

South West - Exeter Research Ethics Committee

Annual Report

01 April 2016 - 31 March 2017



Part 1 – Committee Membership and Training

| | |
|------------------------------|--|
| Name of REC: | South West - Exeter Research Ethics Committee |
| Type of REC: | Authorised |
| Type of Flag: | Medical Devices |
| Chair: | Dr Denise Sheehan (Chair) |
| Vice-Chair: | Mrs Joan Ramsay |
| Alternate Vice-Chair: | Professor Malcolm Cowburn |
| REC Manager: | Mrs Naazneen Nathoo |
| REC Assistant: | Miss Fran Race (until 15/01/2017) Vacant (from 15/01/2017) |
| Committee Address: | Whitefriars Level 3 Block B Lewins Mead Bristol BS1 2NT |
| Telephone: | 0207 104 8028 |
| Email: | nrescommittee.southwest-exeter@nhs.net |

Chair's overview of the past year:

South West - Exeter Research Ethics Committee Membership

| Name | Profession | Expert or Lay | Dates | |
|---------------------------|--|---------------|------------|------------|
| | | | Appointed | Left |
| Mrs Rosamund Bagnald | Retired Store Manager | Lay Plus | 01/11/2014 | 05/05/2016 |
| Dr Julia Barnes | Doctor | Expert | 11/01/2016 | |
| Mrs Isobel Brooks | Retired Social Care Manager | Lay Plus | 01/04/2010 | |
| Professor Malcolm Cowburn | Emeritus Professor of Applied Social Science | Lay Plus | 16/06/2014 | |
| Prof. Ann Demaine | Specialist Register for Diabetes and Endocrinology | Expert | 09/05/2016 | |
| Dr Nicole Dorey | Consultant Clinical Oncologist | Expert | 05/02/2009 | 19/09/2016 |
| Dr. Roy J. Powell | Research Design Consultant | Expert | 01/04/2010 | |
| Mrs Joan Ramsay | Retired Associate Director of Nursing (Women and Children) | Lay | 01/03/2009 | |
| Dr Lettie E Rawlins | Junior Doctor | Expert | 01/03/2014 | 05/08/2016 |
| Mr Phil Regan | Minister of Religion | Lay Plus | 05/06/2009 | |
| Mrs Carol Richardson | Senior Nurse (Retired) | Lay | 01/05/2009 | |
| Dr Denise Sheehan | Consultant Oncologist | Expert | 01/04/2010 | |
| Dr Jo Thompson Coon | Senior Research Fellow in Health Services Research | Lay | 01/11/2014 | 01/07/2016 |
| Dr Chris Vallance | Retired chemist (non-research) | Lay Plus | 01/04/2010 | |
| Mr Royston Van Tromp | Retired Headmaster | Lay Plus | 01/07/2011 | |

South West - Exeter Research Ethics Committee: Deputy Members

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

South West - Exeter Research Ethics Committee: Co-opted Members

| Name | Profession | Status | Meeting date attended |
|----------------|------------|--------|-----------------------|
| Susan Bradford | Solicitor | Member | 02 June 2016 |

South West - Exeter Research Ethics Committee: Members' Declarations of Interest:

| Name | Declaration of Interest | Date |
|---------------------------|--|-------------|
| Dr Julia Barnes | None | 31/03/2017 |
| Mrs Isobel Brooks | None | 31/03/2017 |
| Professor Malcolm Cowburn | Professor Emeritus in Applied Social Science, Sheffield Hallam University; Visiting Professor in Criminology, Plymouth University. Volunteer/helper - Marie Curie. | 31/03/2017 |
| Prof. Ann Demaine | None | 07/07/2016 |
| Dr. Roy J. Powell | Work for the NIHR-funded Research Design Service - Exeter office (0.7 WTE). Office is based in the R&D dept of the Royal Devon & Exeter Hospital. Funded for 0.3 WTE by the R&D directorate to provide statistical advice service and involvement in feasibility studies. Hon. snr. lecturer, University of Exeter Medical School. | 31/03/2017 |
| Mrs Joan Ramsay | None | 31/03/2017 |
| Mr Phil Regan | None | 31/03/2017 |
| Mrs Carol Richardson | None | 31/03/2017 |
| Dr Denise Sheehan | Consultant Oncologist entering patients into clinical trials | |
| Dr Chris Vallance | None | 31/03/2017 |
| Mr Royston Van Tromp | None | 31/03/2017 |

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

| Month | Date | Number of Members Present at Meeting |
|-----------|------------|--------------------------------------|
| May | 05/05/2016 | 12 |
| June | 02/06/2016 | 9 |
| July | 07/07/2016 | 10 |
| August | 04/08/2016 | 10 |
| September | 01/09/2016 | 8 |
| January | 05/01/2017 | 9 |
| March | 02/03/2017 | 9 |

7 full committee meetings were held during the reporting period.

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

| Month | Date | Number of Members Present at Meeting |
|-----------|------------|--------------------------------------|
| April | 06/04/2016 | 3 |
| May | 18/05/2016 | 3 |
| June | 16/06/2016 | 3 |
| July | 20/07/2016 | 3 |
| August | 17/08/2016 | 3 |
| September | 14/09/2016 | 3 |
| November | 16/11/2016 | 3 |
| December | 15/12/2016 | 3 |
| January | 25/01/2017 | 3 |
| February | 15/02/2017 | 3 |
| March | 02/03/2017 | 9 |
| March | 17/03/2017 | 3 |

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

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

| Month | Date | Number of Members Present at Meeting |
|-----------|------------|--------------------------------------|
| April | 11/04/2016 | 2 |
| April | 25/04/2016 | 2 |
| June | 20/06/2016 | 2 |
| July | 12/07/2016 | 2 |
| July | 15/07/2016 | 2 |
| July | 18/07/2016 | 2 |
| July | 27/07/2016 | 2 |
| August | 10/08/2016 | 2 |
| August | 26/08/2016 | 2 |
| September | 14/09/2016 | 2 |
| October | 10/10/2016 | 2 |
| November | 07/11/2016 | 2 |

| | | |
|----------|------------|---|
| November | 25/11/2016 | 2 |
| December | 05/12/2016 | 2 |
| December | 09/12/2016 | 2 |
| December | 31/12/2016 | 2 |
| January | 16/01/2017 | 2 |
| January | 27/01/2017 | 2 |
| February | 17/02/2017 | 2 |
| March | 17/03/2017 | 2 |
| March | 24/03/2017 | 2 |

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

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

None

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

| Name | Number of Meetings Attended |
|---------------------------|------------------------------------|
| Mrs Rosamund Bagnald | 1 |
| Dr Julia Barnes | 5 |
| Mrs Isobel Brooks | 6 |
| Professor Malcolm Cowburn | 5 |
| Prof. Ann Demaine | 4 |
| Dr Nicole Dorey | 3 |
| Dr. Roy J. Powell | 5 |
| Mrs Joan Ramsay | 6 |
| Dr Lettie E Rawlins | 3 |
| Mr Phil Regan | 7 |
| Mrs Carol Richardson | 6 |
| Dr Denise Sheehan | 5 |
| Dr Chris Vallance | 4 |
| Mr Royston Van Tromp | 6 |

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

| Name | Number of Meetings Attended |
|---------------------------|------------------------------------|
| Dr Julia Barnes | 1 |
| Mrs Isobel Brooks | 9 |
| Professor Malcolm Cowburn | 2 |
| Prof. Ann Demaine | 1 |
| Dr Nicole Dorey | 1 |
| Dr. Roy J. Powell | 3 |
| Mrs Joan Ramsay | 11 |
| Mr Phil Regan | 1 |
| Dr Colette Reid | 1 |
| Mrs Carol Richardson | 3 |
| Dr Denise Sheehan | 5 |
| Dr Chris Vallance | 2 |
| Mr Royston Van Tromp | 1 |

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

| Name | Number of Meetings Attended |
|---------------------------|------------------------------------|
| Professor Malcolm Cowburn | 7 |
| Mrs Joan Ramsay | 17 |
| Dr Denise Sheehan | 18 |

Training 01 April 2016 - 31 March 2017

| Name of Member | Date | Event(s) attended |
|---------------------------|-------------|--|
| Dr Julia Barnes | 14/09/2016 | Handling Health-Related Findings in Research (Joint MRC/HRA) |
| Dr Julia Barnes | 16/02/2017 | National Members training day |
| Mrs Isobel Brooks | 01/12/2016 | Human Tissue Act |
| Professor Malcolm Cowburn | 19/05/2016 | REC Chairs' Network Meeting |
| Prof. Ann Demaine | 01/12/2016 | Human Tissue Act |
| Mrs Joan Ramsay | 01/12/2016 | Human Tissue Act |
| Mr Phil Regan | 01/12/2016 | Human Tissue Act |
| Dr Denise Sheehan | 01/12/2016 | Human Tissue Act |
| Dr Denise Sheehan | 24/02/2017 | Genetics and Genomics |
| Mr Chris Vallance | 01/12/2016 | Human Tissue Act |
| Mrs Carol Richardson | 01/12/2016 | Human Tissue Act |
| Mrs Carol Richardson | 24/02/2017 | Genetics and Genomics |

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 | 0 | 0.00 |
| Phase 1 | 0 | 0.00 |
| Gene Therapy | 0 | 0.00 |
| Research Tissue Bank (including renewals) | 0 | 0.00 |
| Research Database (including renewals) | 2 | 8.00 |
| Others | 23 | 92.00 |
| Total Applications Reviewed | 25 | 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 | 0 |
| Number of student applications reviewed | 7 |
| Number of paediatric applications reviewed | 6 |
| Number of device applications reviewed | 7 |
| 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 | 6 |

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 | 0 | 0.00 |
| Favourable Opinion with Additional Conditions | 1 | 4.00 |
| Unfavourable Opinion | 1 | 4.00 |
| Provisional Opinion | 22 | 88.00 |
| Provisional Opinion Pending Consultation with Referee | 1 | 4.00 |
| Total | 25 | 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 | 12 | 48.00 |
| Further Information Favourable Opinion with Additional Conditions | 10 | 40.00 |
| Further Information Unfavourable Opinion | 0 | 0.00 |
| Favourable Opinion with Standard Conditions | 0 | 0.00 |
| Favourable Opinion with Additional Conditions | 1 | 4.00 |
| Unfavourable Opinion | 1 | 4.00 |
| Provisional Opinion | 0 | 0.00 |
| Provisional Opinion Pending Consultation with Referee | 0 | 0.00 |
| Further Information response not complete | 1 | 4.00 |
| No decision entered on system | 0 | 0.00 |
| Number of studies withdrawn after the meeting | 0 | 0.00 |
| Total | 25 | 100 |

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

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

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

| | |
|--|---|
| Number of applications made invalid by the REC Manager | 7 |
| Number of studies withdrawn prior to the meeting | 1 |
| Number of student applications reviewed | 7 |
| Number of paediatric applications reviewed | 4 |
| Number of device applications reviewed | 3 |
| Number of qualitative applications reviewed | 4 |

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 | 0 | 0.00 |
| Favourable Opinion with Additional Conditions | 4 | 17.39 |
| No Opinion transfer to full committee for review | 3 | 13.04 |
| Provisional Opinion | 14 | 60.87 |
| Unfavourable Opinion | 2 | 8.70 |
| Total | 23 | 100 |

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

| | |
|---|--------|
| Average number of applications reviewed per full meeting | 3.57 |
| Number of completed applications for full ethical review | 25 |
| Number of completed applications for full ethical review over 60 days | 0 |
| Number of completed applications over 60 days as a % of total | 0.00% |
| Number of completed applications for full ethical review over 40 days | 6 |
| Number of completed applications over 40 days as a % of total | 24.00% |
| Number of days taken to final decision – average (mean) | 34 |
| Number of completed proportionate review applications for ethical review | 20 |
| Number of completed proportionate review applications for ethical review over 21 days | 2 |
| Number of completed proportionate review applications over 21 days as a % of total | 10.00% |
| Number of SSAs (non-Phase 1) reviewed | 8 |
| Number of completed applications for SSA review over 25 days | 0 |
| Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs | 0.00% |
| Number of SSAs (Phase 1) reviewed | 0 |
| Number of completed applications for SSA review over 14 days | 0 |
| Number of completed applications for SSA review over 14 days as % of all Phase 1 SSAs | 0.00% |
| Number of substantial amendments reviewed | 43 |
| Number of completed substantial amendments over 35 days | 3 |
| Number of completed substantial amendments over 35 days as a % of total substantial amendments | 6.98% |
| Number of completed substantial amendments over 28 days | 13 |
| Number of completed substantial amendments over 28 days as a % of total substantial amendments | 30.23% |
| Number of modified amendments reviewed | 1 |
| Number of completed modified amendments over 14 days | 0 |
| Number of completed modified amendments over 14 days as a % of total modified amendments | 0.00% |
| Number of non substantial amendments received | 57 |
| Number of substantial amendments received for information | 0 |
| Number of substantial amendments received for new sites/PIs | 11 |
| Number of annual progress reports received | 23 |

| | |
|--|----|
| Number of safety reports received | 4 |
| Number of Serious Adverse Events received | 0 |
| Number of final reports received | 14 |

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

| Further Information Favourable Opinion with Standard Conditions | | |
|--|--|--------------------------------|
| REC Reference | Title | Number of Days on Clock |
| 16/SW/0131 | Pleural Catheter (SNCIPC) for Malignant Pleural Effusions (SWIFT) | 31 |
| 16/SW/0163 | How do mother's view their baby's emotional and social development | 39 |
| 16/SW/0169 | An exploration into the needs of older people approaching end of life | 27 |
| 16/SW/0190 | A study to assess gum health after 26 weeks toothpaste use. | 35 |
| 16/SW/0229 | Identifying treatment for IAPT attendees with personality difficulties | 60 |
| 16/SW/0230 | Retrospective Observational Study (EFFECT) 109MS421 | 28 |
| 16/SW/0254 | NIRS for the measurement of haemodynamic markers in bone tissue (V1). | 25 |
| 16/SW/0266 | Balance Right in Multiple Sclerosis (BRiMS) | 40 |
| 17/SW/0005 | Librata Endometrial Ablation Device for Heavy Menstrual Bleeding | 34 |
| 17/SW/0007 | CSSP Technology for Hypersensitivity Pain Relief V1 | 10 |
| 17/SW/0039 | TOLERANCE AND ACCEPTABILITY EVALUATION OF AYMES 'SOFIA 2' | 43 |

| Further Information Favourable Opinion with Additional Conditions | | |
|--|--|--------------------------------|
| REC Reference | Title | Number of Days on Clock |
| 16/SW/0130 | StartRight Study | 52 |
| 16/SW/0192 | Narrative explorations of families stories of a young persons MUS | 37 |
| 16/SW/0193 | Exploring children's experiences of their parents non-terminal cancer | 49 |
| 16/SW/0214 | Atlas:Ethnographic study of care pathways for hip and knee replacement | 41 |
| 16/SW/0231 | Effects of the geko device in patients with venous leg ulcer. | 28 |
| 16/SW/0256 | Intraoperative Cell Salvage vs Transfusion in Ovarian Cancer (TICTOC) | 29 |
| 16/SW/0261 | E45 in-use tolerance study in babies and children with dry/atopic skin | 25 |
| 16/SW/0265 | Is LiveWellCloz acceptable for patients and healthcare staff? | 23 |
| 17/SW/0002 | Pain Rehabilitation Database: Bath and Bristol | 46 |
| 17/SW/0003 | PluroGel and leg ulcers | 37 |

| 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 |
|---------------|-------|-------------------------|
|---------------|-------|-------------------------|

Favourable Opinion with Additional Conditions

| REC Reference | Title | Number of Days on Clock |
|---------------|--|-------------------------|
| 16/SW/0123 | A modified In-situ model to study dentine tubule occlusion | 16 |

Unfavourable Opinion

| REC Reference | Title | Number of Days on Clock |
|---------------|---------------------------|-------------------------|
| 16/SW/0164 | Effectiveness of MECSH-UK | 25 |

Provisional Opinion

| REC Reference | Title | Number of Days on Clock |
|---------------|------------------|-------------------------|
| 17/SW/0006 | BALLOON study v1 | n/a |

Provisional Opinion Pending Consultation with Referee

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

Further information response not complete

| REC Reference | Title | Number of Days on Clock |
|---------------|---|-------------------------|
| 17/SW/0001 | Cost and clinical outcomes of switching DPP4i | n/a |

Withdrawn after the meeting

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

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

Further Information Favourable Opinion with Standard Conditions

| REC Reference | Title | Number of Days on Clock |
|---------------|--|-------------------------|
| 16/SW/0077 | Optimizing Ovarian Tissue Transplantation | 21 |
| 16/SW/0079 | Investigation into the infectivity levels of HPV in tonsillar tissue | 19 |
| 16/SW/0151 | Head to head extragenital GC and CT study | 9 |
| 16/SW/0182 | CAMALeoN: Communication And Medication Adherence in Lupus Nephritis | 15 |
| 16/SW/0210 | Standards of Care for RA Across Europe - The Patient Perspective | 12 |
| 16/SW/0325 | BME Experiences of the NHS. | 9 |
| 16/SW/0330 | Patient Activation in Multiple Sclerosis (version 1) | 26 |
| 17/SW/0028 | DEEPENS study | 19 |

Further Information Favourable Opinion with Additional Conditions

| REC Reference | Title | Number of Days on Clock |
|---------------|---|-------------------------|
| 16/SW/0100 | Exploring Ethics of Ambulance Trials | 20 |
| 16/SW/0249 | FineSA MRI-calculation of metastatic spinal bone structure | 20 |
| 16/SW/0280 | Dementia Carers Instrument Development:DECIDE Psychometric evaluation | 11 |
| 17/SW/0069 | GSK-Birmingham Tissue Collaborative (GB-TC) | 12 |
| 17/SW/0070 | PHAGO – human cell models | 30 |

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 |
|---------------|-------|-------------------------|
|---------------|-------|-------------------------|

Favourable Opinion with Additional Conditions

| REC Reference | Title | Number of Days on Clock |
|---------------|--|-------------------------|
| 16/SW/0152 | The effect of rivaroxaban on aPTT and anti-Xa levels | 9 |
| 16/SW/0181 | Analysis of teeth from the ALSPAC study, v1 | 10 |
| 16/SW/0279 | Multifocal Lens Design Combination: Dispensing Study | 12 |
| 17/SW/0042 | CF and the gut: what adults would tell their younger selves. Version 1 | 7 |

Unfavourable Opinion

| REC Reference | Title | Number of Days on Clock |
|----------------------|---|--------------------------------|
| 16/SW/0153 | Validation of molecular assay for foetal Rh D genotype | 8 |
| 17/SW/0029 | CBT for Insomnia Workshop: factor analysis and cohort studies | 13 |

Provisional Opinion

| REC Reference | Title | Number of Days on Clock |
|----------------------|--|--------------------------------|
| 17/SW/0056 | Mechanical advantage in children with cerebral palsy | n/a |

Further information response not complete

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

Withdrawn after the meeting

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

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

| Favourable opinion | | | | |
|--------------------------------|--|--------------------------|-------------|--------------------------------|
| Amendment REC Reference | Title | Version | Date | Number of Days on Clock |
| 05/MRE06/32/AM08 | NET 01 Version 1 | 10 | 08/03/2016 | 35 |
| 09/H0206/4/AM01 | Long term stability, survival and tolerability of a (novel) Baha® implant system | 1 | 09/04/2016 | 38 |
| 11/SW/0052/AM07 | The psychological impact of Early Pregnancy Loss - Version 2 | 7 | 15/08/2016 | 35 |
| 11/SW/0061/AM05 | Phenotyping RPGR Retinal Dystrophy Patients for Gene Therapy Trials | 3 | 20/01/2017 | 34 |
| 11/SW/0222/AM10 | PREDICTING SERIOUS DRUG SIDE EFFECTS IN GASTROENTEROLOGY | 6 Date: 21 November 2016 | 21/11/2016 | 7 |
| 12/SW/0143/AM04 | Observational study of patients prescribed pazopanib for renal cancer | 2 | 04/11/2016 | 21 |
| 12/SW/0323/AM09 | Personalized Anti-TNF Therapy in Crohn's Disease (PANTS) | 7 | 14/06/2016 | 18 |
| 12/SW/0323/AM10 | Personalized Anti-TNF Therapy in Crohn's Disease (PANTS) | 8 | 12/12/2016 | 34 |
| 13/SW/0001/AM05 | RAPID version 2 | 3 | 05/08/2016 | 27 |
| 13/SW/0001/AM06 | RAPID version 2 | 4 | 08/12/2016 | 37 |
| 13/SW/0108/AM01 | The Effect of Diabetes on Heart Metabolism; A Hyperpolarized MRI Study | 1 | 31/03/2016 | 22 |
| 13/SW/0261/AM05 | Effect of GSK1120212, GSK2118436 + Panitumumab in colorectal cancer | 7 | 23/03/2016 | 34 |
| 13/SW/0261/AM06 | Effect of GSK1120212, GSK2118436 + Panitumumab in colorectal cancer | 8 | 11/08/2016 | 34 |
| 13/SW/0289/AM02 | Imaging for reconstructive plastic surgery | 2 | 29/07/2016 | 20 |
| 14/SW/0019/AM07 | RELIEF v2.5 | 2 18 August 2016 | 18/08/2016 | 34 |
| 14/SW/0061/AM02 | Muscle metabolic, pH and blood oxygenation exercise response in CF | 2 | 02/05/2016 | 21 |
| 14/SW/0105/AM03 | Prolongation PREFER in AF Registry | SA 01 Dated 1 July 2016 | 01/07/2016 | 11 |
| 14/SW/0119/AM02 | Identifying + validating molecular targets in low grade brain tumours | 2 | 14/01/2016 | 23 |
| 14/SW/0119/AM04 | Identifying + validating molecular targets in low grade brain tumours | 2.1 | 21/09/2016 | 13 |
| 14/SW/1018/AM03 | Assessing the effect of caffeine on attention in Dementia. | 2nd Amendment, | 10/11/2016 | 27 |

| | | | | |
|-----------------|---|-----------------------------------|------------|-----|
| | Version 2 | 10/11/2016 | | |
| 15/SW/0021/AM01 | fATDIVA-Exeter (for Adipose Tissue Diabetes VARIants) | 1 | 05/05/2016 | 18 |
| 15/SW/0126/AM03 | Skills for weight loss Maintenance (SkiM) | 3 | 30/03/2016 | 27 |
| 15/SW/0126/AM04 | Skills for weight loss Maintenance (SkiM) | 4 | 15/07/2016 | 2 |
| 15/SW/0137/AM02 | Treating CNV secondary to PM with Lucentis | 2 | 17/05/2016 | 4 |
| 15/SW/0137/AM03 | Treating CNV secondary to PM with Lucentis | 3 | 14/06/2016 | 18 |
| 15/SW/0137/AM04 | Treating CNV secondary to PM with Lucentis | 4 | 21/11/2016 | 18 |
| 15/SW/0153/AM02 | MooDFOOD | 3 | 26/01/2017 | 6 |
| 15/SW/0156/AM03 | TARGET Trial | 3 | 27/04/2016 | 20 |
| 15/SW/0156/AM04 | TARGET Trial | 5 | 21/10/2016 | 8 |
| 15/SW/0179/AM03 | Injectable Valve Implantation Trial (Invite) | 2 | 10/06/2016 | 8 |
| 15/SW/0215/AM04 | Edwards CENTERA Transcatheter Heart Valve System | 3 | 26/08/2016 | 26 |
| 15/SW/0250/AM01 | Impact of email/websites for sharing information in families - V1 | Amendment 1, 10th November 201 | 10/11/2016 | 11 |
| 15/SW/0354/AM04 | Skin metabolites in Parkinson's disease | 1 (10/1/17) | 10/01/2017 | 36 |
| 16/SW/0004/AM01 | Making exercise safe in humans with hypertension | 1 | 16/05/2016 | 24 |
| 16/SW/0023/AM02 | Heimlich Valves in Secondary Spontaneous Pneumothorax: Enhancing Care | Hi-SPEC protocol V3.0 24/10/16 | 24/10/2016 | -15 |
| 16/SW/0024/AM01 | Identifying bacterial respiratory infection by e-nose technology | 1 | 21/03/2016 | 16 |
| 16/SW/0046/AM01 | MPAL-Sarcoma | 2 | 26/10/2016 | 33 |
| 16/SW/0049/AM01 | Outcomes for patients with Alcohol Dependence Syndrome. | 1 | 09/05/2016 | 21 |
| 16/SW/0130/AM05 | StartRight Study | 1 | 13/01/2017 | 17 |
| 16/SW/0131/AM01 | Pleural Catheter (SNCIPC) for Malignant Pleural Effusions (SWIFT) | 2 | 08/10/2016 | 5 |
| 16/SW/0190/AM01 | A study to assess gum health after 26 weeks toothpaste use. | 1 | 05/09/2016 | 24 |
| 16/SW/0279/AM01 | Multifocal Lens Design Combination: Dispensing Study | 1.2 | 07/12/2016 | 29 |

Unfavourable opinion

| Amendment REC Reference | Title | Version | Date | Number of Days on Clock |
|-------------------------|-----------------------------------|---------|------------|-------------------------|
| 14/SW/0120/AM08 | School-based Asthma Project (SAP) | 9 | 30/11/2016 | 33 |

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

| Favourable opinion timeline | | | | |
|------------------------------------|-----------------------------------|----------------|-------------|--------------------------------|
| Amendment REC Reference | Title | Version | Date | Number of Days on Clock |
| 14/SW/0120/AM08/1 | School-based Asthma Project (SAP) | 9 Mod | 01/02/2017 | 4 |

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

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

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

Proportionate review applications for ethical review over 14 day timeline

| REC Reference | Title | Number of Days on Clock |
|---------------|--|-------------------------|
| 16/SW/0330 | Patient Activation in Multiple Sclerosis (version 1) | 26 |
| 17/SW/0070 | PHAGO – human cell models | 22 |

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 |
|-------------------------|--|-------------|------------|-------------------------|
| 09/H0206/4/AM01 | Long term stability, survival and tolerability of a (novel) Baha® implant system | 1 | 09/04/2016 | 38 |
| 13/SW/0001/AM06 | RAPID version 2 | 4 | 08/12/2016 | 37 |
| 15/SW/0354/AM04 | Skin metabolites in Parkinson's disease | 1 (10/1/17) | 10/01/2017 | 36 |

Modified Amendments over 14 day timeline

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