Cystinosis patients and their significant other | 57 |
| 14/LO/1347 | The use of guided self-help in Anorexia Nervosa | 27 |
| 14/LO/1356 | WO29217 - Neo-adjuvant Pertuzumab in Breast Cancer | 55 |
| 14/LO/1392 | Phase 3 study of CT P13 vs Remicade in patients with Crohn's disease | 35 |
| 14/LO/1406 | Open-label study of GDC-0199 in follicular lymphoma patients | 65 |
| 14/LO/1649 | SAD & MAD study to assess safety tolerability PK PD and FE of AZD7986 | 25 |
| 14/LO/1691 | Safety, Tolerability & PK of SAD, MAD & FE ASP2205 in Healthy Subjects | 30 |
| 14/LO/1828 | Single Ascending Intravenous Infusion Study in Healthy Subjects | 38 |
| 14/LO/1857 | RCT in children with ESES syndrome | 41 |
| 14/LO/2103 | PKPD of intravenous salbutamol in paediatric acute severe asthma | 41 |
| 14/LO/2111 | EVOLUTION VERSION 1 | 23 |
| 15/LO/0066 | Effect of ASP2151 on the blood levels of midazolam, version 1 | 33 |
| 15/LO/0096 | Phase 1 Pilocarpine effect study on Salivary Secretion & Pupillometry | 29 |
| 15/LO/0104 | Albumin To prevenT Infection in chronic liveR failurE (ATTIRE) | 34 |
| 15/LO/0115 | TR2-A single dose study; version 1 | 18 |
| 15/LO/0212 | A study to see if GS-6615 shortens QT interval in patients with LQT3 | 58 |
| 15/LO/0395 | Single & multiple dose, food effect, gender and age study | 35 |
| 15/LO/0517 | YOSEMITE Ph 2 study in subjects with Pancreatic Ductal Adenocarcinoma | 43 |

| 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** |
| 14/LO/0404 | Safety and blood levels of DS-1093a; version 1 | 23 |
| 14/LO/0699 | Phase 2 study with BAY63-2521 in PH associated with IIP | 28 |
| 14/LO/0763 | Pathways to Psychological Therapy for Black Africans - V1 | 28 |
| 14/LO/1213 | Effect of ritonavir on the blood levels of ASP2151; version 1 | 18 |
| 14/LO/1344 | Bioavailability study of Omega-3 Food Supplements | 28 |
| 14/LO/1357 | A Study to Investigate Single and Multiple Doses of TD139 | 28 |
| 14/LO/1595 | TR2 single dose study; version 1 | 17 |
| 14/LO/1670 | GSK2618960, an anti-IL7-R monoclonal antibody, in healthy volunteers | 27 |
| 14/LO/1683 | Improving dignity for older people in hospital | 27 |
| 14/LO/1695 | DiPEP: Diagnosis of Pulmonary Embolism (PE) in Pregnancy | 35 |
| 14/LO/2059 | STUDY TO INVESTIGATE THE EFFECT OF RO5186582 ON RENAL TRANSPORTER | 21 |
| 15/LO/0087 | A Phase I Clinical Trial of DARC | 30 |
| 15/LO/0090 | Safety & efficacy of AMG557/MEDI5872 in Sjogren's syndrome | 23 |

| Favourable Opinion with Additional Conditions | | |
|---|---|---|
| **REC Reference** | **Title** | **Number of Days on Clock** |
| 14/LO/0620 | Participatory action research into mental health service user recovery | 34 |
| 14/LO/0696 | PK & safety study of SD GP2015 & Enbrel in healthy male volunteers | 26 |
| 14/LO/1061 | PK of daily CD5789 in healthy Japanese and non-Japanese subjects | 23 |
| 14/LO/1070 | Phase 1 TAK-079 Single Dose Escalation Study in Healthy Subjects | 31 |
| 14/LO/1155 | Is Highly Sensitive Troponin better than Sensitive Troponin in women? | 30 |
| 14/LO/1284 | Circulating tumour cells in primary lung cancer patients | 36 |
| 14/LO/1343 | PRC-4016 - Drug interaction Study | 25 |
| 14/LO/1362 | Effects of age, gender and race on blood levels of DS-1971a, v1 | 16 |
| 14/LO/1580 | VX14-770-116: Ph IV - Observational Study for CF Patients | 27 |
| 14/LO/1748 | WHEAT: WithHolding Enteral feeds Around packed red cell Transfusion | 28 |
| 14/LO/1790 | Safety, Tolerability, PK and PD of ALN PCSSC in Elevated LDL-C | 18 |
| 14/LO/2105 | ToSCA: Trial of Sertraline versus CBT for generalised Anxiety | 16 |
| 15/LO/0095 | The therapeutic relationship in using the Mental Health Recovery Star | 23 |
| 15/LO/0099 | SAATELLITE - Phase 2 study of MEDI4893 in mechanically ventilated pts | 23 |
| 15/LO/0106 | Body Perception and Satiation In Males Detained In Secure Hospital | 23 |
| 15/LO/0237 | MGB-BP-3 - first doses in humans. version 1 | 27 |
| 15/LO/0360 | A drug interaction study of DS-1971a; ver 1 | 27 |

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

| 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** |
| 14/LO/1071 | Safety, Tolerability and PK of MK-8892 in Healthy Japanese Subjects | 42 |

***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** |
| 14/LO/1257 | A Peer Support Group for Stroke | 14 |
| 14/LO/1260 | Attachment and Emotion Regulation in Psychosis - Version 1 | 10 |
| 14/LO/1877 | Opioid Prescribing Practices and Satisfaction in Medical Patients | 13 |

| 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** |
| 14/LO/1145 | What do people with ID understand about the experience of ageing? | 10 |
| 14/LO/1331 | Chronic viral gastroenteritis in post-transplant  patients | 15 |
| 14/LO/1853 | The effect of a single shot of Gentamicin on patient outcomes V 1.1 | 14 |
| 15/LO/0233 | Hypothalamic hormone deficiencies and quality of life | 13 |
| 15/LO/0378 | Mental Health Services for Deaf Children and Adolescents in Tayside | 12 |
| 15/LO/0382 | Using thoracic ultrasound to predict pleurodesis success in MPE | 14 |

| Favourable Opinion with Additional Conditions | | |
|---|---|---|
| **REC Reference** | **Title** | **Number of Days on Clock** |
| 14/LO/1147 | Investigate prevalance of Restless Leg Syndrome with Sleep Apnoea | 9 |
| 14/LO/1715 | The use of Next Generation sequencing in newborn screening | 6 |
| 14/LO/1866 | Genetics and Epigenetics of Disease Progression in Fatty Liver Disease | 12 |
| 14/LO/2102 | Is there an association between total vitamin D and CRP? | 9 |

| 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** |
| 09/H0717/74/AM03 | Ilaris Registry with CAPS patients | Updated Protocol/ICF & Assent | 17/04/2014 | 9 |
| 10/H0717/14/AM16 | Prognostic Evaluation of Diagnostic IGRA Consortium - UK PREDICT Study | Substantial Amendment- Documen | 01/05/2014 | 4 |
| 10/H0717/14/AM17 | Prognostic Evaluation of Diagnostic IGRA Consortium - UK PREDICT Study | version 8 dated 9.12.14 (our r | 09/12/2014 | 28 |
| 10/H0717/14/AM18 | Prognostic Evaluation of Diagnostic IGRA Consortium - UK PREDICT Study | Version 9 dated 03.02.15 | 10/02/2015 | 24 |
| 10/H0717/68/AM23 | V212 in Recipients of Autologous Hematopoietic Cell Transplants (001) | SA24 V212-001-04 2014/09/22 (o | 22/10/2014 | 7 |
| 11/LO/0978/AM04 | Ranibizumab (Lucentis) for treatment of Uveitic Macular Oedema (LIMO) | OKHN1005 version 2 2012/12/19 | 30/06/2014 | 13 |
| 11/LO/1684/AM03 | Seeking help and receiving appropriate treatment for OCD | AM03 (Our REC Ref No. AM03) | 24/02/2015 | 20 |
| 11/LO/1853/AM11 | Siltuximab in Patients with High-risk Smoldering Multiple Myeloma | Sub Amendment - 3 Dec 2014 IB | 03/12/2014 | 2 |
| 11/LO/1853/AM12 | Siltuximab in Patients with High-risk Smoldering Multiple Myeloma | Substantial Amendment 4; Date: | 12/03/2015 | 10 |
| 11/LO/1909/AM04 | Renal Denervation in Congestive Cardiac Failure | Amendment 4; Date: 15.10.14 | 24/10/2014 | 18 |
| 11/LO/2005/AM22 | Tocilizumab (TCZ) for the treatment of systemic sclerosis | Updated UK ICF Version 3 | 25/04/2014 | 6 |
| 11/LO/2005/AM23 | Tocilizumab (TCZ) for the treatment of systemic sclerosis | Investigators | 07/11/2014 | 7 |

| | | | | |
|---|---|---|---|---|
| | | Brochure Annual | | |
| 11/LO/2025/AM04 | The Impact of Omalizumab Treatment in UK Clinical Practice | Substantial Amendment 4 - 10.0 | 25/03/2014 | 12 |
| 12/LO/0119/AM05 | Parent-child interactions & treatment of anxious adolescents (v1) | Amendment 05. 30 June 2014 | 15/07/2014 | 11 |
| 12/LO/0119/AM06 | Parent-child interactions & treatment of anxious adolescents (v1) | Amendment 06, Date: 23 October | 23/10/2014 | 7 |
| 12/LO/0139/AM06 | New technologies to nutrition research | Amendment 6; Date: (13/01/2015 | 13/01/2015 | 11 |
| 12/LO/0440/AM24 | AMG 785/Placebo in Postmenopausal Women with Osteoporosis- 20070337 | Substantial Amendment 13 | 10/04/2014 | 8 |
| 12/LO/0440/AM26 | AMG 785/Placebo in Postmenopausal Women with Osteoporosis- 20070337 | Substantial Amendment 14 - Ret | 14/08/2014 | 11 |
| 12/LO/0440/AM29 | AMG 785/Placebo in Postmenopausal Women with Osteoporosis- 20070337 | Substantial Amendment 16 - PI | 30/09/2014 | 22 |
| 12/LO/0440/AM31 | AMG 785/Placebo in Postmenopausal Women with Osteoporosis- 20070337 | Our REC Ref No. AM31 | 09/01/2014 | 8 |
| 12/LO/0631/AM05 | Effects of blood transfusion on serum markers and tumour MRI | v8.0 April 2014 (our ref: AM05 | 02/07/2014 | 7 |
| 12/LO/0639/AM07 | A-PREDICT | 4 | 23/05/2014 | 1 |
| 12/LO/0996/AM03 | Cervico-vaginal immune responses to 3 deltoid or thigh IM TicoVac | CRC 306 version 5.0 2014/07/22 | 23/07/2014 | 13 |
| 12/LO/1265/AM09 | A study of blood levels & side effects of avibactam and aztreonam; v1 | Our REC Ref No. AM09 | 08/01/2015 | 7 |
| 12/LO/1291/AM02 | Detecting Retinal Changes in ARSACS & Other Ataxias Using OCT | Amendmentextending 1 the study | 19/02/2015 | 6 |
| 12/LO/1434/AM05 | RENEW study | CLN0009 Version E 02/07/2014 | 23/07/2014 | 7 |
| 12/LO/1472/AM03 | EBGen | 3.0 30/07/2014 | 31/07/2014 | 17 |
| 12/LO/1661/AM04 | Evaluation of the effects of treatment on cancer tissue V1.1 | Amendment 4 10/12/2014 | 20/01/2015 | 28 |
| 12/LO/1876/AM10 | GO28141 PhIII Vemurafenib Vs Vemurafenib + GDC-0973 in Melanoma | Substantial Amendment- IB | 13/05/2014 | 7 |

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|---|---|---|---|---|
| 12/LO/1950/AM06 | C25003 Ph3 A+AVD vs ABVD Frontline in Patients with Hodgkin Lymphoma | Protocol Amendment 6 2014/05/2 | 04/07/2014 | 24 |
| 12/LO/1966/AM07 | TELESTAR (Telotristat Etiprate for SSA Refractory Carcinoid Syndrome) | Substantial Amendment 4 UK REC | 20/08/2014 | 19 |
| 12/LO/1966/AM08 | TELESTAR (Telotristat Etiprate for SSA Refractory Carcinoid Syndrome) | Substantial Amendment 5 UK REC | 13/11/2014 | 10 |
| 12/LO/1966/AM09 | TELESTAR (Telotristat Etiprate for SSA Refractory Carcinoid Syndrome) | Amendment 5; Date: 2015/01/20 | 05/02/2015 | 27 |
| 13/LO/0386/AM04 | Nilotinib treatment-free remission study in CML patients-ENESTFreedom | CAMN10712201; version 02; date | 03/09/2014 | 13 |
| 13/LO/0550/AM01 | IUI vs IVF for first line treatment of unexplained infertility - A RCT | Substantial Amendment 1-Updat | 11/06/2014 | 36 |
| 13/LO/0551/AM03 | PEPtalk 2 | SA-02 version 1.0 2014/10/31 ( | 09/12/2014 | 4 |
| 13/LO/0681/AM03 | Multiboost - MCC plus pertussis booster in adolescents | Multiboost version 4 2014/08/0 | 07/08/2014 | 15 |
| 13/LO/0729/AM02 | Size of the HIV-1 reservoir and ongoing replication in defined cohorts | Amendment 1; Dated 3 December | 19/12/2014 | 17 |
| 13/LO/0855/AM07 | Idelalisib in Combination with Rituximab for Previously Treated iNHL | Am08 | 23/05/2014 | 4 |
| 13/LO/0855/AM09 | Idelalisib in Combination with Rituximab for Previously Treated iNHL | GS-US-313-0124-Version 6- 201 | 07/10/2014 | 8 |
| 13/LO/0855/AM10 | Idelalisib in Combination with Rituximab for Previously Treated iNHL | AM10 | 16/10/2014 | 25 |
| 13/LO/0855/AM11 | Idelalisib in Combination with Rituximab for Previously Treated iNHL | Amendment 11 IB11, ICF & Closu | 19/11/2014 | 29 |
| 13/LO/0855/AM12 | Idelalisib in Combination with Rituximab for Previously Treated iNHL | 10; Date: 2015/02/18 | 18/02/2015 | 2 |
| 13/LO/0882/AM02 | SWS And daytime Functioning in chronic FatiguE syndrome (SAFFE) | SA02, Version 1, 2014/09/22 | 22/09/2014 | 7 |
| 13/LO/1022/AM06 | 308: Phase 3 study of XL184 vs Everolimus in subjects with RCC | 1.0; Date: 2014/04/17 | 20/05/2014 | 2 |

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| 13/LO/1022/AM08 | 308: Phase 3 study of XL184 vs Everolimus in subjects with RCC | Updated Investigator's Brochur | 03/11/2014 | 29 |
| 13/LO/1084/AM01 | Phenotype/genotype correlation of inherited corneal dystrophies v1 | 1; Date: 14/04/2014 | 14/04/2014 | 19 |
| 13/LO/1378/AM02 | Dose-escalation Trial to assess selumetinib Safety,Tolerability & PK | Substantial Amendment - D1532C | 03/04/2014 | 14 |
| 13/LO/1536/AM02 | Exenatide-PD | Amendment 3, 2014/11/13 (our r | 13/11/2014 | 25 |
| 13/LO/1536/AM03 | Exenatide-PD | Amendment 4: Date: 2014/12/19 | 22/12/2014 | 56 |
| 13/LO/1575/AM02 | Study of safety and effects of HTL0009936 in healthy subjects | Substantial Amendment 1, Proto | 15/04/2014 | 14 |
| 13/LO/1575/AM05 | Study of safety and effects of HTL0009936 in healthy subjects | Substantial Amendment 2 (our r | 05/09/2014 | 5 |
| 13/LO/1580/AM01 | FiH, single-rising dose study with ASP7962, incl. food-effect in HVs. | Substantial Amendment 1, Protc | 26/03/2014 | 12 |
| 13/LO/1618/AM03 | TELEPATH (Expanded Treatment for Carcinoid Syndrome Symptoms) | Protocol Amendment 1: Date: 31 | 30/05/2014 | 6 |
| 13/LO/1618/AM04 | TELEPATH (Expanded Treatment for Carcinoid Syndrome Symptoms) | Substantial Amendment 3 - drug | 14/07/2014 | 5 |
| 13/LO/1618/AM05 | TELEPATH (Expanded Treatment for Carcinoid Syndrome Symptoms) | Code number: 4 Version: 2 Date | 10/11/2014 | 25 |
| 13/LO/1666/AM02 | The HALT-LTBI Study | 4; Date: 2014/12/01 | 20/01/2015 | 49 |
| 13/LO/1682/AM06 | Study of Maintenance Rucaparib in Relapsed High-grade Ovarian Cancer | 4 | 10/01/2015 | 29 |
| 13/LO/1690/AM02 | GSK2793660 - first doses in humans; version 1 | Substantial Amendment 2: Proto | 12/05/2014 | 1 |
| 13/LO/1690/AM04 | GSK2793660 - first doses in humans; version 1 | Substantial | 06/06/2014 | 1 |

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| | | Amendment 3-Inform | | |
| 13/LO/1722/AM02 | Sleep and VicksRub | Amendment 2 | 07/08/2014 | 19 |
| 13/LO/1722/AM03 | Sleep and VicksRub | 1 | 22/09/2014 | 3 |
| 13/LO/1722/AM04 | Sleep and VicksRub | Our REC Ref No. AM04; Date: 20 | 20/01/2015 | 24 |
| 13/LO/1792/AM01 | A PET scan study of [18F]-FBA-A20FMDV2; ver 1 | Protocol amendment 01 dated 28 | 27/06/2014 | 34 |
| 13/LO/1792/AM02 | A PET scan study of [18F]-FBA-A20FMDV2; ver 1 | Protocol Amendment 03, dated 1 | 10/12/2014 | 1 |
| 13/LO/1792/AM03 | A PET scan study of [18F]-FBA-A20FMDV2; ver 1 | Generic information and consen | 08/01/2015 | 7 |
| 13/LO/1800/AM02 | Tachycardia electrograms for testing S-ICD discrimination algorithm | Substantial Amendment 2-Updat | 07/07/2014 | 2 |
| 13/LO/1800/AM03 | Tachycardia electrograms for testing S-ICD discrimination algorithm | Amendment number 3 1st Decembe | 02/12/2014 | 19 |
| 14/LO/0102/AM04 | SNF472 SAD & MAD in healthies, SAD in haemodialysis patients | Substantial Amendment 1-Updat | 15/05/2014 | 3 |
| 14/LO/0102/AM05 | SNF472 SAD & MAD in healthies, SAD in haemodialysis patients | 2 | 18/08/2014 | 24 |
| 14/LO/0102/AM06 | SNF472 SAD & MAD in healthies, SAD in haemodialysis patients | Substantial Amendment 3 - Cons | 11/11/2014 | 10 |
| 14/LO/0102/AM10 | SNF472 SAD & MAD in healthies, SAD in haemodialysis patients | Protocol v6.0; Date: 2015/02/0 | 26/02/2015 | 11 |
| 14/LO/0117/AM01 | Ablation Versus Anti-arrhythmic Therapy in reducing hospital episodes | Substantial Amendment 1-Revis | 15/05/2014 | 4 |
| 14/LO/0205/AM02 | First study of DS-1971a in humans; version 1 | DS1971-A-E101 protocol, versio | 20/06/2014 | 14 |

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| 14/LO/0274/AM01 | SARAH pilot study | 3.0; Date: 2014/12/03 | 12/12/2014 | 36 |
| 14/LO/0330/AM01 | Imagery rescripting with people with psychosis and social anxiety | Substantial Amendment 1- Study | 04/06/2014 | 8 |
| 14/LO/0404/AM01 | Safety and blood levels of DS-1093a; version 1 | Protocol amendment 1, version | 08/10/2014 | 28 |
| 14/LO/0404/AM02 | Safety and blood levels of DS-1093a; version 1 | Generic information and consen | 07/01/2015 | 7 |
| 14/LO/0696/AM05 | PK & safety study of SD GP2015 & Enbrel in healthy male volunteers | Protocol version 3.0: Date: 20 | 23/09/2014 | 27 |
| 14/LO/0699/AM01 | Phase 2 study with BAY63-2521 in PH associated with IIP | Substantial Amendment 1- Updat | 06/06/2014 | 4 |
| 14/LO/0699/AM02 | Phase 2 study with BAY63-2521 in PH associated with IIP | 13605_coreNaf_09 Oct2014_AMD04 | 17/11/2014 | 16 |
| 14/LO/1070/AM01 | Phase 1 TAK-079 Single Dose Escalation Study in Healthy Subjects | Substantial Amendment 1: Tempo | 05/09/2014 | 2 |
| 14/LO/1070/AM02 | Phase 1 TAK-079 Single Dose Escalation Study in Healthy Subjects | Substantial Amendment 2 Protoc | 29/10/2014 | 16 |
| 14/LO/1145/AM01 | What do people with ID understand about the experience of ageing? | Amendment number 1, 11/8/14 | 11/08/2014 | 12 |
| 14/LO/1284/AM01 | Circulating tumour cells in primary lung cancer patients | v3; Date: 16th Dec 2014 | 12/01/2015 | 16 |
| 14/LO/1331/AM01 | Chronic viral gastroenteritis in post-transplant patients | Amendment 1 (09/12/2014) (our | 10/12/2014 | 28 |
| 14/LO/1343/AM01 | PRC-4016 - Drug interaction Study | 2; Date: 2014/07/28 | 11/08/2014 | 8 |
| 14/LO/1347/AM02 | The use of guided self-help in Anorexia Nervosa | Amendment n.1; Date: 09/01/201 | 09/01/2015 | 6 |
| 14/LO/1357/AM03 | A Study to Investigate Single and Multiple Doses of TD139 | GB-HV-01 FINAL 3.0 / 28 Novemb | 02/12/2014 | 17 |

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| 14/LO/1357/AM04 | A Study to Investigate Single and Multiple Doses of TD139 | GB-HV-01 FINAL 3.0; Date: 28 N | 02/12/2014 | 34 |
| 14/LO/1362/AM01 | Effects of age, gender and race on blood levels of DS-1971a, v1 | Investigator's Brochure, versi | 12/11/2014 | 7 |
| 14/LO/1406/AM01 | Open-label study of GDC-0199 in follicular lymphoma patients | Updated radiation assessment a | 03/12/2014 | 6 |
| 14/LO/1406/AM02 | Open-label study of GDC-0199 in follicular lymphoma patients | 2 | 27/02/2015 | 12 |
| 14/LO/1670/AM01 | GSK2618960, an anti-IL7-R monoclonal antibody, in healthy volunteers | 2013N173840_01; Date: 2014/10/ | 21/10/2014 | 15 |
| 14/LO/1695/AM02 | DiPEP: Diagnosis of Pulmonary Embolism (PE) in Pregnancy | 1 | 16/01/2015 | 4 |
| 14/LO/1695/AM03 | DiPEP: Diagnosis of Pulmonary Embolism (PE) in Pregnancy | 2; Date: 30/01/2015 | 05/02/2015 | 4 |
| 14/LO/1790/AM03 | Safety, Tolerability, PK and PD of ALN PCSSC in Elevated LDL-C | Amendment 1; Date: 19/Feb/2015 | 25/02/2015 | 12 |
| 14/LO/1828/AM01 | Single Ascending Intravenous Infusion Study in Healthy Subjects | 1; Date: 2014/11/25 | 08/01/2015 | 11 |
| 14/LO/1857/AM01 | RCT in children with ESES syndrome | 03 | 16/06/2015 | 17 |
| 14/LO/2059/AM01 | STUDY TO INVESTIGATE THE EFFECT OF RO5186582 ON RENAL TRANSPORTER | B; Date: 2014/12/23 | 05/01/2015 | 16 |
| 15/LO/0087/AM01 | A Phase I Clinical Trial of DARC | 2.0; Date: 2015/02/19 | 02/03/2015 | 25 |

| **Unfavourable opinion** | | | | |
|---|---|---|---|---|
| **Amendment REC Reference** | **Title** | **Version** | **Date** | **Number of Days on Clock** |
| 12/LO/0781/AM02 | SIGNIFY Version 1.6 | Amendment 4 (2nd Substantial A | 27/10/2014 | 23 |
| 14/LO/0645/AM01 | Colonic Propionate, Appetite and Glucose Homeostasis | Amendment 1 01/12/2014 (our re | 01/12/2014 | 9 |

***Table 10.2:*** **Breakdown of current status of all modified amendments reviewed within the reporting period**

| **Favourable opinion timeline** |
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| Amendment REC Reference | Title | Version | Date | Number of Days on Clock |
|---|---|---|---|---|
| 12/LO/0781/AM02/1 | SIGNIFY Version 1.6 | Modified Amendment 4 (2nd Subs | 27/11/2014 | 7 |
| 14/LO/0645/AM01/1 | Colonic Propionate, Appetite and Glucose Homeostasis | Amendment 2; Date: 11/02/2015 | 13/02/2015 | 5 |

| 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** |
| 14/LO/1406 | Open-label study of GDC-0199 in follicular lymphoma patients | 65 |

| **Proportionate review applications for ethical review over 14 day timeline** | | |
|---|---|---|
| **REC Reference** | **Title** | **Number of Days on Clock** |
| 14/LO/1331 | Chronic viral gastroenteritis in post-transplant  patients | 15 |

| **SSAs (non Phase 1) over 25 day timeline** | | |
|---|---|---|
| **REC Reference** | **Title** | **Number of Days on Clock** |
| 14/LO/1177 | Enumeration and characterizati | 33 |
| 14/LO/1845 | A Multicenter, International, | 41 |

| **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** |
| 13/LO/0550/AM01 | IUI vs IVF for first line treatment of unexplained infertility - A RCT | Substantial Amendment 1-Updat | 11/06/2014 | 36 |
| 13/LO/1536/AM03 | Exenatide-PD | Amendment 4: Date: 2014/12/19 | 22/12/2014 | 56 |
| 13/LO/1666/AM02 | The HALT-LTBI Study | 4; Date: 2014/12/01 | 20/01/2015 | 49 |
| 14/LO/0274/AM01 | SARAH pilot study | 3.0; Date: 2014/12/03 | 12/12/2014 | 36 |

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