

**South Central - Hampshire B Research Ethics  
Committee**

**Annual Report**

**01 April 2015 - 31 March 2016**



## Part 1 – Committee Membership and Training

|                              |   |
|------------------------------|---|
| <b>Name of REC:</b>          | South Central - Hampshire B Research Ethics Committee   |
| <b>Type of REC:</b>          | RECs recognised to review CTIMPS in patients - type iii   |
| <b>Type of Flag:</b>         | Establishing Research Tissue Banks<br>IRB Registered  |
| <b>Chair:</b>                | Professor Ron King  |
| <b>Vice-Chair:</b>           | Dr Giles Tan (01/04/2013 - 14/09/2015)<br>Dr Andrew Scott (14/09/2015 – present)  |
| <b>Alternate Vice-Chair:</b> | Dr Andrew Scott (17/03/2015 – 14/09/2015)<br>Mr Brian Birch (23/09/2015 – present)  |
| <b>REC Manager:</b>          | Miss Libby Watson (upto 01/05/2015)<br>Mrs Maeve Ip Groot Bluemink (01/05/2015 – 01/10/2015)<br>Mrs Siobhan Bawn (01/10/2015 – present) |
| <b>REC Assistant:</b>        | Natasha Bridgeman (upto 01/05/2015)<br>Sadie McKeown-Keegan (01/05/2015 – 01/10/2015)   |
| <b>Committee Address:</b>    | Level 3 Block B<br>Whitefriars<br>Lewins Mead<br>Bristol<br>BS1 2NT   |
| <b>Telephone:</b>            | 0207 104 8052   |
| <b>Email:</b>                | <a href="mailto:nrescommittee.southcentral-hampshireb@nhs.net">nrescommittee.southcentral-hampshireb@nhs.net</a>                        |

## Chair's overview of the past year:

This year the main Committee has dealt with 47 applications, all within the 60 day time limit but it is slightly disappointing to note that 4 exceeded the key performance target of 40 days. For various reasons, including problems encountered in 22 cases at the validation stage, the various Proportionate Review Sub-Committees dealt with only 14 validated applications, but completed them all within the 14 day target. Ordinary Sub-Committees dealt with no less than 119 Substantial Amendments with just 7 extending to 28 days but none as long as 35 days. Whilst the work of the Committee can be assessed only in part in such numerical terms, these figures indicate a continuing commitment to undertaking its review work for the HRA both diligently and efficiently. All contributing members, as well as those backing them up in the South Central office, are to be congratulated on this.

There have been several changes at officer level during the year. We were sorry to lose Giles Tan whose service as Vice-Chair had been invaluable. He was always a thoughtful contributor to discussions within the Committee and was particularly good at questioning researchers. As Chair, I am greatly indebted to him for his practical support and encouragement over many years. Having deputised for Giles for some time, Andrew Scott formally took over as Vice-Chair, with Brian Birch being appointed later in the year as Alternate Vice-Chair. They have both played a significant role not only in the deliberations of the main Committee, but also in chairing various Sub-Committees.

Changes have also taken place at REC Manager level. Last year we welcomed Maeve Groot Bluemink to this post, but her appointment turned out to be temporary while a major re-shuffle took place at the Bristol office. Maeve was succeeded by Siobhan Bawn, to whom much of the credit must go for the smooth functioning of the Committee this year. In the absence of any permanent Assistant, Siobhan was supported in her part-time role by a number of assistants - and also at times of need by Libby Watson.

As far as Committee membership is concerned, we lost Megan Barlow-Pay after all too short a time with us, and also Ita Berry who had been a founder member of the merged Committee. She could always be relied upon to uphold the interests of research participants and took on more than her share of work at a time when we were very short of lay members. To relieve the situation Lisa Armstrong has now joined us on a short term basis. Then the membership was further boosted with Ravina Barrett, Diane Ackerley, Alessandro di Nicola and Becci Petch all joining us in quick succession. The strength of the new team was particularly evident in the case of one particular study involving a number of ethical issues, where post-meeting email correspondence was necessary in connection with an external expert review. I believe that that the deliberations both in the meeting itself and subsequently in correspondence, showed both new and old members working extremely effectively together to achieve an appropriate consensus.

Having announced my own departure after 10 years on the Hampshire B Committee and its predecessor Southampton B, I can report I am leaving at a time when the combined membership has rarely, if ever, been stronger. It has been a pleasure and a privilege to serve as a member and Chair, and to have worked with so many volunteers and supporting personnel who are all intent on protecting participants whilst facilitating high quality medical research. I wish the Committee well in all its future endeavours.

## South Central - Hampshire B Research Ethics Committee Membership

| Name                    | Profession  | Expert or Lay | Dates      |            |
|-------------------------|---|---------------|------------|------------|
|                         |   |               | Appointed  | Left       |
| Dr Diane Ackerley       | Retired Doctor  | Expert        | 01/01/2016 |            |
| Mrs Lisa Armstrong      | Senior Lecturer Social Work   | Lay           | 10/12/2015 |            |
| Ms Megan Barlow-Pay     | Patient and Public Involvement Officer                                  | Lay Plus      | 21/04/2015 | 09/11/2015 |
| Mrs Ravina Barrett      | Pharmacist  | Expert        | 25/11/2015 |            |
| Mrs Ita Berry           | Clinical Psychologist (Retired)   | Lay           | 01/04/2013 | 25/08/2015 |
| Mr Brian Birch          | Consultant Urological Surgeon   | Expert        | 01/04/2013 |            |
| Mrs Janet Brember       | Pharmacist  | Expert        | 01/04/2013 |            |
| Ms Julie Brinton        | Speech and Language Therapist   | Expert        | 23/02/2015 |            |
| Mr Mark Cassidy         | Senior Lecturer in Radiography  | Expert        | 01/04/2013 |            |
| Dr Alessandro di Nicola | Lecturer in Philosophy  | Lay Plus      | 01/01/2016 |            |
| Ms Susan Edwards        | Lead Contract Manager, NHS South West and Central Contract Support Unit | Lay           | 27/01/2015 |            |
| Mrs Angela Iveson       | Acute Oncology Clinical Nurse Specialist                                | Expert        | 01/04/2013 |            |
| Professor Ron King      | Mathematician (Retired)   | Lay Plus      | 01/04/2013 |            |
| Mr Geoff Lowndes        | Chartered Engineer (Retired)  | Lay Plus      | 01/04/2013 |            |
| Miss Becci Petch        | Clinical Trial Coordinator  | Lay           | 08/02/2016 |            |
| Dr Andrew Scott         | Course Leader, M.Sc. Clinical Exercise Science                          | Expert        | 01/04/2013 |            |
| Dr Giles Tan            | Consultant Psychiatrist   | Expert        | 01/04/2013 | 12/11/2015 |

## South Central - Hampshire B Research Ethics Committee: Deputy Members

| Name | Profession | Status | Meeting date attended |
|------|------------|--------|-----------------------|
|      |            |        |                       |

## South Central - Hampshire B Research Ethics Committee: Co-opted Members

| Name               | Profession           | Status   | Meeting date attended  |
|--------------------|----------------------|----------|------------------------|
| Ms Stephanie Ellis | Former Civil Servant | Lay Plus | 26/08/2015, 30/09/2016 |

## South Central - Hampshire B Research Ethics Committee: Members' Declarations of

| Name                    | Declaration of Interest  | Date       |
|-------------------------|--|------------|
| Dr Diane Ackerley       | None   | 19/01/2016 |
| Mrs Lisa Armstrong      | Currently working on a piece of research in Hampshire with Mencop, Cares Togells, and Princess Royal Trust for carers  | 25/01/2016 |
| Ms Megan Barlow-Pay     | Researcher Advisor for Research Design Service   | 14/05/2015 |
| Mrs Ravina Barrett      | None   | 30/11/2015 |
| Mr Brian Birch          | Has previously acted as a paid advisor (ad hoc) for Astellas and Janssen.either received honoraria to speak at, chair and attend meetings or liased/received educational material from representatives of the following companies: Astellas, Pfizer, Ipsen, Glaxo Smith Kline, Sanofi, Lilly, Bayer, Amgen, Ferring, Takeda, AstraZeneca, Janssen-Cilag, Janssen | 01/02/2016 |
| Mrs Janet Brember       | None   | 19/01/2016 |
| Ms Julie Brinton        | Part-time consultancy for Advanced Bionics, manufacturers of cochlear implants. Advanced Bionics is a division of Phonak, a learning aid manufacturer. Parent Company is Sonus.  | 02/04/2015 |
| Mr Mark Cassidy         | Year 3 'Developing Project Skills' Unit Leader, BSc Radiography, University of Portsmouth  | 25/01/2016 |
| Dr Alessandro Di Nicola | None   | 12/01/2016 |
| Ms Susan Edwards        | None   | 29/03/2016 |
| Mrs Angela Iveson       | Employed as Research Nurse by Salisbury NHS Foundation Trust   | 31/03/2016 |
| Professor Ron King      | Share holds in pharmaceutical companies though managed by a 3rd party.   | 29/03/2016 |
| Mr Geoff Lowndes        | None   | 28/10/2015 |
| Miss Becci Petch        | None   | 10/02/2016 |
| Dr Andrew Scott         | None   | 12/01/2016 |
| Dr Alessandro Di Nicola | None   | 12/01/2016 |

### Meetings for Full Ethical Review 01 April 2015 - 31 March 2016:

| Month     | Date       | Number of Members Present at Meeting |
|-----------|------------|--------------------------------------|
| April     | 29/04/2015 | 9                                    |
| May       | 27/05/2015 | 9                                    |
| July      | 29/07/2015 | 11                                   |
| August    | 26/08/2015 | 9                                    |
| September | 30/09/2015 | 8                                    |
| October   | 28/10/2015 | 8                                    |
| November  | 25/11/2015 | 8                                    |
| January   | 27/01/2016 | 13                                   |
| February  | 24/02/2016 | 10                                   |

9 full committee meetings were held during the reporting period.

### Proportionate Review Sub-Committee Meetings held during 01 April 2015 - 31 March 2016:

| Month     | Date       | Number of Members Present at Meeting |
|-----------|------------|--------------------------------------|
| July      | 29/07/2015 | 3                                    |
| September | 30/09/2015 | 3                                    |
| November  | 25/11/2015 | 3                                    |
| December  | 09/12/2015 | 7                                    |
| January   | 27/01/2016 | 3                                    |
| February  | 24/02/2016 | 3                                    |
| March     | 30/03/2016 | 3                                    |

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

### Sub-Committee Meetings held during 01 April 2015 - 31 March 2016:

| Month     | Date       | Number of Members Present at Meeting |
|-----------|------------|--------------------------------------|
| April     | 01/04/2015 | 2                                    |
| April     | 15/04/2015 | 2                                    |
| April     | 29/04/2015 | 3                                    |
| May       | 06/05/2015 | 2                                    |
| May       | 20/05/2015 | 2                                    |
| June      | 03/06/2015 | 2                                    |
| June      | 17/06/2015 | 2                                    |
| June      | 30/06/2015 | 2                                    |
| July      | 06/07/2015 | 2                                    |
| July      | 21/07/2015 | 2                                    |
| August    | 05/08/2015 | 2                                    |
| August    | 19/08/2015 | 2                                    |
| September | 10/09/2015 | 2                                    |
| September | 16/09/2015 | 2                                    |
| October   | 05/10/2015 | 2                                    |

|          |            |    |
|----------|------------|----|
| October  | 07/10/2015 | 2  |
| October  | 12/10/2015 | 2  |
| October  | 21/10/2015 | 2  |
| November | 04/11/2015 | 2  |
| November | 18/11/2015 | 2  |
| November | 20/11/2015 | 2  |
| November | 27/11/2015 | 2  |
| December | 02/12/2015 | 2  |
| December | 04/12/2015 | 2  |
| December | 04/12/2015 | 2  |
| December | 04/12/2015 | 2  |
| December | 04/12/2015 | 2  |
| December | 11/12/2015 | 2  |
| December | 16/12/2015 | 2  |
| December | 30/12/2015 | 2  |
| January  | 20/01/2016 | 2  |
| February | 03/02/2016 | 2  |
| February | 05/02/2016 | 13 |
| February | 12/02/2016 | 3  |
| February | 17/02/2016 | 2  |
| March    | 02/03/2016 | 2  |
| March    | 16/03/2016 | 2  |

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

### Attendance of Members at full committee meetings: 01 April 2015 - 31 March 2016

| Name                    | Number of Meetings Attended |
|-------------------------|-----------------------------|
| Dr Diane Ackerley       | 2                           |
| Mrs Lisa Armstrong      | 2                           |
| Ms Megan Barlow-Pay     | 3                           |
| Mrs Ravina Barrett      | 3                           |
| Mrs Ita Berry           | 3                           |
| Mr Brian Birch          | 7                           |
| Mrs Janet Brember       | 8                           |
| Ms Julie Brinton        | 8                           |
| Mr Mark Cassidy         | 6                           |
| Dr Alessandro di Nicola | 1                           |
| Ms Susan Edwards        | 8                           |
| Mrs Angela Iveson       | 7                           |
| Professor Ron King      | 9                           |
| Mr Geoff Lowndes        | 8                           |
| Miss Becci Petch        | 1                           |
| Dr Andrew Scott         | 6                           |
| Dr Giles Tan            | 1                           |

### Attendance of Members at proportionate review sub-committee meetings: 01 April 2015 - 31 March 2016

| Name               | Number of Meetings Attended |
|--------------------|-----------------------------|
| Mrs Ita Berry      | 1                           |
| Mr Brian Birch     | 3                           |
| Mrs Janet Brember  | 3                           |
| Ms Julie Brinton   | 2                           |
| Mr Mark Cassidy    | 2                           |
| Ms Susan Edwards   | 3                           |
| Mrs Angela Iveson  | 2                           |
| Professor Ron King | 6                           |
| Mr Geoff Lowndes   | 1                           |
| Dr Andrew Scott    | 2                           |

### Attendance of Members at sub-committee meetings: 01 April 2015 - 31 March 2016

| Name               | Number of Meetings Attended |
|--------------------|-----------------------------|
| Dr Diane Ackerley  | 1                           |
| Mrs Lisa Armstrong | 1                           |
| Dr Ronja Bahadori  | 1                           |



|                         |    |
|-------------------------|----|
| Mrs Ravina Barrett      | 1  |
| Mrs Ita Berry           | 3  |
| Mr Brian Birch          | 7  |
| Mrs Janet Brember       | 6  |
| Ms Julie Brinton        | 9  |
| Mr Mark Cassidy         | 9  |
| Dr Alessandro di Nicola | 1  |
| Ms Susan Edwards        | 3  |
| Mrs Angela Iveson       | 5  |
| Professor Ron King      | 20 |
| Mr Geoff Lowndes        | 3  |
| Dr Andrew Scott         | 17 |

**Training 01 April 2015 - 31 March 2016**

| <b>Name of Member</b>   | <b>Date</b> | <b>Event(s) attended</b>   |
|-------------------------|-------------|--|
| Dr Diane Ackerley       | 22/02/2016  | Equality and Diversity Training  |
| Dr Diane Ackerley       | 10/03/2016  | Member Induction Training  |
| Mrs Lisa Armstrong      | 08/12/2015  | Hampshire A Training Day   |
| Ms Megan Barlow-Pay     | 22/07/2015  | Training - Research Involving the Disadvantaged and Vulnerable: a Workshop for Researchers and Reviewers |
| Mrs Ravina Barrett      | 13/10/2015  | Unconscious Bias ENEI  |
| Mrs Ravina Barrett      | 13/10/2015  | Diversity in the Workplace   |
| Mrs Ravina Barrett      | 31/03/2016  | Self-Directed Learning   |
| Mr Brian Birch          | 26/10/2015  | Equality and Diversity Training  |
| Mr Brian Birch          | 14/11/2015  | Training for New REC Chairs  |
| Mr Brian Birch          | 19/11/2015  | Personal Data in Research - A Workshop   |
| Mr Brian Birch          | 03/12/2015  | HRA Workshop: Pragmatic or Point of Care trials  |
| Mr Brian Birch          | 08/12/2015  | Local Training Day - Hampshire A   |
| Mr Brian Birch          | 14/01/2016  | New Chair's Training   |
| Mrs Janet Brember       | 08/04/2015  | Ethics & GCP Forum ICR   |
| Mrs Janet Brember       | 08/12/2015  | Local Training Day - Hampshire A   |
| Ms Julie Brinton        | 29/04/2015  | Equality and Diversity Training  |
| Ms Julie Brinton        | 17/06/2015  | Member Induction Training  |
| Ms Julie Brinton        | 27/11/2015  | CTIMP Training Day   |
| Mr Mark Cassidy         | 22/07/2015  | Qualitative Research and Ethical Review  |
| Mr Mark Cassidy         | 03/12/2015  | HRA Workshop: Pragmatic or Point of Care trials  |
| Dr Alessandro di Nicola | 04/01/2016  | Equality and Diversity e-module  |
| Ms Susan Edwards        | 24/09/2015  | Member Induction Training  |
| Professor Ron King      | 04/09/2015  | Joint Oxford Training Day  |
| Professor Ron King      | 27/11/2015  | CTIMP Training   |
| Professor Ron King      | 03/02/2016  | Handling Health-Related Findings in Research   |
| Professor Ron King      | 03/02/2016  | Handling Health-Related Findings in Research (Joint MRC/HRA)   |
| Professor Ron King      | 03/02/2016  | Handling Health-Related Findings   |
| Dr Andrew Scott         | 03/06/2015  | NREAP South Central Chairs' Meeting  |
| Dr Andrew Scott         | 08/12/2015  | Local Training Day - Hampshire A   |
| Dr Andrew Scott         | 12/01/2016  | Equality and Diversity   |

## PART 2: REC WORKLOAD AND ACTIVITY DURING THE REPORTING PERIOD

**Table 1: Applications assigned to a full committee meeting held within the reporting period:**

| <b>Applications for full ethical review – Study Type</b> | <b>Number</b> | <b>%</b>   |
|--|---------------|------------|
| Clinical Trial of Investigational Medicinal Product      | 15            | 31.25      |
| Phase 1  | 0             | 0.00       |
| Gene Therapy   | 0             | 0.00       |
| Research Tissue Bank (including renewals)                | 1             | 2.08       |
| Research Database (including renewals)                   | 0             | 0.00       |
| Others   | 32            | 66.67      |
| <b>Total Applications Reviewed</b>                       | <b>48</b>     | <b>100</b> |

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

|   |    |
|---|----|
| Number of applications made invalid by the REC Manager          | 2  |
| Number of applications withdrawn prior to the meeting           | 0  |
| Number of student applications reviewed                         | 19 |
| 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  | 2  |
| Number of qualitative applications reviewed                     | 6  |

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

| <b>Decisions taken at meetings following review of applications</b>     | <b>Number</b> | <b>%</b>   |
|---|---------------|------------|
| Favourable Opinion with Standard Conditions                             | 0             | 0.00       |
| Favourable Opinion with Additional Conditions                           | 6             | 12.77      |
| Unfavourable Opinion  | 2             | 4.26       |
| Provisional Opinion   | 38            | 80.85      |
| Provisional Opinion Pending Consultation with Referee                   | 1             | 2.13       |
| <b>Total</b>  | <b>47</b>     | <b>100</b> |
| 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**

| <b>Status of applications at date of generation of report</b>     | <b>Number</b> | <b>%</b>   |
|---|---------------|------------|
| Further Information Favourable Opinion with Standard Conditions   | 22            | 46.81      |
| Further Information Favourable Opinion with Additional Conditions | 16            | 34.04      |
| Further Information Unfavourable Opinion                          | 0             | 0.00       |
| Favourable Opinion with Standard Conditions                       | 0             | 0.00       |
| Favourable Opinion with Additional Conditions                     | 6             | 12.77      |
| Unfavourable Opinion  | 2             | 4.26       |
| 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             | 2.13       |
| <b>Total</b>  | <b>47</b>     | <b>100</b> |

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

|                                    |           |
|------------------------------------|-----------|
| <b>Total Applications Reviewed</b> | <b>14</b> |
|------------------------------------|-----------|

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

|  |    |
|--|----|
| Number of applications made invalid by the REC Manager | 22 |
| Number of studies withdrawn prior to the meeting       | 1  |
| Number of student applications reviewed                | 7  |
| Number of paediatric applications reviewed             | 1  |
| Number of device applications reviewed                 | 0  |
| Number of qualitative applications reviewed            | 1  |

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

| <b>Decisions taken at proportionate review sub-committee meetings</b> | <b>Number</b> | <b>%</b>   |
|---|---------------|------------|
| Favourable Opinion with Standard Conditions                           | 2             | 14.29      |
| Favourable Opinion with Additional Conditions                         | 4             | 28.57      |
| No Opinion transfer to full committee for review                      | 0             | 0.00       |
| Provisional Opinion   | 8             | 57.14      |
| Unfavourable Opinion  | 0             | 0.00       |
| <b>Total</b>  | <b>14</b>     | <b>100</b> |

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

|   |       |
|---|-------|
| <b>Average number of applications reviewed per full meeting</b>                                       | 5.22  |
| <b>Number of completed applications for full ethical review</b>                                       | 46    |
| <b>Number of completed applications for full ethical review over 60 days</b>                          | 0     |
| <b>Number of completed applications over 60 days as a % of total</b>                                  | 0.00% |
| <b>Number of completed applications for full ethical review over 40 days</b>                          | 4     |
| <b>Number of completed applications over 40 days as a % of total</b>                                  | 8.51% |
| <b>Number of days taken to final decision – average (mean)</b>  | 33    |
| <b>Number of completed proportionate review applications for ethical review</b>                       | 14    |
| <b>Number of completed proportionate review applications for ethical review over 14 days</b>          | 0     |
| <b>Number of completed proportionate review applications over 14 days as a % of total</b>             | 0.00% |
| <b>Number of SSAs (non-Phase 1) reviewed</b>  | 8     |
| <b>Number of completed applications for SSA review over 25 days</b>                                   | 0     |
| <b>Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs</b>     | 0.00% |
| <b>Number of SSAs (Phase 1) reviewed</b>  | 0     |
| <b>Number of completed applications for SSA review over 14 days</b>                                   | 0     |
| <b>Number of completed applications for SSA review over 14 days as % of all Phase 1 SSAs</b>          | 0.00% |
| <b>Number of substantial amendments reviewed</b>  | 119   |
| <b>Number of completed substantial amendments over 35 days</b>  | 1     |
| <b>Number of completed substantial amendments over 35 days as a % of total substantial amendments</b> | 0.84% |
| <b>Number of completed substantial amendments over 28 days</b>  | 7     |
| <b>Number of completed substantial amendments over 28 days as a % of total substantial amendments</b> | 5.88% |
| <b>Number of modified amendments reviewed</b>   | 5     |
| <b>Number of completed modified amendments over 14 days</b>   | 0     |
| <b>Number of completed modified amendments over 14 days as a % of total modified amendments</b>       | 0.00% |
| <b>Number of minor amendments received</b>  | 71    |
| <b>Number of substantial amendments received for information</b>                                      | 1     |
| <b>Number of substantial amendments received for new sites/Pis</b>                                    | 17    |
| <b>Number of annual progress reports received</b>   | 239   |

|  |    |
|--|----|
| <b>Number of safety reports received</b>         | 80 |
| <b>Number of Serious Adverse Events received</b> | 6  |
| <b>Number of final reports received</b>          | 81 |

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

| <b>Further Information Favourable Opinion with Standard Conditions</b> |   |                                |
|--|---|--------------------------------|
| <b>REC Reference</b>   | <b>Title</b>  | <b>Number of Days on Clock</b> |
| 15/SC/0173   | Understanding the Narratives of Alcohol Related Liver Disease         | 32                             |
| 15/SC/0256   | Inhaled Interferon Beta-1a vs placebo in asthma patients              | 24                             |
| 15/SC/0415   | Quality of life of patients with cancer of known and unknown primary  | 35                             |
| 15/SC/0429   | Prospective study of understudied drugs in children                   | 28                             |
| 15/SC/0430   | JVDB: Second Line Gastric/Gastroesophageal Cancer                     | 35                             |
| 15/SC/0442   | The ANODE Trial   | 35                             |
| 15/SC/0461   | Does Gut Permeability Alter after Gastric Bypass in Type 2 Diabetes?  | 40                             |
| 15/SC/0478   | The DON'T ITCH Trial. Version 1.0                                     | 28                             |
| 15/SC/0565   | Targeted Radiotherapy for AL-Amyloidosis –'TRALA'                     | 32                             |
| 15/SC/0569   | Royal Brompton & Harefield NHS Foundation Trust Tissue Bank V2.0      | 38                             |
| 15/SC/0573   | Prevalence of depression and anxiety post-myocardial infarction       | 25                             |
| 15/SC/0592   | LittleEARS study  | 31                             |
| 15/SC/0619   | Liver function assessment by breath analysis                          | 23                             |
| 15/SC/0627   | comparison of fish oil with modified seed oil                         | 33                             |
| 15/SC/0633   | Delcath PHP-HCC-202 study, v6   | 25                             |
| 15/SC/0720   | The Six-Minute Walk Test in Pregnant Women – a Reference Range Study  | 29                             |
| 16/SC/0036   | Phase 1b Study of Necitumumab with Pembrolizumab in Advanced NSCLC    | 35                             |
| 16/SC/0040   | Exploring mindfulness for older adults with dementia and their carers | 34                             |
| 16/SC/0083   | Breathing patterns before and after breathing retraining for asthma   | 41                             |
| 16/SC/0103   | TrueColours Ulcerative Colitis Version 1.0                            | 30                             |
| 16/SC/0106   | POINT, v1.1 06Aug15   | 32                             |

| <b>Further Information Favourable Opinion with Additional Conditions</b> |   |                                |
|--|---|--------------------------------|
| <b>REC Reference</b>   | <b>Title</b>  | <b>Number of Days on Clock</b> |
| 15/SC/0253   | TB EYE  | 32                             |
| 15/SC/0265   | The effect of ulcerative colitis on personal relationships            | 35                             |
| 15/SC/0312   | Particulate production during debond of orthodontic fixed appliances  | 36                             |
| 15/SC/0436   | Prevalence and Correlates of Debt in Bipolar Disorder and Depression. | 35                             |
| 15/SC/0439   | The relationship between clients with BPD and their Care Coordinators | 35                             |
| 15/SC/0451   | True NTH UK – Post Surgical Follow up                                 | 38                             |
| 15/SC/0482   | Psychological symptoms in Carcinoid Syndrome. v1.0                    | 36                             |



|            |   |    |
|------------|---|----|
| 15/SC/0486 | Woman's wellbeing, Aquanatal exercise and Peer Support (Version 2)    | 29 |
| 15/SC/0506 | Mybirthplace ; useful for helping inform womens decision making ? 3.0 | 51 |
| 15/SC/0623 | Emergency and Urgent Admissions for Psychiatric Conditions            | 32 |
| 15/SC/0640 | CALYPSO   | 35 |
| 15/SC/0702 | Growth in gastroschisis   | 35 |
| 15/SC/0725 | Gait Cycle Analysis after Physica KR Total Knee Replacement           | 50 |
| 16/SC/0041 | Integrating palliative care into management of advanced liver disease | 35 |
| 16/SC/0082 | HCN channel function in human tissue                                  | 33 |

### 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 |
|---------------|---|-------------------------|
| 400/02/W      | Alcohol Consumpition Studies in Hepatology Patients | 26                      |

### Favourable Opinion with Additional Conditions

| REC Reference | Title   | Number of Days on Clock |
|---------------|---|-------------------------|
| 15/SC/0289    | AMG 319 in HPV negative HNSCC                                     | 26                      |
| 15/SC/0291    | MO29518 - A phase II Study of MPDL3280A in Advanced Solid Tumours | 26                      |
| 15/SC/0315    | BP29360 - RO5479599 in advanced or metastatic squamous NSCLC      | 26                      |
| 15/SC/0567    | Cystic fibrosis diagnosis in adulthood: Patients' views Version 1 | 24                      |
| 15/SC/0630    | Endorings assisted colonoscopy for polyp detection (version 1.0)  | 20                      |
| 15/SC/0784    | Exercise training in oesophageal/gastric cancer patient           | 54                      |

### Unfavourable Opinion

| REC Reference | Title  | Number of Days on Clock |
|---------------|--|-------------------------|
| 15/SC/0189    | Woman's wellbeing, Aquanatal exercise and Peer Support | 23                      |
| 15/SC/0297    | Outcomes of obstetric anal sphincter injuries          | 26                      |

### 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 |
|---------------|---------------------------------|-------------------------|
| 16/SC/0030    | South Coast Observational Study | n/a                     |
| 16/SC/0038    | Anxiety and sexual function     | n/a                     |

#### Withdrawn after the meeting

| REC Reference | Title   | Number of Days on Clock |
|---------------|---|-------------------------|
| 16/SC/0026    | HIMM-AD - HICSD in Mild to Moderate Alzheimer's Disease | 34                      |

**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 |
|---------------|---|-------------------------|
| 15/SC/0496    | Test-retest operator typical error for tHb-mass measurement.  | 10                      |
| 15/SC/0614    | EBC biomarkers and cough in IPF                               | 12                      |
| 15/SC/0760    | Outcomes of tension-free vaginal tape for stress incontinence | 11                      |
| 16/SC/0127    | COMBAT-ID 1   | 13                      |

#### Further Information Favourable Opinion with Additional Conditions

| REC Reference | Title   | Number of Days on Clock |
|---------------|---|-------------------------|
| 15/SC/0756    | The VANTAGE Study   | 11                      |
| 15/SC/0757    | Exploring perceptions of blood transfusion in haematology       | 10                      |
| 15/SC/0762    | Babies' Early Language Development (Version 01)                 | 11                      |
| 16/SC/0057    | Assessment of the accuracy of an alternative lung function test | 10                      |

| <b>Further Information Unfavourable Opinion</b> |              |                                |
|---|--------------|--------------------------------|
| <b>REC Reference</b>                            | <b>Title</b> | <b>Number of Days on Clock</b> |

| <b>Favourable Opinion with Standard Conditions</b> |   |                                |
|--|---|--------------------------------|
| <b>REC Reference</b>                               | <b>Title</b>  | <b>Number of Days on Clock</b> |
| 15/SC/0611   | Enhancing Prognostication in Uveal Melanoma                           | 10                             |
| 16/SC/0126   | Perineal trauma in women having vaginal delivery after previous OASIS | 7                              |

| <b>Favourable Opinion with Additional Conditions</b> |   |                                |
|--|---|--------------------------------|
| <b>REC Reference</b>                                 | <b>Title</b>  | <b>Number of Days on Clock</b> |
| 15/SC/0612   | Impact of Dental Sensitivity on Oral Health Related Quality of Life   | 10                             |
| 16/SC/0060   | EQUIP: Training to promote user involvement in care planning SP-audit | 6                              |
| 16/SC/0128   | Hypoglycaemia in young people with type 1 diabetes v1                 | 7                              |
| 16/SC/0177   | Assessment of the obese patient for total knee arthroplasty           | 13                             |

| <b>Unfavourable Opinion</b> |              |                                |
|-----------------------------|--------------|--------------------------------|
| <b>REC Reference</b>        | <b>Title</b> | <b>Number of Days on Clock</b> |

| <b>Provisional Opinion</b> |              |                                |
|----------------------------|--------------|--------------------------------|
| <b>REC Reference</b>       | <b>Title</b> | <b>Number of Days on Clock</b> |

| <b>Further information response not complete</b> |              |                                |
|--|--------------|--------------------------------|
| <b>REC Reference</b>                             | <b>Title</b> | <b>Number of Days on Clock</b> |

| <b>Withdrawn after the meeting</b> |              |                                |
|------------------------------------|--------------|--------------------------------|
| <b>REC Reference</b>               | <b>Title</b> | <b>Number of Days on Clock</b> |

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

| <b>Favourable opinion</b>      |   |                                |             |                                |
|--------------------------------|---|--------------------------------|-------------|--------------------------------|
| <b>Amendment REC Reference</b> | <b>Title</b>  | <b>Version</b>                 | <b>Date</b> | <b>Number of Days on Clock</b> |
| 08/H0501/17/AM09               | New markers of allergic reactions and anaphylaxis                     | Amendment 8                    | 10/03/2015  | 34                             |
| 08/H0504/73/AM09               | A3671024 A study for patients who have received CP-675,206 previously | SA4                            | 08/04/2015  | 8                              |
| 08/H0504/73/AM11               | A3671024 A study for patients who have received CP-675,206 previously | Amendment 5                    | 26/06/2015  | 17                             |
| 09/H0504/125/AM05              | Genetics of Paediatric Inflammatory Bowel Disease                     | SA4; 20/11/2015                | 20/11/2015  | 7                              |
| 09/H0504/129/AM10              | 3rd Generation Isle of Wight Birth Cohort (Version 1)                 | SA6                            | 12/03/2015  | 22                             |
| 10/H0501/26/AM06               | The PADPROM Project: quality of life of pad users questionnaire.      | 5                              | 23/03/2015  | 14                             |
| 10/H0501/39/AM05               | Myeloid-derived suppressor cells in haematological malignancies       | 4                              | 26/03/2015  | 19                             |
| 10/H0504/73/AM01               | Breast cancer biomarker translational research and validation study.  | Substantial Amendment 1        | 10/07/2015  | 9                              |
| 10/H0504/90/AM13               | TREATMENT OF IRON DEFICIENCY ANAEMIA IN ADOLESCENTS WITH IBD.         | Protocol Amendment 4; v7.2     | 21/07/2015  | 10                             |
| 10/H0504/93/AM12               | A Phase III Study of INC424 in Polycythemia Vera Patients             | 07/04/2015 DMC                 | 07/04/2015  | 8                              |
| 11/SC/0084/AM08                | ProT4 (Prophylactic Transfer of CD4 Lymphocytes)                      | 05, 08.09.2015                 | 08/09/2015  | 28                             |
| 11/SC/0412/AM09                | Development of Symptom Based Questionnaires for patients with cancer  | SA7                            | 01/04/2015  | 22                             |
| 11/SC/0529/AM01                | Modelling Placental Nutrient Transport                                | Substantial Amendment 1        | 31/03/2015  | 19                             |
| 12/SC/0107/AM04                | EAST: Early treatment of AF for Stroke prevention Trial: 09-Dec-2011  | Amendment 3 (substantial): 10t | 10/07/2015  | 28                             |
| 12/SC/0115/AM03                | ICoS (Inflammation, Cognition, and Stress) Version 1.0                | Amendment 3.0                  | 22/06/2015  | 31                             |
| 12/SC/0176/AM05                | Inflammation and disability progression in multiple sclerosis         | Substantial Amendment 3        | 14/05/2015  | 34                             |
| 12/SC/0391/AM11                | COAST - Cisplatin Ototoxicity attenuated by Aspirin Trial             | Substantial Amendment 8        | 15/05/2015  | 14                             |
| 12/SC/0391/AM12                | COAST - Cisplatin Ototoxicity attenuated by Aspirin Trial             | AM12 Substantial Amendment: SA | 18/09/2015  | 16                             |
| 12/SC/0394/AM13                | COMPLEMENT A + B:   | Amendment 7 -                  | 28/08/2015  | 23                             |

|                 |  | Signature page                       |            |    |
|-----------------|--|--------------------------------------|------------|----|
| 12/SC/0411/AM10 | Physiotherapy Rehabilitation for Osteoporotic Vertebral fracture(PROVE | Sub Amend 9<br>23.04.15              | 23/04/2015 | 8  |
| 12/SC/0428/AM07 | YoDA Young Onset Dementia Assessment Study                             | SA6                                  | 05/03/2015 | 14 |
| 12/SC/0487/AM01 | NeuroNEC   | Substantial<br>Amendment 1           | 16/06/2015 | 23 |
| 12/SC/0492/AM08 | OXWATCH- Women and Wellbeing Study                                     | 6                                    | 08/04/2015 | 7  |
| 12/SC/0526/AM02 | Arden Tissue Bank  | 2                                    | 21/04/2015 | 9  |
| 12/SC/0580/AM02 | Views & Experience of Magnetic Resonance imaging during pregnancy      | 3 29/09/2015                         | 29/09/2015 | 24 |
| 12/SC/0580/AM04 | Views & Experience of Magnetic Resonance imaging during pregnancy      | 4                                    | 15/12/2015 | 24 |
| 13/SC/0041/AM03 | Consent and confidentiality in genetic medicine                        | SA1                                  | 30/03/2015 | 16 |
| 13/SC/0041/AM04 | Consent and confidentiality in genetic medicine                        | 2                                    | 18/06/2015 | 21 |
| 13/SC/0041/AM05 | Consent and confidentiality in genetic medicine                        | AM05 Substantial<br>Amendment: 3     | 09/12/2015 | 14 |
| 13/SC/0081/AM01 | What is the experience of Young People being Taught Mindfulness in DBT | 1                                    | 28/01/2014 | 24 |
| 13/SC/0092/AM12 | CBAF312A2304 siponimod in secondary progressive multiple sclerosis v1  | Protocol Amend 02                    | 19/03/2015 | 21 |
| 13/SC/0092/AM13 | CBAF312A2304 siponimod in secondary progressive multiple sclerosis v1  | Substantial<br>Amendment;<br>27.04.2 | 27/04/2015 | 9  |
| 13/SC/0092/AM14 | CBAF312A2304 siponimod in secondary progressive multiple sclerosis v1  | AM 14 -<br>Substantial<br>Amendment  | 08/07/2015 | 22 |
| 13/SC/0092/AM15 | CBAF312A2304 siponimod in secondary progressive multiple sclerosis v1  | Protocol v03                         | 27/11/2015 | 25 |
| 13/SC/0102/AM11 | MK3475-010-00  | SA9                                  | 12/06/2015 | 26 |
| 13/SC/0102/AM13 | MK3475-010-00  | Protocol<br>amendment 010            | 06/07/2015 | 14 |
| 13/SC/0102/AM17 | MK3475-010-00  | IB Edition 10,<br>PISCF v10, GP I    | 09/10/2015 | 17 |
| 13/SC/0102/AM18 | MK3475-010-00  | AM18 Substantial<br>Amendment        | 20/01/2016 | 19 |
| 13/SC/0105/AM04 | Southampton Women's Survey 10-12yr follow-up                           | Substantial                          | 19/06/2015 | 27 |

|                 |  |                                |            |    |
|-----------------|--|--------------------------------|------------|----|
|                 |  | Amendment 2                    |            |    |
| 13/SC/0268/AM08 | Ease of use of TIP compared to TIS and colistimethate in P. aeruginosa | AM08                           | 21/09/2015 | 15 |
| 13/SC/0279/AM08 | Phase 3 study of TAF-containing combination STR in HIV-1 subjects      | Substantial Amendment 5        | 15/05/2015 | 25 |
| 13/SC/0287/AM01 | Development of a HRQOL questionnaire module for anal cancer patients   | SA1                            | 05/02/2015 | 15 |
| 13/SC/0323/AM08 | PCI-32765DBL3001   | INT2                           | 14/09/2015 | 7  |
| 13/SC/0384/AM05 | Tremilimumab in pleural or peritoneal malignant mesothelioma           | Substantial Amendment 4        | 29/07/2015 | 27 |
| 13/SC/0394/AM06 | METRIC(MR Enterography or uTRasound In Crohn's disease)                | Amendment no. 4¼ 15th June 201 | 15/06/2015 | 20 |
| 13/SC/0409/AM03 | SPRING Southampton Pregnancy Intervention for the Next Generation      | Substantial Amendment 3        | 01/06/2015 | 39 |
| 13/SC/0435/AM02 | ABICUS Trial: Version 2  | 2                              | 29/07/2015 | 23 |
| 13/SC/0478/AM17 | LGX818, MEK162 and LGX818 vs vemurafenib in melanoma patients.         | Substantial Amendment 10       | 21/05/2015 | 7  |
| 13/SC/0478/AM18 | LGX818, MEK162 and LGX818 vs vemurafenib in melanoma patients.         | Substantial Amendment 11 – upd | 15/09/2015 | 19 |
| 13/SC/0478/AM19 | LGX818, MEK162 and LGX818 vs vemurafenib in melanoma patients.         | AM19: Substantial Amendment: T | 05/11/2015 | 14 |
| 13/SC/0495/AM02 | Study to evaluate biology of keloids after different treatments v1.0   | 2                              | 11/05/2015 | 21 |
| 13/SC/0559/AM05 | Telotristat Etiprate for Carcinoid Syndrome Therapy – TELECAST         | 5                              | 16/12/2015 | 27 |
| 13/SC/0592/AM01 | Barts Pancreas Tissue Bank   | 1                              | 01/04/2015 | 18 |
| 13/SC/0644/AM07 | UNBLOCS: UriNary oBstruction relieved by Laser Or Conventional Surgery | Amendment 3                    | 12/05/2015 | 13 |
| 13/SC/0645/AM02 | PHOENIX Study - Version 1  | SA2                            | 10/03/2015 | 27 |
| 13/SC/0645/AM04 | PHOENIX Study - Version 1  | AM04 - SA3 - 03 7 October 2015 | 07/10/2015 | 8  |
| 14/SC/0039/AM04 | PDSAFE trial   | 4                              | 12/03/2015 | 16 |
| 14/SC/0039/AM05 | PDSAFE trial   | Amendment 5                    | 02/07/2015 | 15 |
| 14/SC/0051/AM03 | Frailty in older adults living with HIV - version 1.0                  | Substantial Amendment: Third   | 26/10/2015 | 15 |

|                 |  | a                              |            |    |
|-----------------|--|--------------------------------|------------|----|
| 14/SC/0066/AM01 | EDICT - Exercise inDuced changes In Colorectal Cancer Tissues      | AM01 Substantial Amendment     | 04/02/2016 | 21 |
| 14/SC/0098/AM01 | UK Brain Archive Information Network (BRAIN UK)                    | Substantial Amendment 1        | 17/04/2015 | 14 |
| 14/SC/0102/AM04 | Neural responses to reward and aversion in depressed adolescents   | Substantial Amendment 4        | 05/05/2015 | 21 |
| 14/SC/0160/AM03 | iFAAM  | Amendment 3                    | 05/06/2015 | 17 |
| 14/SC/0160/AM04 | iFAAM  | Amendment 4                    | 12/08/2015 | 25 |
| 14/SC/0221/AM03 | CONCEPT  | Amendment 3                    | 01/06/2015 | 27 |
| 14/SC/0221/AM05 | CONCEPT  | AM05 Substantial Amendment 4,  | 15/01/2016 | 24 |
| 14/SC/1034/AM02 | Prostate Cancer UK Module 3 Phase 1: Evaluation of existing clamps | SA2                            | 09/04/2015 | 20 |
| 14/SC/1034/AM03 | Prostate Cancer UK Module 3 Phase 1: Evaluation of existing clamps | Amendment 3                    | 08/07/2015 | 6  |
| 14/SC/1034/AM04 | Prostate Cancer UK Module 3 Phase 1: Evaluation of existing clamps | AM04: Substantial Amendment 4  | 01/10/2015 | 17 |
| 14/SC/1034/AM05 | Prostate Cancer UK Module 3 Phase 1: Evaluation of existing clamps | 5                              | 03/12/2015 | 15 |
| 14/SC/1034/AM06 | Prostate Cancer UK Module 3 Phase 1: Evaluation of existing clamps | 6                              | 03/02/2016 | 28 |
| 14/SC/1126/AM03 | GALA-BIDD  | Amendment 3                    | 27/01/2016 | 25 |
| 14/SC/1156/AM01 | JAVA-P   | SA1                            | 20/02/2015 | 16 |
| 14/SC/1156/AM07 | JAVA-P   | AM07 Substantial Amendment 2 1 | 10/11/2015 | 18 |
| 14/SC/1167/AM02 | A study of patritumab with erlotinib in subjects with NSCLC        | Substantial Amendment 1        | 22/05/2015 | 32 |
| 14/SC/1167/AM04 | A study of patritumab with erlotinib in subjects with NSCLC        | AM04 - Updated IB, PIS and CF  | 24/11/2015 | 28 |
| 14/SC/1169/AM03 | SPACE FOR COPD in primary care: a pragmatic trial                  | Amendment 4 (1st Substantial A | 19/05/2015 | 15 |
| 14/SC/1169/AM06 | SPACE FOR COPD in primary care: a pragmatic trial                  | AM06 (2nd substantial amendmen | 25/06/2015 | 20 |
| 14/SC/1169/AM08 | SPACE FOR COPD in primary care: a pragmatic trial                  | 3                              | 11/12/2015 | 28 |

|                 |  |                                   |            |    |
|-----------------|--|-----------------------------------|------------|----|
| 14/SC/1177/AM03 | Prostate Cancer UK Module 4 Phase 1: Evaluation of existing products     | Substantial Amendment: 3<br>08/10 | 08/10/2015 | 28 |
| 14/SC/1200/AM01 | Investigating immunogenicity to biopharmaceuticals cross sectional study | AM01                              | 11/11/2015 | 9  |
| 14/SC/1223/AM05 | CALIBER  | AM05: CALIBER -<br>Substantial Am | 26/01/2016 | 13 |
| 14/SC/1227/AM01 | Patients' expectations and experience of caudal epidural injections      | 1                                 | 04/09/2015 | 8  |
| 14/SC/1236/AM02 | GO28399 Open label extension study of Vemurafenib                        | SA2 Protocol<br>GO28399, V4, IB12 | 11/06/2015 | 27 |
| 14/SC/1323/AM01 | EDC Biomarker Discovery in Colorectal and Lung Cancer                    | Substantial<br>Amendment 1        | 14/07/2015 | 8  |
| 14/SC/1334/AM01 | PREHEAT Trial - local heat preconditioning and wound healing             | SA1                               | 26/03/2015 | 9  |
| 14/SC/1337/AM03 | 200977 Study of Albiglutide in patients with Type 2 Diabetes Mellitus    | 2                                 | 26/03/2015 | 14 |
| 14/SC/1337/AM05 | 200977 Study of Albiglutide in patients with Type 2 Diabetes Mellitus    | Substantial<br>Amendment 3        | 01/06/2015 | 20 |
| 14/SC/1337/AM08 | 200977 Study of Albiglutide in patients with Type 2 Diabetes Mellitus    | AM08 Substantial<br>Amendment: 4  | 24/09/2015 | 14 |
| 14/SC/1337/AM09 | 200977 Study of Albiglutide in patients with Type 2 Diabetes Mellitus    | 4.0                               | 12/12/2015 | 26 |
| 14/SC/1340/AM09 | LEGATO-HD (Laquinimod Efficacy and Safety in a GlobAI Trial Of HD)       | Global Protocol<br>Amendment v03; | 24/09/2015 | 17 |
| 14/SC/1340/AM11 | LEGATO-HD (Laquinimod Efficacy and Safety in a GlobAI Trial Of HD)       | AM11                              | 03/02/2016 | 20 |
| 14/SC/1340/AM12 | LEGATO-HD (Laquinimod Efficacy and Safety in a GlobAI Trial Of HD)       | Protocol<br>Amendment 4           | 16/02/2016 | 19 |
| 14/SC/1377/AM01 | Evaluation of a milk ladder & immune markers in clinical practice        | SA1                               | 12/03/2015 | 20 |
| 14/SC/1377/AM02 | Evaluation of a milk ladder & immune markers in clinical practice        | Sub Amend 2<br>13/05/2015         | 13/05/2015 | 18 |
| 14/SC/1377/AM03 | Evaluation of a milk ladder & immune markers in clinical practice        | AM03 Substantial<br>Amendment: No | 13/11/2015 | 14 |
| 14/SC/1441/AM01 | Development of new blood grouping reagents from excluded blood donors    | Amendment<br>number 1 08          | 11/11/2015 | 12 |



|                 |   |                                   |            |    |
|-----------------|---|-----------------------------------|------------|----|
|                 |   | October                           |            |    |
| 15/SC/0041/AM01 | Nerve function and hyperthermia v1.4                                  | 1.7                               | 24/11/2015 | 15 |
| 15/SC/0085/AM01 | Role of vinegar in identifying abnormal cells in Barrett's oesophagus | 13/07/2015<br>Amendment No. 3     | 13/07/2015 | 11 |
| 15/SC/0104/AM01 | Sarcopenia, nutritional intakes and outcomes in stem cell transplant  | Amendment 1                       | 07/08/2015 | 26 |
| 15/SC/0256/AM04 | Inhaled Interferon Beta-1a vs placebo in asthma patients              | AM04: Substantial<br>Amendment 3  | 11/02/2016 | 21 |
| 15/SC/0289/AM02 | AMG 319 in HPV negative HNSCC   | AM02 Substantial<br>Amendment: CT | 12/02/2016 | 20 |
| 15/SC/0291/AM01 | MO29518 - A phase II Study of MPDL3280A in Advanced Solid Tumours     | Substantial<br>Amendment 1        | 15/06/2015 | 21 |
| 15/SC/0291/AM05 | MO29518 - A phase II Study of MPDL3280A in Advanced Solid Tumours     | AM05 - Substantial<br>Amendment   | 14/10/2015 | 20 |
| 15/SC/0315/AM01 | BP29360 - RO5479599 in advanced or metastatic squamous NSCLC          | Substantial<br>Amendment 1        | 19/06/2015 | 31 |
| 15/SC/0442/AM01 | The ANODE Trial   | AM01 Substantial<br>Amendment: 1  | 03/12/2015 | 18 |
| 15/SC/0619/AM01 | Liver function assessment by breath analysis                          | AM01 Substantial<br>Amendment 1 - | 19/02/2016 | 28 |
| 15/SC/0640/AM01 | CALYPSO   | AM01 Substantial<br>Amendment 1,  | 18/02/2016 | 19 |
| 264/01/w/AM09   | Radiolabelled Anti-CD66 monoclonal antibody (BW250/183)               | AM09 Substantial<br>Amendment: 9  | 10/11/2015 | 26 |

### Unfavourable opinion

| Amendment REC Reference | Title   | Version                           | Date       | Number of Days on Clock |
|-------------------------|---|-----------------------------------|------------|-------------------------|
| 10/H0504/25/AM06        | Oxford Vaccine Centre Biobank                             | Substantial<br>Amendment 2        | 10/06/2015 | 32                      |
| 10/H0504/93/AM14        | A Phase III Study of INC424 in Polycythemia Vera Patients | 05                                | 16/02/2016 | 27                      |
| 12/SC/0428/AM09         | YoDA Young Onset Dementia Assessment Study                | AM09 Substantial<br>Amendment 7 1 | 15/10/2015 | 26                      |
| 14/SC/0160/AM05         | iFAAM   | AM05 Substantial<br>Amendment 5,  | 06/11/2015 | 15                      |
| 14/SC/1072/AM01         | POMP v0.1   | AM01 Substantial                  | 26/01/2016 | 24                      |

|                 |  |                                |            |    |
|-----------------|--|--------------------------------|------------|----|
|                 |  | Amendment1, 2                  |            |    |
| 14/SC/1340/AM01 | LEGATO-HD (Laquinimod Efficacy and Safety in a GlobAI Trial Of HD) | N/A                            | 06/05/2015 | 21 |
| 14/SC/1340/AM07 | LEGATO-HD (Laquinimod Efficacy and Safety in a GlobAI Trial Of HD) | AM07 Substantial Amendment: GI | 16/02/2015 | 15 |
| 15/SC/0045/AM01 | THERAPIST Version 1.0  | SA1                            | 17/03/2015 | 20 |
| 15/SC/0496/AM01 | Test-retest operator typical error for tHb-mass measurement.       | 1.2                            | 28/08/2015 | 21 |
| 400/02/SW/AM01  | Alcohol Consumption Studies in Hepatology Patients                 | Substantial Amendment 7, 08.06 | 08/06/2015 | 26 |

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

| <b>Favourable opinion timeline</b> |   |                        |             |                                |
|------------------------------------|---|------------------------|-------------|--------------------------------|
| <b>Amendment REC Reference</b>     | <b>Title</b>  | <b>Version</b>         | <b>Date</b> | <b>Number of Days on Clock</b> |
| 10/H0504/25/AM06/1                 | Oxford Vaccine Centre Biobank                                     | Amendment 2 (modified) | 10/06/2015  | 11                             |
| 12/SC/0428/AM09/1                  | YoDA Young Onset Dementia Assessment Study                        | MA7                    | 11/12/2015  | 3                              |
| 12/SC/0580/AM01/1                  | Views & Experience of Magnetic Resonance imaging during pregnancy | SA2                    | 27/04/2015  | 6                              |
| 15/SC/0045/AM01/1                  | THERAPIST Version 1.0   | Modified Amendment 1   | 07/05/2015  | 1                              |

| <b>Unfavourable opinion timeline</b> |  |                              |             |                                |
|--------------------------------------|--|------------------------------|-------------|--------------------------------|
| <b>Amendment REC Reference</b>       | <b>Title</b>   | <b>Version</b>               | <b>Date</b> | <b>Number of Days on Clock</b> |
| 14/SC/1340/AM01/1                    | LEGATO-HD (Laquinimod Efficacy and Safety in a GlobAI Trial Of HD) | Global Protocol Amendment 02 | 16/02/2015  | 10                             |

**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 14 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 |
|-------------------------|---|-------------------------|------------|-------------------------|
| 13/SC/0409/AM03         | SPRING Southampton Pregnancy Intervention for the Next Generation | Substantial Amendment 3 | 01/06/2015 | 39                      |

**Modified Amendments over 14 day timeline**

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