

Central Health and Disability Ethics Committee

Annual Report
2014

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# About the committee

The Central Health and Disability Ethics Committee (HDEC) is a Ministerial committee established under section 11 of the [New Zealand Public Health and Disability Act 2000](http://www.legislation.govt.nz/act/public/2000/0091/latest/DLM80051.html). Its members are appointed by the Minister of Health through the public appointments process.

The primary function of the Committee is to provide independent ethical review of health research and innovative practice in order to safeguard the rights, health and wellbeing of consumers and research participants and, in particular, those persons with diminished autonomy.

The Committee is required by its [Terms of Reference](http://www.ethicscommittees.health.govt.nz/moh.nsf/indexcm/ethics-about-central#tor) to submit an Annual Report to the Minister of Health. The Annual Report must include information on the membership of the Committee, a summary of the applications reviewed during the year, details of any complaints received (and how they were resolved), and areas of review that caused difficulty when making decisions, among other matters.

## Approvals and registrations

The Central HDEC is approved by the Health Research Council Ethics Committee for the purposes of section 25(1)(c) of the [Health Research Council Act 1990](http://legislation.govt.nz/act/public/1990/0068/latest/DLM213017.html).

The Central HDEC is registered (number IRB00008712) with the United States’ Office for Human Research Protections. This registration enables the committee to review research conducted or supported by the US Department of Health and Human Services.

# Chairperson’s report

The Central team has finished another successful year. The processes and their coordination have improved out of sight during the last year and this is in no small part due to the HDEC secretariat with their efficiency and dedication.

The Chairs meet as regularly as possible to address the short-comings of the processes and, with the guidance of the secretariat, endeavour to improve them. The online portal is continuing to make things more streamlined and is being improved where possible and when finances allow.

The greatest improvement to the committee process is the regular attendance of most researchers at their application hearings. This occurs either personally or by teleconference. I can’t stress enough how this simple move shortens the timeframe for the approval of an application when questions can be answered immediately.

The number of first time approvals is also increasing as the quality of application increases. Those researchers or administrators applying for the first time should seek advice in the process to enable their research to get the prompt start it deserves.

The few time over runs occurred on applications is not ideal but is explainable and it must always be remembered that the committee members also all have day jobs.

The Central Committee has a great team of dedicated members who take their roles extremely seriously to ensure the safety and respect of participants. This year we were joined by Dr Cordelia Thomas and Dr Kay de Vries, this has brought us back up to our full complement for the first time in a while. Training was undertaken by them, which they both found enlightening and extremely helpful. Thanks to the team for your hard work and support.

Each year I am impressed with the amount and quality of research that is emanating from New Zealand. It makes me proud to be a small part of this wonderful community.

****

Helen Walker

Chairperson

Central Health and Disability Ethics Committee

# Membership and attendance

No meetings were postponed or cancelled due to inability to make quorum. Two members joined the Committee in 2014.

## Membership

### Lay members

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| --- |
| Mrs Helen Walker (Chair) |
| Membership category: | Community representative |
| Date of appointment: | 1 July 2012 |
| Current term expires: | 1 July 2015 |

Mrs Helen Walker is currently the Chairman of the Medical Sciences Council, Chairman of Audit for Health Hawkes Bay Ltd, a Kaitiaki/Guardian of the Turnbull Library and the owner and financial controller of Kilgaren Farming Partnership. She completed a Bachelor of Science at Massey University (1975) and a Certificate in Company Direction through the New Zealand Institute of Directors (2002). Mrs Walker is a previous Director of Unison Networks Ltd (2004-2010), the Hawke’s Bay District Health Board (2001-2007) and Chairman of the Central Hawke’s Bay Consumers Power Trust (1993-2003). On a voluntary basis she is the President of the Waipawa Musical and Dramatic Club (1999-present), a member of the Waipawa Municipal Theatre Refurbishment Trust and Trustee of the New Zealand Singing School.

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| Mr Paul Barnett |
| Membership category: | The Law |
| Date of appointment: | 1 July 2012 |
| Current term expires: | 1 July 2015 |

Mr Paul Barnett is currently the Principal /Director at Barnett Law, Solicitor, (2004-present). Prior to this, he was a Wellington Partner at the national law firm Chapman Tripp, (1980-2004). He has completed a Master of Laws (1973) and a Bachelor of Laws with Honours (1971) at Victoria University of Wellington. He was appointed a Notary Public in 1984. He is Deputy Chair of the Board of Ronald McDonald House Wellington Trust (2005-present), a cost reviser for the Wellington branch of the New Zealand Law Society (2009-present) and was a cost reviser for the Wellington District Law Society (1990-2008). He is also a member of a Standards Committee of the New Zealand Law Society and a member of the Ethics Committee of the Wellington branch of that Society.

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| Ms Sandy Gill |
| Membership category: | Community perspectives |
| Date of appointment: | 1 July 2012 |
| Current term expires: | 1 July 2015 |

Ms Gill has her own consulting company and also works on a voluntary basis with various community groups assisting with policy and procedure, writing programmes and evaluations, clinical supervision of staff, business plans and strategic planning. Her qualifications include an MA in Management (Massey), a MA in Criminal Justice (Victoria) along with post graduate qualifications in Dispute Resolution (Massey) and Human Resources (Victoria). She was a member of the New Zealand Parole Board from 2002 through to 2008, and has been a guest lecturer at Victoria University in the field of criminology. Prior to that she was Standards Manager at the Medical Council of New Zealand. She has also been involved in counseling and reintegration planning for offenders and youth at risk, and in the area of Māori mental health. She has a lifelong addiction to learning and loves to travel and learn about different cultures and history. She is Ngā Puhi and the proud mother of three and nana of one and an Associate Member of AMINZ.

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| Dr Cordelia Thomas |
| Membership category: | The law / moral reasoning |
| Date of appointment: | 19 May 2014 |
| Current term expires: | 19 May 2017 |

### Dr Cordelia Thomas LLB (Otago), LLM(Hons) and PhD (VUW). Barrister and Solicitor. Cordelia is currently Associate Health and Disability Commissioner – Investigations. She was a Specialist Senior Legal Advisor to the Health and Disability Commissioner. She took up that position in 2009 after working as a Senior Legal Adviser to the Bioethics Council working at the Ministry for the Environment. Earlier, she was for many years a law lecturer at Wellington Polytechnic and then Massey University at Wellington. She is currently the New Zealand Law Society’s National Course Director of the Legal Executive Programme. Cordelia is the author of the 5th and 6th editions of Forsyth’s Outline of the Law Relating to Trusts Wills Executors & Administrators, which is the textbook recommended by the New Zealand Law Society for Estates Law and Practice. The 6th edition was published in 2009.

### Non-lay members

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| --- |
| Dr Dean Quinn |
| Membership category: | Interventional studies |
| Date of appointment: | 1 July 2012 |
| Current term expires: | 1 July 2015 |

Dr Dean Quinn is a registered medical practitioner, currently the Manager of the Wellington P3 Research unit (2004-present). He has a particular interest in early phase respiratory clinical trials. Prior to this, he has completed a BSc (Hons) (1988) Victoria University of Wellington and MBChB (1993) at the University of Otago. He was formerly a member of the Central ethics committee (2009-2011) and Multi-region ethics committee (2011-2012).

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| Mrs Gael Donoghue |
| Membership category: | Pharmacist/Pharmacologist |
| Date of appointment: | 1 July 2012 |
| Current term expires: | 1 July 2015 |

Mrs Gael Donoghue is a pharmacist working as a pharmaceutical manager at Lucanus Corporation (2004-present), and worked at the Open Polytechnic of New Zealand as a tutor and assessor (2000-2011). Prior to this she worked in the Central Districts region as a Field Educator for the Pharmaceutical Society of New Zealand (1993-2003). Mrs Donoghue is a Fellow of the Pharmaceutical Society of New Zealand, of which she was also made the first Life Member in 2010. She was a member of the Drugs Advisory Committee (1984-1988). She was also the pharmacist member on the Manawatu Well Child Health Forum (2003-2010) and a member of the Executive of the New Zealand College of Pharmacists (1995-2000). She has held the post of President of the Central Districts Pharmaceutical Society of New Zealand on a number of occasions (most recently in 2004-2005) and has a history of community service and committee membership. Gael was awarded MNZM in this year’s Queen's Birthday Honours for services to the Pharmaceutical Profession.

**Dr Patries Herst**

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| Membership category: | Intervention studies |
| Date of appointment: | 1 July 2013 |
| Current term expires: | 1 July 2015 |

Dr Patries Herst is currently a senior lecturer at the Department of Radiation Therapy, University of Otago, Wellington and a visiting scientist at Victoria University and the Malaghan Institute. She completed a PhD in cancer cell biology at the Malaghan Institute of Medical Research/Otago University in Wellington (2006), a Master of Philosophy (microbiology) at Waikato University in Hamilton (1984) and a Master of Science (biology) at Nijmegen University (Netherlands) in 1982. Dr Herst conducts cell based medical research at the Malaghan Institute as well as clinical trials that investigate better management options for acute side effects caused by radiation therapy in various hospitals in New Zealand. She is the secretary of the New Zealand Oncological Society and the immediate past president of the Wellington Health and Biomedical Research Society. She is also a committee member of the Animal Ethics Committee at the University of Otago, Wellington and joined the Central HDEC as a non-lay member in July 2012.

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| Ms Kay de Vries |
| Membership category: | Observational studies |
| Date of appointment: | 19 May 2014 |
| Current term expires: | 19 May 2015 |

Dr Kay de Vries is the Head of School for Graduate School of Nursing, Midwifery and Health at Victoria University of Wellington. Dr Vries completed her PhD at the University of Surrey. Dr Vries has experience in observational research. Her research, education and clinical interest are related to all areas of end of life care, old age and dementia care in acute, community and care home environments and in virtue ethics, with a focus on humility.

##

## Attendance

The Central HDEC held 11 meetings in 2014.

|  |  |  |
| --- | --- | --- |
| **Members** | **Meetings** | **Total** |
| Jan | Feb | Mar | Apr | May | Jun | Jul | Aug | Sep | Oct | Nov | Dec |  |
| Lay members | Cm | Mrs Helen Walker (Chair) | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | ***A*** | ***A*** | **✓** | **✓** |  | 9/11 |
| L | Mr Paul Barnett | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | ***A*** | **✓** | **✓** |  | 10/11 |
| E | Dr Cordelia Thomas |  |  |  |  | **✓** | **✓** | **X** | ***A*** | **✓** | **✓** | **✓** |  | 5/7 |
| Cm | Ms Sandy Gill | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** |  | 11/11 |
|  | Cm | Ms Raewyn Idoine (co-opted from Southern Committee) |  |  |  |  |  |  |  | **✓** |  |  |  |  | 1/1 |
| Non-lay members | P | Mrs Gael Donoghue | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** |  | 11/11 |
| HR | Dr Kay de Vries |  |  |  |  | **✓** | **✓** | **✓** | ***A*** | **✓** | **✓** | **✓** |  | 6/7 |
| HR | Dr Dean Quinn | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** |  | 11/11 |
| HR | Dr Patries Herst | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | ***A*** | **✓** | ***A*** | ***A*** | **✓** |  | 8/11 |

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| --- | --- | --- | --- | --- | --- | --- |
| Key: | L | Lawyer | P | Pharmacist/pharmacologist | **✓** | present |
|  | E | Ethicist | B | Biostatistician | ***A*** | apologies |
|  | Cm | Community representative | HP | Health practitioner | **X** | absent |
|  | Cn | Consumer representative | HR | Health researcher |  | not applicable |

## Training and conferences

New members of the Central HDEC had training on how to conduct ethical review on 26 September 2014.

## Chairpersons’ meetings

Mrs Helen Walker attended two Chairs’ day meetings in 2014. Both meetings were held in Wellington.

The first Chairpersons’ meeting was held on 20 February 2014 in the Medsafe boardroom. The second Chairpersons’ meeting was held at 1 The Terrace on Level 2 on 9 June 2014.

# Applications reviewed

The Central HDEC received 135 applications in 2014. From the 135 applications 84 applications were reviewed by the full committee and 51 were reviewed through the expedited pathway.

|  |  |  |
| --- | --- | --- |
| Full | Approved | 77 |
| Declined | 3 |
| Provisional Approval (as at 31 December 2014) | 4 |
| *Total (with a decision at 31 December 2014)* | 84 |
| Expedited | Approved | 49 |
| Declined | 1 |
| Provisional Approval (as at 31 December 2014) | 1 |
| *Total (with a decision at 31 December 2014)* | 51 |
| **Total applications reviewed** | **135** |

A summary of these applications can be found in Appendix 1.

# Complaints and overdue applications

This section outlines complaints about decisions made by the Committee during 2014.

## Complaints received

The Central Committee did not receive any complaints about the decision making process in 2014.

## Overdue review

During 2014, there were 14 instances where the review time was over 35 days for full applications and 35 where the review time was over 15 days for expedited applications.

See Appendix 1 for more information.

# Appendix 1: Details of applications reviewed:

## Applications reviewed by full committee

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Study reference | Study status | Short title | Co-ordinating investigator | Application type | Date application validated | Date of first decision | Provisional response received | Date of final decision |
| 14/CEN/10 | Approve | Probiotic intervention to reduce streptococcal disease burden in NZ children | Professor Julian Crane | Intervention | 15/01/2014 | 7/02/2014 | 5/05/2014 | 14/05/2014 |
| 14/CEN/1 | Approve | Phase II PI3K inhibitor in relapsed, indolent or aggressive NHL | Dr J.E. Edwards | Intervention | 16/01/2014 | 7/02/2014 | 14/02/2014 | 14/03/2014 |
| 14/CEN/8 | Approve | Carrageenan Cold Prevention Spray Study | Professor Julian Crane | Intervention | 16/01/2014 | 7/02/2014 | 28/03/2014 | 28/03/2014 |
| 14/CEN/2 | Approve | Gestational diabetes screening | Dr Adele Barr | Observational | 20/01/2014 | 17/02/2014 | 18/02/2014 | 28/02/2014 |
| 14/CEN/11 | Approve | COG AEPI10N5:Genetic Epidemiology of Ewing Sarcoma | Dr Mark Winstanley | Observational | 13/02/2014 |  |  | 27/02/2014 |
| 14/CEN/13 | Approve | COG ACNS1123 | Dr Stephen Laughton | Intervention | 13/02/2014 |  |  | 27/02/2014 |
| 14/CEN/15 | Approve | CRAIn II | Ms Molly Kallesen | Observational | 13/02/2014 | 27/02/2014 | 14/05/2014 | 15/05/2014 |
| 14/CEN/16 | Approve | Children's modified onset of sleep study | Dr Nicholas Reid | Intervention | 13/02/2014 | 27/02/2014 | 24/09/2014 | 21/10/2014 |
| 14/CEN/17 | Approve | Te Waka Oranga; bringing the recovery destination to whānau | Dr Hinemoa Elder | Intervention | 13/02/2014 | 27/02/2014 | 17/03/2014 | 21/03/2014 |
| 14/CEN/34 | Approve | Gut Health and Glucose Tolerance | Miss Renee Wilson | Observational | 13/03/2014 | 31/03/2014 | 8/04/2014 | 11/04/2014 |
| 14/CEN/36 | Approve | Healthy Relationships | Dr Christine Wilson | Intervention | 13/03/2014 | 31/03/2014 | 26/05/2014 | 11/06/2014 |
| 14/CEN/39 | Approve | An Australian-lead, investigator-initiated, multi-centre, prospective, randomised, parallel group, double-blind, placebo-controlled trial to establish the effect(s) of routine administration of fluoxe | Dr John Gommans | Intervention | 13/03/2014 | 31/03/2014 | 15/04/2014 | 17/04/2014 |
| 14/CEN/40 | Approve | Non-Suicidal Self-Injury in Rangatahi Māori | Miss Tahlia Kingi | Observational | 13/03/2014 | 31/03/2014 | 9/05/2014 | 29/05/2014 |
| 14/CEN/41 | Approve | The transition from acute to chronic post-surgical pain - a prospective, randomised controlled trial | Mr Campbell MacLachlan | Intervention | 13/03/2014 | 31/03/2014 | 1/04/2014 | 2/04/2014 |
| 14/CEN/42 | Approve | ORBIT 4 | Dr Conor O'Dochartaigh | Intervention | 13/03/2014 | 31/03/2014 | 14/04/2014 | 22/04/2014 |
| 14/CEN/43 | Approve | Alios BioPharma ALS-8176-503 | Dr Thorsten Stanley | Intervention | 13/03/2014 | 31/03/2014 | 7/05/2014 | 28/05/2014 |
| 14/CEN/50 | Approve | Efficacy and safety of liraglutide and metformin in children and adolescents with type 2 diabetes mellitus | Professor Paul Hofman | Intervention | 10/04/2014 | 29/04/2014 | 28/05/2014 | 25/06/2014 |
| 14/CEN/54 | Provisionally approve | Tardive dyskinesia in rest home residents taking antipsychotics | Dr Angela O'Brien | Observational | 10/04/2014 | 29/04/2014 |  |  |
| 14/CEN/57 | Approve | Endometriosis Extension Study M12-821 | Dr Dean Quinn | Intervention | 10/04/2014 | 29/04/2014 | 3/06/2014 | 16/06/2014 |
| 14/CEN/58 | Approve | Reversal of the Anticoagulant Effect of Dabigatran Using Idarucizumab | Dr Gordon Royle | Intervention | 10/04/2014 | 29/04/2014 | 18/06/2014 | 4/07/2014 |
| 14/CEN/59 | Approve | Housing Effects About Rheumatic fever (HEART) | Prof Philippa Howden-Chapman | Observational | 10/04/2014 | 29/04/2014 | 7/07/2014 | 21/08/2014 |
| 14/CEN/60 | Approve | A study to evaluate efficacy and safety of the combination of Ertugliflozin (MK8835) with sitagliptin compared to MK8835 alone and sitagliptin alone in adult subjects with Type II diabetes | Dr Simon Carson | Intervention | 10/04/2014 | 29/04/2014 | 8/05/2014 | 15/05/2014 |
| 14/CEN/61 | Approve | A study evaluating MK8408 in patients with Hepatitis C | Professor Edward Gane | Intervention | 10/04/2014 |  |  | 29/04/2014 |
| 14/CEN/67 | Approve | Fatigue in Inflammatory Bowel Disease | Mr Rashid Almandhari | Intervention | 15/05/2014 |  |  | 4/06/2014 |
| 14/CEN/72 | Approve | Lipoprotein biomarkers in Māori and Pacific communities | Dr Allamanda Faatoese | Observational | 15/05/2014 | 4/06/2014 | 2/07/2014 | 9/07/2014 |
| 14/CEN/73 | Approve | Abbvie Veliparib in NSCLC | Dr David Gibbs | Intervention | 15/05/2014 | 4/06/2014 | 7/07/2014 | 15/07/2014 |
| 14/CEN/74 | Approve | The Cxbladder Repeatability Study | Dr P Johnston | Observational | 15/05/2014 | 4/06/2014 | 17/07/2014 | 1/08/2014 |
| 14/CEN/76 | Approve | RSV in children hospitalised with lower respiratory tract infections | Dr Tristram Ingham | Observational | 15/05/2014 | 4/06/2014 | 5/06/2014 | 19/06/2014 |
| 14/CEN/77 | Approve | SAND | Professor Bridget Robinson | Intervention | 15/05/2014 | 4/06/2014 | 20/06/2014 | 11/07/2014 |
| 14/CEN/81 | Approve | AMG 416 Open Label Extension Study - 20130213 | Dr Chris Hood | Intervention | 15/05/2014 |  |  | 4/06/2014 |
| 14/CEN/82 | Approve | The impacts of cancer, chronic disease and acute health events on future employment, earnings and benefit receipt | Ms Sarah Crichton | Observational | 15/05/2014 |  |  | 4/06/2014 |
| 14/CEN/83 | Approve | The relationships between obesity, lifestyle behaviours, and cardiovascular health in children | Mr Nicholas Castro | Observational | 15/05/2014 | 4/06/2014 | 11/06/2014 | 26/06/2014 |
| 14/CEN/84 | Decline | Overflow Movements in Parkinson's Disease | Dr Sepehr Sadeghi | Observational | 15/05/2014 |  |  | 4/06/2014 |
| 14/CEN/100 | Approve | The Experience of Diabulimia in People with Type I Diabetes | Ms Lisa Hoyle | Observational | 12/06/2014 | 27/06/2014 | 15/09/2014 | 9/10/2014 |
| 14/CEN/88 | Approve | DPM-CF-303 | Prof. John Kolbe | Intervention | 12/06/2014 |  |  | 27/06/2014 |
| 14/CEN/89 | Approve | A Two Part, Phase I/IIa Assessment of Citramel | Dr Chris Wynne | Intervention | 12/06/2014 |  |  | 27/06/2014 |
| 14/CEN/90 | Approve | AQX-1125-202/ FLAGSHIP Study | Dr Dean Quinn | Intervention | 12/06/2014 |  |  | 27/06/2014 |
| 14/CEN/91 | Approve | Diamond COPD Study | Dr Dean Quinn | Intervention | 12/06/2014 |  |  | 27/06/2014 |
| 14/CEN/92 | Approve | Infant TBI Genetics study | Dr Kelly Jones | Observational | 12/06/2014 | 27/06/2014 | 1/07/2014 | 30/07/2014 |
| 14/CEN/94 | Approve | A Study of Adalimumab in Paediatric Subjects with Moderate to Severe Ulcerative Colitis.- M11-290 | Prof Andrew Day | Intervention | 12/06/2014 | 27/06/2014 | 19/08/2014 | 19/08/2014 |
| 14/CEN/96 | Approve | Total hip joint arthoplasty skin sealing with steristrips vs. skin glue | Dr Liam Dunbar | Intervention | 12/06/2014 |  |  | 27/06/2014 |
| 14/CEN/97 | Approve | The STRENGTH trial | Professor Richard Troughton | Intervention | 12/06/2014 | 27/06/2014 | 30/07/2014 | 18/08/2014 |
| 14/CEN/99 | Approve | RELIEF II Study | Assoc Prof Peter Gilling | Intervention | 12/06/2014 |  |  | 27/06/2014 |
| 14/CEN/107 | Approve | FiCare | Assoc Prof Roland Broadbent | Intervention | 10/07/2014 |  |  | 28/07/2014 |
| 14/CEN/108 | Approve | Pacific Islands Families: Understanding growth | Professor Elaine Rush | Observational | 10/07/2014 |  |  | 28/07/2014 |
| 14/CEN/109 | Approve | A study to evaluate if the study drug refametinib in combination with sorafenib is safe and effective in patients with liver cancer carrying a specific gene mutation (RAS mutation) | Professor Edward Gane | Intervention | 10/07/2014 | 28/07/2014 | 5/08/2014 | 26/08/2014 |
| 14/CEN/110 | Approve | Phase 3 Study of Sofosbuvir + GS-5816 Or Ribavirin in Subjects with Chronic HCV Infection | Professor Edward Gane | Intervention | 10/07/2014 |  |  | 28/07/2014 |
| 14/CEN/111 | Approve | Hydros and Hydros-TA Joint Therapy for Pain associated with knee OA Associated with Knee OA | Dr Alan Doube | Intervention | 10/07/2014 |  |  | 28/07/2014 |
| 14/CEN/112 | Approve | A Study assessing the efficacy and safety of PF-06410293 in patients with Rheumatoid Arthritis | Dr Alan Doube | Intervention | 10/07/2014 |  |  | 28/07/2014 |
| 14/CEN/113 | Approve | Assessment of the trial drug GS-5745, following single doses in healthy adults | Dr Chris Wynne | Intervention | 10/07/2014 |  |  | 28/07/2014 |
| 14/CEN/114 | Approve | Legionnaires' Disease in New Zealand - LegiNZ Study | Prof David Murdoch | Observational | 10/07/2014 |  |  | 28/07/2014 |
| 14/CEN/122 | Approve | The effect on Fampyra on visual function following optic neuritis | Dr Jennifer Taylor | Intervention | 14/08/2014 |  |  | 1/09/2014 |
| 14/CEN/125 | Approve | SILVERLINA | Dr John Baker | Intervention | 14/08/2014 |  |  | 1/09/2014 |
| 14/CEN/127 | Approve | Social context and smoking by people experiencing mental illness | Ms Stella McGough | Observational | 14/08/2014 |  |  | 1/09/2014 |
| 14/CEN/128 | Approve | A study assessing the similarity of Avastin and a new cancer drug, BS-503A (AVA-1) as compared to commercially available bevacizumab (Avastin®) from the US | Dr Rod Ellis-Pegler | Intervention | 14/08/2014 |  |  | 1/09/2014 |
| 14/CEN/129 | Approve | HPV related Oropharyngeal Cancer Study | Dr Swee T Tan | Observational | 14/08/2014 |  |  | 1/09/2014 |
| 14/CEN/130 | Approve | Citizens' interactions with public services | Ms Sarah Crichton | Observational | 14/08/2014 | 2/09/2014 | 8/09/2014 | 16/09/2014 |
| 14/CEN/136 | Approve | RESPECT ESUS | Dr. Jeremy Lanford | Intervention | 11/09/2014 | 29/09/2014 | 20/10/2014 | 21/10/2014 |
| 14/CEN/145 | Decline | MLN9708 Plus Lenalidomide and Dexamethasone Versus Placebo Plus Lenalidomide and Dexamethasone in Adult Patients With Newly Diagnosed Multiple Myeloma | Dr Steven Gibbons | Intervention | 11/09/2014 |  |  | 29/09/2014 |
| 14/CEN/147 | Approve | The IMPERATIVE-HF trial | Professor Richard Troughton | Intervention | 11/09/2014 | 29/09/2014 | 2/10/2014 | 21/10/2014 |
| 14/CEN/148 | Approve | Omega-3 fatty acids and cognition | Miss Alexia Mengelberg | Intervention | 11/09/2014 | 29/09/2014 | 14/10/2014 | 28/10/2014 |
| 14/CEN/149 | Approve | A 52-week, double-blind, randomised, multi-centre, phase III, parallel-group study in patients 12 years and older with asthma, evaluating Symbicort Turbuhaler 160/4.5ug ‘as needed’ compared with Pulmi | Dr Simon Carson | Intervention | 11/09/2014 | 29/09/2014 | 28/10/2014 | 5/11/2014 |
| 14/CEN/150 | Approve | Intranasal Oxytocin for the treatment of high frequency episodic and chronic migraine | Dr Dean Quinn | Intervention | 11/09/2014 | 29/09/2014 | 8/10/2014 | 22/10/2014 |
| 14/CEN/153 | Approve | CLL14 | Dr Robert Weinkove | Intervention | 11/09/2014 | 29/09/2014 | 15/10/2014 | 3/11/2014 |
| 14/CEN/157 | Approve | COG SJMB12 - Medulloblastoma | Dr Stephen Laughton | Intervention | 9/10/2014 | 28/10/2014 | 17/11/2014 | 24/11/2014 |
| 14/CEN/162 | Approve | ABX203-002: ABX203 therapeutic vaccine in HBeAg negative patients with chronic hepatitis B | Professor Edward Gane | Intervention | 9/10/2014 | 28/10/2014 | 3/11/2014 | 17/11/2014 |
| 14/CEN/163 | Approve | Managing gout in the community | Professor Lisa Stamp | Observational | 9/10/2014 | 28/10/2014 | 31/10/2014 | 13/11/2014 |
| 14/CEN/166 | Approve | Ibrutinib in Combination with Obinutuzumab versus Chlorambucil in Combination with Obinutuzumab in participants with Treatment-naive Chronic Lymphocytic Leukaemia or Small Lymphocytic Lymphoma | Dr Gillian Corbett | Intervention | 9/10/2014 | 28/10/2014 | 20/11/2014 | 25/11/2014 |
| 14/CEN/168 | Approve | SWITCH: Short Intravenous Study for Cellulitis | Dr Mark Birch | Intervention | 9/10/2014 |  |  | 28/10/2014 |
| 14/CEN/169 | Approve | Plasma CNP peptides in Parkinson’s Disease | Dr Zoe Woodward | Observational | 9/10/2014 | 28/10/2014 | 10/11/2014 | 25/11/2014 |
| 14/CEN/171 | Approve | Safety of tofacitinib compared to etanercept in Rheumatoid Arthritis (A3921133) | Dr Sunil Kumar | Intervention | 9/10/2014 | 28/10/2014 | 13/11/2014 | 24/11/2014 |
| 14/CEN/172 | Approve | Preterm birth and developmental outcomes | Dr Shieak YC Tzeng | Observational | 9/10/2014 | 28/10/2014 | 31/10/2014 | 14/11/2014 |
| 14/CEN/173 | Approve | Study investigating ABT-493 and ABT-530 in Subjects with Normal and Impaired Hepatic Function | Professor Edward Gane | Intervention | 9/10/2014 | 28/10/2014 | 6/11/2014 | 13/11/2014 |
| 14/CEN/174 | Approve | A clinical trial to evaluate safety and efficacy of combination of ertugliflozin with sitagliptin in the treatment of participants with type II diabetes with inadequate glycaemic control on diet | Dr Michael Williams | Intervention | 9/10/2014 |  |  | 28/10/2014 |
| 14/CEN/175 | Approve | A study of ABT493 and ABT530 with or without RBV in patients with chronic Genotype 2 or 3 HCV | Professor Edward Gane | Intervention | 9/10/2014 | 28/10/2014 | 20/11/2014 | 10/12/2014 |
| 14/CEN/186 | Provisionally approve | Roche RO6864018 treatment in Hepatitis B participants | Prof Ed Gane | Intervention | 13/11/2014 | 26/11/2014 |  |  |
| 14/CEN/187 | Provisionally approve | Infection prophylaxis in central venous access devices – a randomized controlled trial comparing monthly tissue Plasminogen Activator with heparin locks in children with a CVAD | Dr Peter Bradbeer | Intervention | 13/11/2014 | 26/11/2014 |  |  |
| 14/CEN/188 | Decline | Pediatric Vasculitis Initiative or PedVas | Dr. Arno Ebner | Observational | 13/11/2014 |  |  | 26/11/2014 |
| 14/CEN/189 | Approve | Prevalence of cognitive impairment and mood disorders in patients with Type 2 Diabetes in the Older Person in the Middlemore Area | Mr Aik Haw Tan | Observational | 13/11/2014 | 26/11/2014 | 11/12/2014 | 17/12/2014 |
| 14/CEN/190 | Approve | Prevalence of VTEC and toxigenic C. dif in the Auckland community | Dr Arlo Upton | Observational | 13/11/2014 |  |  | 26/11/2014 |
| 14/CEN/194 | Approve | Protein supplementation and glucose tolerance | Dr Lee Stoner | Intervention | 13/11/2014 | 26/11/2014 | 4/12/2014 | 15/12/2014 |
| 14/CEN/198 | Provisionally approve | Development of a tool for protein counting on a restricted carbohydrate diet | Dr Amber Parry Strong | Intervention | 13/11/2014 | 26/11/2014 | 17/12/2014 |  |
| 14/CEN/200 | Approve | HBV-001: A study of INO-1800 alone or in combination with INO-9112 for Chronic Hepatitis B patients to evaluate safety, tolerability, and immunogenicity | Professor Edward Gane | Intervention | 13/11/2014 | 26/11/2014 | 8/12/2014 | 17/12/2014 |
| 14/CEN/217 | Approve | Tricyclic Antidepressant Used for Somnolence Properties in Patients with Radiculopathy | Dr Carl Chisholm | Intervention | 8/12/2014 |  |  | 8/12/2014 |

## Applications reviewed by expedited review

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| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Study reference | Study status | Short title | Co-ordinating Investigator | Application type | Date Application Validated | Date of First Decision | Provisional Response Received | Date of final Decision |
| 14/CEN/7 | Approve | Detection of Liver and Renal Function Abnormalities after the Fontan Procedure | Dr Tom Gentles | Observational | 16/01/2014 | 7/02/2014 | 21/02/2014 | 17/09/2014 |
| 14/CEN/12 | Approve | Experiencing Place: People with Younger Onset Dementia (YOD) in 'Aged' Care Facilities | Dr Brenda (B) Sally Rimkeit | Observational | 31/01/2014 |  |  | 20/02/2014 |
| 14/CEN/24 | Approve | T1D youth mHealth survey | Ms Rosie Dobson | Observational | 18/02/2014 | 7/03/2014 | 14/03/2014 | 18/03/2014 |
| 14/CEN/27 | Approve | Supervised Practice of Systemic Family Therapy | Mr Craig Whisker | Observational | 20/02/2014 | 7/03/2014 | 26/03/2014 | 4/04/2014 |
| 14/CEN/28 | Approve | The potential impact of primary HPV testing on cervical cancer in New Zealand | Dr Naomi Brewer | Observational | 20/02/2014 |  |  | 7/03/2014 |
| 14/CEN/31 | Approve | Fluid-TRIPS | Dr Paul Young | Observational | 27/02/2014 |  |  | 13/03/2014 |
| 14/CEN/30 | Approve | PEPTIC feasibility study | Dr Paul Young | Observational | 5/03/2014 |  |  | 18/03/2014 |
| 14/CEN/44 | Approve | Massey University Biological Monitoring Study | Dr Andrea 't Mannetje | Observational | 14/03/2014 | 18/03/2014 | 11/04/2014 | 5/05/2014 |
| 14/CEN/45 | Approve | Blackcurrant supplementation on sporting performance in adolescent hockey players | Dr Suzanne Hurst | Intervention | 27/03/2014 | 4/04/2014 | 14/04/2014 | 16/04/2014 |
| 14/CEN/55 | Approve | Safety of screening for rheumatic heart disease | Assoc Prof Diana Sarfati | Observational | 10/04/2014 | 15/04/2014 | 9/05/2014 | 23/06/2014 |
| 14/CEN/64 | Decline | Stability of alcohol in blood collected in evacuated tubes | Dr Allan Stowell | Observational | 5/05/2014 |  |  | 28/05/2014 |
| 14/CEN/66 | Approve | Green Kiwifruit and Gut Health | Associate Professor Richard Gearry | Intervention | 12/05/2014 | 29/05/2014 | 4/06/2014 | 12/06/2014 |
| 14/CEN/79 | Approve | HART Mortality Data Linkage Project | Dr Andy Towers | Observational | 19/05/2014 | 22/05/2014 | 29/05/2014 | 26/06/2014 |
| 14/CEN/86 | Approve | Incidence of Acute Rheumatic Fever study | Assoc Prof Diana Sarfati | Observational | 27/05/2014 | 23/06/2014 | 25/06/2014 | 4/07/2014 |
| 14/CEN/87 | Approve | The PATU Project | Assoc. Prof. Rachel Forrest | Observational | 30/05/2014 | 25/06/2014 | 26/06/2014 | 1/07/2014 |
| 14/CEN/95 | Approve | An Observational Study to Evaluate the Effect of Family Start Home Visiting Program | Prof Rhema Vaithianathan | Observational | 11/06/2014 |  |  | 25/06/2014 |
| 14/CEN/102 | Approve | Transitional vertebrae pelvic parameters | Dr Richard Cowley | Observational | 12/06/2014 | 26/06/2014 | 3/09/2014 | 11/09/2014 |
| 14/CEN/104 | Approve | Bi-level Positive Airway Pressure - Efficacy and Comfort | Mr Hamish Collie | Intervention | 25/06/2014 |  |  | 10/07/2014 |
| 14/CEN/105 | Approve | Antibiotic resistance and childhood hospital admissions | Dr Sara Filoche | Observational | 2/07/2014 | 24/07/2014 | 28/08/2014 | 4/09/2014 |
| 14/CEN/106 | Approve | Ease of walking on low impact flooring | Dr Carl Hanger | Intervention | 7/07/2014 |  |  | 24/07/2014 |
| 14/CEN/116 | Approve | The effects of moderate altitude on people with obesity hypoventilation syndrome and obstructive sleep apnoea | A/Prof Lutz Beckert | Observational | 14/07/2014 | 30/07/2014 | 11/08/2014 | 14/08/2014 |
| 14/CEN/117 | Approve | Clinical effectiveness of footwear in people with gout | Professor Keith Rome | Intervention | 18/07/2014 |  |  | 6/08/2014 |
| 14/CEN/118 | Approve | MRI as biomarker for rheumatoid arthritis | Professor Fiona McQueen | Observational | 28/07/2014 |  |  | 13/08/2014 |
| 14/CEN/119 | Approve | Manawa a mua: the Māori cardiac rehabilitation experience | Dr Geoffrey Kira | Observational | 30/07/2014 | 14/08/2014 | 18/08/2014 | 20/08/2014 |
| 14/CEN/121 | Approve | Mechanisms of quadriceps fatigue in knee injured patients | Professor Peter McNair | Observational | 6/08/2014 | 18/08/2014 | 20/10/2014 | 23/10/2014 |
| 14/CEN/133 | Approve | OSA risk in a clinical paediatric cohort and their parents | Dr Angela Campbell | Observational | 19/08/2014 |  |  | 4/09/2014 |
| 14/CEN/134 | Approve | Addressing avoidable harm suffered by Māori babies | Assoc Prof Beverley Lawton | Observational | 21/08/2014 |  |  | 4/09/2014 |
| 14/CEN/135 | Approve | The impact of dabigatran on anticoagulant practice | Dr Paul Harper | Observational | 27/08/2014 |  |  | 15/09/2014 |
| 14/CEN/137 | Approve | Mortality and cancer incidence in sawmill workers exposed to pentachlorophenol | Dr David McLean | Observational | 27/08/2014 |  |  | 15/09/2014 |
| 14/CEN/138 | Approve | Describing active surveillance of patients with subclinical or borderline Rheumatic Heart Disease | Assoc Prof Diana Sarfati | Observational | 28/08/2014 |  |  | 16/09/2014 |
| 14/CEN/143 | Approve | Characteristics and outcomes of Medical Emergency Team (MET) calls in New Zealand hospitals | Dr. Alex Psirides | Observational | 3/09/2014 |  |  | 16/09/2014 |
| 14/CEN/144 | Approve | The resource utilization in medically unexplained physical symptoms | Dr Frederick Sundram | Observational | 8/09/2014 |  |  | 22/09/2014 |
| 14/CEN/154 | Approve | Phenoxy herbicide workers cohort | Dr Andrea Mannetje | Observational | 16/09/2014 | 15/10/2014 | 23/10/2014 | 24/10/2014 |
| 14/CEN/155 | Approve | Mortality and Cancer Incidence in Meat Workers: A 10 year extended follow-up | Dr David McLean | Observational | 17/09/2014 | 15/10/2014 | 15/10/2014 | 23/10/2014 |
| 14/CEN/159 | Approve | Preventing Chronic Conditions: Learnings from Participatory Research with Māori | Dr Heather Gifford | Observational | 26/09/2014 | 17/10/2014 | 1/12/2014 | 4/12/2014 |
| 14/CEN/160 | Approve | Bereaved Women Survey 2014 | Mrs Katrina Magill | Observational | 29/09/2014 |  |  | 17/10/2014 |
| 14/CEN/158 | Provisionally approve | Wellington Lions Keratoconus Study (WeLKS) | Mr Reece Hall | Observational | 30/09/2014 | 17/10/2014 | 17/12/2014 |  |
| 14/CEN/176 | Approve | Knowledge, attitudes and beliefs in the prevention of HPV-related cancer. Factors affecting HPV vaccination uptake | Ms Karen Howard | Observational | 9/10/2014 |  |  | 24/10/2014 |
| 14/CEN/179 | Approve | National Diabetes baseline - renal measure | Dr Nick Polaschek | Observational | 14/10/2014 |  |  | 31/10/2014 |
| 14/CEN/180 | Approve | The Garden to Table project evaluation | Dr Amber Parry Strong | Intervention | 16/10/2014 | 31/10/2014 | 4/11/2014 | 17/11/2014 |
| 14/CEN/181 | Approve | Hyperglycaemia and teen drivers with type 1 diabetes | Dr Joanna McClintock | Intervention | 28/10/2014 | 13/11/2014 | 1/12/2014 | 4/12/2014 |
| 14/CEN/182 | Approve | The Investigation of Jupiter Full Face Mask for Positive Pressure Therapy | Bhavi Ogra | Intervention | 28/10/2014 |  |  | 12/11/2014 |
| 14/CEN/185 | Approve | Rotavirus Vaccine – Impact on Paediatric Hospital Admissions with Gastroenteritis in Hawke’s Bay. | Dr Debra Gibb | Observational | 4/11/2014 |  |  | 19/11/2014 |
| 14/CEN/206 | Approve | The burden of asbestos-related cancer in New Zealand | Dr Amanda Eng | Observational | 17/11/2014 |  |  | 4/12/2014 |
| 14/CEN/196 | Approve | Use of t-PA/DNase via indwelling pleural catheters to relieve loculated malignant pleural effusions | Dr Samantha Herath | Observational | 25/11/2014 |  |  | 10/12/2014 |
| 14/CEN/208 | Approve | Development of a patient-focused app for managing rheumatoid arthritis | Dr Rebecca Grainger | Observational | 25/11/2014 | 10/12/2014 | 18/12/2014 | 22/12/2014 |
| 14/CEN/207 | Approve | Glycaemic potency of kiwifruit | Dr John Monro | Intervention | 26/11/2014 |  |  | 10/12/2014 |
| 14/CEN/210 | Approve | Review of end-of-life care for patients at HVDHB Hospital | Dr Hannah Walker | Observational | 26/11/2014 | 10/12/2014 | 18/12/2014 | 22/12/2014 |
| 14/CEN/211 | Approve | Self sampling for cervical screening | Dr. Sunia Foliaki | Observational | 27/11/2014 | 11/12/2014 | 12/12/2014 | 18/12/2014 |
| 14/CEN/212 | Approve | Life 10 years after prostate cancer treatment | Professor David Lamb | Observational | 28/11/2014 | 11/12/2014 | 18/12/2014 | 23/12/2014 |
| 14/CEN/213 | Approve | A smartphone-based intervention for reducing problem gambling harm | Associate Professor Chris Bullen | Observational | 4/12/2014 |  |  | 22/12/2014 |

## Overdue full applications

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| --- | --- | --- | --- |
| Study reference | Short title | Days overdue | Reason |
| 14/CEN/147 | The IMPERATIVE-HF trial | 2 | **Reviewer delay** |
| 14/CEN/153 | CLL14 | 2 | **Reviewer delay** |
| 14/CEN/2 | Gestational diabetes screening | 2 | **Public holidays** |
| 14/CEN/40 | Non-Suicidal Self-Injury in Rangatahi Māori | 3 | **Reviewer delay** |
| 14/CEN/175 | A study of ABT493 and ABT530 with or without RBV in patients with chronic Genotype 2 or 3 HCV | 4 | **Reviewer delay** |
| 14/CEN/100 | The Experience of Diabulimia in People with Type I Diabetes | 4 | **Reviewer delay** |
| 14/CEN/109 | A study to evaluate if the study drug refametinib in combination with sorafenib is safe and effective in patients with liver cancer carrying a specific gene mutation (RAS mutation) | 4 | **Reviewer delay** |
| 14/CEN/16 | Children's modified onset of sleep study | 6 | **Reviewer delay** |
| 14/CEN/77 | SAND | 6 | **Reviewer delay** |
| 14/CEN/92 | Infant TBI Genetics study | 9 | **Reviewer delay** |
| 14/CEN/50 | Efficacy and safety of liraglutide and metformin in children and adolescents with type 2 diabetes mellitus | 12 | **Reviewer delay** |
| 14/CEN/1 | Phase II PI3K inhibitor in relapsed, indolent or aggressive NHL | 15 | **Public holidays, reviewer delay** |
| 14/CEN/59 | Housing Effects About Rheumatic fever (HEART) | 29 | **Reviewer delay** |
| 14/CEN/43 | Alios BioPharma ALS-8176-503 | 41 | **Reviewer delay** |

## Overdue expedited applications

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| --- | --- | --- | --- |
| Study reference | Short title | Days overdue | Reason |
| 14/CEN/118 | MRI as biomarker for rheumatoid arthritis | 1 | **Reviewer delay** |
| 14/CEN/133 | OSA risk in a clinical paediatric cohort and their parents | 1 | **Reviewer delay** |
| 14/CEN/106 | Ease of walking on low impact flooring | 2 | **Reviewer delay** |
| 14/CEN/119 | Manawa a mua: the Maori cardiac rehabilitation experience | 2 | **Reviewer delay** |
| 14/CEN/179 | National Diabetes baseline - renal measure | 2 | **Reviewer delay** |
| 14/CEN/206 | The burden of asbestos-related cancer in New Zealand | 2 | **Reviewer delay** |
| 14/CEN/160 | Bereaved Women Survey 2014 | 3 | **Reviewer delay** |
| 14/CEN/210 | Review of end-of-life care for patients at HVDHB Hospital | **3** | **Reviewer delay** |
| 14/CEN/212 | Life 10 years after prostate cancer treatment | **3** | **Secretariat delay** |
| 14/CEN/213 | A smartphone-based intervention for reducing problem gambling harm | 3 | **Reviewer delay** |
| 14/CEN/116 | The effects of moderate altitude on people with obesity hypoventilation syndrome and obstructive sleep apnoea | 4 | **Reviewer delay** |
| 14/CEN/117 | Clinical effectiveness of footwear in people with gout | 4 | **Reviewer delay** |
| 14/CEN/135 | The impact of dabigatran on anticoagulant practice | 4 | **Reviewer delay** |
| 14/CEN/137 | Mortality and cancer incidence in sawmill workers exposed to pentachlorophenol | 4 | **Reviewer delay** |
| 14/CEN/138 | Describing active surveillance of patients with subclinical or borderline Rheumatic Heart Disease | 4 | **Reviewer delay** |
| 14/CEN/181 | Hyperglycaemia and teen drivers with type 1 diabetes | 4 | **Reviewer delay** |
| 14/CEN/208 | Development of a patient-focused app for managing rheumatoid arthritis | **4** | **Reviewer delay** |
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| **14/CEN/12** |

 | Experiencing Place: People with Younger Onset Dementia (YOD) in 'Aged' Care Facilities | 5 | **Reviewer delay** |
| 14/CEN/211 | Self-sampling for cervical screening | 5 | **Reviewer delay** |
| 14/CEN/24 | T1D youth mHealth survey | 6 | **Secretariat delay /Reviewer delay** |
| 14/CEN/102 | Transitional vertebrae pelvic parameters | 7 | **Reviewer delay** |
| 14/CEN/64 | Stability of alcohol in blood collected in evacuated tubes | 8 | **Secretariat delay /Reviewer delay** |
| 14/CEN/159 | Preventing Chronic Conditions: Learnings from Participatory Research with Māori | 9 | **Reviewer delay** |
| 14/CEN/27 | Supervised Practice of Systemic Family Therapy | 9 | **Reviewer delay** |
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| **14/CEN/7** |

 | Green Kiwifruit and Gut Health | **10** | **Secretariat delay /** |
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| **14/CEN/7** |

 | Detection of Liver and Renal Function Abnormalities after the Fontan Procedure | 12 | **Secretariat delay /** |
| 14/CEN/180 | The Garden to Table project evaluation | 13 | **Reviewer delay** |
| 14/CEN/44 | Massey University Biological Monitoring Study | 13 | **Reviewer delay** |
| 14/CEN/105 | Antibiotic resistance and childhood hospital admissions | 14 | **Reviewer delay** |
| 14/CEN/154 | Phenoxy herbicide workers cohort | 15 | **Secretariat delay** |
| 14/CEN/79 | HART Mortality Data Linkage Project | 16 | **Secretariat delay /** |
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| **14/CEN/87** |  |  |

 | The PATU Project | 16 | **Secretariat delay /** |
| 14/CEN/155 | Mortality and Cancer Incidence in Meat Workers: A 10 year extended follow-up | 21 | **Secretariat delay** |
| 14/CEN/86 | Incidence of Acute Rheumatic Fever study | 21 | **Secretariat delay /** |
| 14/CEN/55 | Safety of screening for rheumatic heart disease | 35 | **Reviewer delay** |