

Central Health and Disability Ethics Committee

Annual Report 2022

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About this report

This report is a summary of the activities of the Central Health and Disability Ethics Committees (HDEC) for the period of 01 July 2021 – 30 June 2022. It includes a summary of the applications reviewed during the year, details of any complaints received (and how they were resolved), and a list of new applications submitted. Previous HDEC annual reports included information on committee membership and attendance. These details are no longer included in the report.

About the committee

The Central Health and Disability Ethics Committees (HDEC) is a Ministerial committee established under section 87 of the Pae Ora (Healthy Futures) Act 2022). 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 by checking that it meets or exceeds established ethical <a href="eth

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 <u>Health Research Council Act 1990</u>.

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

Another year has flown by for Central Ethics, as a consequence of the large number of research proposals we have assessed. Full applications, expedited, amendments, progress reports, protocol deviations all make for a busy time. Busy not only for us, our administration team needs a huge vote of thanks for coordinating all this for us.

I would also like to extend our thanks to our Researchers. The quality of application has improved immensely, following templates which mean they comply with the ethical guidelines required by New Zealand and making the approval process faster. It is always harder when they are working with an overseas company, but we are all making progress.

In the year ending June 2022, the committee reviewed a total of 198 applications. 102 applications were reviewed at full committee meetings, while 96 were reviewed through the expedited (low risk) pathway.

I would like to thank the Central Committee for their time, dedication and good humour during the past year and it has been a privilege to work with them. Welcome to our new members it is always better with a full committee and you are proving this.

Helen Walker QSM Chair – Central HDEC

Applications reviewed

Summary of applications received by full EC

The Secretariat notes that HDEC cannot defer, however they can provisionally approve. We have answered as if defer is a provisional approval.

| No. of applications approved | 3 |
|--|-----|
| No. of applications approved subject to conditions (minor, non-standard conditions) | 35 |
| No. of applications deferred and subsequently approved (provisionally approved before approval) | 40 |
| No. of applications deferred as at time of report (provisionally approved) | 4 |
| No. of applications that were declined in part because of no/insufficient consultation with appropriate Māori/whanau/iwi/hapu | 4 |
| No. of applications that were declined in part because of no/insufficient consultation with appropriate cultural group | 1 |
| No. of applications declined (this <u>excludes</u> those with no/insufficient consultation with appropriate Māori/whanau/iwi/hapu/cultural group) | 7 |
| No. of applications which were invalidated for incompleteness | 5 |
| No. of applications which do not require ethics committee approval (applications submitted to all Committees that were out of scope (total across Committees)) Note: this number is greatly increased from prior reports due to the new Ethics Review Manager automatic scope check process | 382 |
| No. of studies withdrawn by researcher (none made to meetings or reviewed) | 3 |
| No. of studies terminated by sponsor | 0 |
| No. of studies transferred to another EC | 0 |
| Total number of applications received by full EC | 102 |

Summary of applications received under expedited / low risk review

| No. of applications approved | 17 |
|---|----|
| No. of applications approved subject to conditions | 16 |
| No. of applications deferred and subsequently approved | 48 |
| No. of applications deferred as at time of report | 1 |
| No. of applications which do not require ethics committee approval (applications submitted to Committee that were incomplete or out of scope) | 4 |
| No. of applications referred for full committee review | 2 |
| No. of applications declined | 10 |
| No. of studies withdrawn by researcher | 0 |
| Total number of applications received under expedited / low risk review | 96 |

Total number of applications received

198

Complaints and overdue application summary

This section outlines complaints about decisions made by the Committee during 2022.

Complaints received

No complaints were received during the reporting period regarding any Central HDEC matters.

Overdue review

Average review times consider the time taken for the Secretariat to process applications and the time taken for the Committee to review applications. The clock is stopped when a decision letter is emailed to applicants. Average review times exclude time taken for researchers to respond to requests for further information. Researchers have up to 90 days to respond.

Average review time was 26 days for expedited applications. Target timeframe for expedited applications is 15 calendar days. (<u>Standard Operating Procedures for Health and Disability Ethics Committees</u>, para 9-102).

Average review time was 42 days for full applications. Target timeframe for full applications is 35 days. (Standard Operating Procedures for Health and Disability Ethics Committees, para 54-59).

In both review pathways, the clock days went over. This appears to be primarily due to the changeover of review system the HDECs were using partway through the reporting period, causing delays as a result of committee members, secretariat and researchers becoming more familiar with the system and able to respond in a timely manner.

Appendix 1: Details of applications reviewed¹

Applications reviewed by the committee

| Review reference | Project title | Coordinating investigator | Review date received | Date of first review | Outcome of first review | Review status | Date of final outcome | Coordinating investigator organisation | Sponsor organisation |
|------------------|---|---------------------------|----------------------------|----------------------------|--------------------------|---------------|-----------------------|--|--|
| 21/CEN/232 | (duplicate) Improving Health Care for Cook Islands people with Chronic Kidney Disease | Dr Debbie Ryan | 20/08/2021 | 22/09/2021 | Approved | Approved | 22/09/2021 | Pacific Perspectives Ltd, Pacific Perspectives Limited, Pacific Perspectives Limited | Pacific Perspectives Ltd, Pacific Perspectives Limited, Pacific Perspectives Limited |
| 2022 EXP 12543 | 12176 - Text based support following a suicide attempt - new application | Dr Lillian Ng | 16/05/2022 | 5/05/2022 | Provisionally Approve | Approved | 31/05/2022 | The University of Auckland | The University of Auckland |
| 2022 FULL 12061 | 1404-0010: A Study to Evaluate and Compare BI 456906 in Healthy Participants and in Patients with Liver Disease | Prof. Edward Gane | 9/02/2022 | 11/03/2022 | Approved | Approved | 11/03/2022 | New Zealand Clinical Research Ltd., New Zealand Clinical Research Ltd., Boehringer Ingelheim Pharma GmbH, Boehringer Ingelheim Pty Ltd. | New Zealand Clinical Research Ltd., New Zealand Clinical Research Ltd., Boehringer Ingelheim Pharma GmbH, Boehringer Ingelheim Pty Ltd. |
| 2022 EXP 11335 | 2022 Survey of Whānau/Families. Experience of the Maternity System and Survey for Whānau/Families who have Lost a Pēpe/Baby | Mr Emanuel Kalafatelis | 4/02/2022 | 19/11/2021 | Provisionally Approve | Approved | 18/02/2022 | Research New Zealand, Ministry of Health | Research New Zealand, Ministry of Health |
| 2022 FULL 11532 | A clinical trial to evaluate the efficacy of ISIS 678354 among patients with elevated levels of triglyceride | Dr. Jocelyne Benatar | 21/06/2022 | 5/05/2022 | Provisionally Approve | Approved | 27/06/2022 | Auckland City Hospital, Auckland City Hospital, Ionis Pharmaceuticals, Inc., CARSL Consulting (Clinical and Regulatory Services) | Auckland City Hospital, Auckland City Hospital, Ionis Pharmaceuticals, Inc., CARSL Consulting (Clinical and Regulatory Services) |
| 21/CEN/217 | A dose escalation and expansion study of MT-5111 in patients with previously treated advanced HER2-positive solid tumours | Dr Rajiv Kumar | 5/08/2021 | 21/10/2021 | Approved | Approved | 21/10/2021 | Pharmaceutical Solutions, New Zealand Clinical Research CHC, Molecular Templates, Inc. | Pharmaceutical Solutions, New Zealand Clinical Research CHC, Molecular Templates, Inc. |
| 2022 FULL 12615 | A Phase 1 Study to Evaluate the Safety and Tolerability of | Prof Edward Gane | 18/05/2022 | 5/05/2022 | Provisionally Approve | Approved | 31/05/2022 | New Zealand Clinical Research, New Zealand | New Zealand Clinical Research, New Zealand |

¹ Data is directly reported from the online system. Any errors in spelling is reflected due to errors made by the applicant.

| | Orally Administered JNJ- 64457744 | | | | | | | Clinical Research, Janssen Research & Development, LLC., Janssen-Cilag New Zealand Ltd | Clinical Research, Janssen Research & Development, LLC., Janssen-Cilag New Zealand Ltd |
|-----------------|--|----------------------------|------------|------------|--------------------------|----------|----------------|--|--|
| 2022 FULL 11653 | A Phase 3 Study of Elranatamab (PF-06863135) Monotherapy and Elranatamab + Daratumumab Versus Daratumumab + Pomalidomide + Dexamethasone in Participants with Relapsed/Refractory Multiple Myeloma | Dr Henry Chan | 10/02/2022 | 3/12/2021 | Provisionally Approve | Approved | 30/03/2022 | North Shore Hospital, North Shore Hospital, Pfizer Inc., Pfizer New Zealand Limited | North Shore Hospital, North Shore Hospital, Pfizer Inc., Pfizer New Zealand Limited |
| 21/CEN/236 | A primary care-led weight management intervention: DiRECT to Aotearoa New Zealand | Dr Kim Ma'ia'i | 20/08/2021 | 23/09/2021 | Decline | Declined | No Approval | University of Otago, Te Kaika general practice, University of Otago, Ōtŕ kou Health Limited | Capital eye Specialists, Capital Eye Specialists, Capital Eye Specialists, Allergan Australia Pty Ltd |
| 2022 FULL 12143 | A Study of Baloxavir Marboxil for the Reduction of Direct Transmission of Influenza from Otherwise Healthy Patients to Household Contacts | Dr Michael Williams | 10/05/2022 | 29/03/2022 | Provisionally Approve | Approved | 27/05/2022 | Lakeland Clinical Trials, Roche Products (New Zealand) Limited | Lakeland Clinical Trials, Roche Products (New Zealand) Limited |
| 21/CEN/179 | A study of R131-2 vaginal soft gel capsule in healthy volunteers | Dr Noelyn Hung | 1/07/2021 | 16/08/2021 | Approved | Approved | 16/08/2021 | Zenith Technology Corporation Limited, Zenith Technology Corporation Limited, Zenith Technology Corporation Limited, Douglas Pharmaceuticals Ltd | Zenith Technology Corporation Limited, Zenith Technology Corporation Limited, Zenith Technology Corporation Limited, Douglas Pharmaceuticals Ltd |
| 2021 FULL 11190 | A Study of SP-104 Compared to Immediate Release Naltrexone Capsules | Dr Chris Wynne | 15/09/2021 | 14/10/2021 | Approved | Approved | 14/10/2021 | New Zealand Clinical Research, New Zealand Clinical Research, InClin PTY LTD | New Zealand Clinical Research, New Zealand Clinical Research, InClin PTY LTD |
| 21/CEN/243 | A Study to Investigate the Clinical Effectiveness and Safety of AK120 in Adults with Moderate-to-Severe Atopic Dermatitis | Prof. Marius Rademaker | 19/08/2021 | 20/01/2022 | Approved | Approved | 20/01/2022 | Clinical Trials NZ, Clinical Trials New Zealand, , Akesobio Australia Pty Ltd. | Clinical Trials NZ, Clinical Trials New Zealand, Akesobio Australia Pty Ltd. |
| 21/CEN/216 | A Study to Investigate the Clinical Effectiveness and Safety of ARO-APOC3-2002 in Adults with Mixed Dyslipidemia | Dr Joanna Wojciechowska | 4/08/2021 | 10/09/2021 | Approved | Approved | 10/09/2021 | Middlemore Clinical Trials, Counties Manukau District Health Board/Middlemore Clinical Trials, Middlemore | Middlemore Clinical Trials, Counties Manukau District Health Board/Middlemore Clinical Trials, Middlemore |

| | | | | | | | | Clinical Trials, IQVIA RDS Pty Limited | Clinical Trials, IQVIA RDS Pty Limited |
|-----------------|--|--|------------|------------|--------------------------|----------|------------|--|--|
| 2022 EXP 12775 | A tailored iSupport virtual group intervention for Chinese dementia carers living in New Zealand: a feasibility study | Assoc. Professor John Parsons | 25/05/2022 | 17/05/2022 | Provisionally Approve | Approved | 13/06/2022 | University of Auckland, School of Nursing University of Auckland | University of Auckland, School of Nursing University of Auckland |
| 2022 FULL 11324 | Symptoms and Side Effects – a Modified Delphi Study | Dr Ross Drake | 22/04/2022 | 11/03/2022 | Provisionally Approve | Approved | 1/06/2022 | Auckland District Health Board, Auckland District Health Board, IMPACCT Trials Coordination Centre (ITCC) | Auckland District Health Board, Auckland District Health Board, IMPACCT Trials Coordination Centre (ITCC) |
| 2021 EXP 11047 | Accuracy of Automated Echo Measurements by Novices | Dr. Sierra Beck | 14/09/2021 | 23/09/2021 | Approved | Approved | 23/09/2021 | University of Otago/Southern District Health Board, Heath Research South | University of Otago/Southern District Health Board, Heath Research South |
| 2021 EXP 11072 | Acoustic therapy to relieve rhinitis symptoms | Dr Jim Bartley | 16/10/2021 | 13/10/2021 | Provisionally Approve | Approved | 2/11/2021 | Counties Manukau Super Clinic, AUT Ventures | Counties Manukau Super Clinic, AUT Ventures |
| 2021 EXP 11384 | ACT for IBD | Prof Richard Gearry | 2/12/2021 | 15/10/2021 | Provisionally Approve | Approved | 14/12/2021 | University of Otago Christchurch, Deakin University | University of Otago Christchurch, Deakin University |
| 2022 EXP 12252 | Acute kidney injury in neonates | Dr Angelica Fletcher | 23/03/2022 | 12/04/2022 | Approved | Approved | 12/04/2022 | CCDHB, The Centenary Hospital for Women and Children | CCDHB, The Centenary Hospital for Women and Children |
| 21/CEN/230 | ADHD, Cognition, and Fidgeting | Associate Professor Justin Fernandez | 11/08/2021 | 14/10/2021 | Approved | Approved | 14/10/2021 | Matai Medical Research Institute, University of Auckland, University of Auckland, MÄ• tai Medical Research Institute | Matai Medical Research Institute, University of Auckland, University of Auckland, MÄ• tai Medical Research Institute |
| 21/CEN/202 | ALG-020572-401: A Study of ALG-020572 in Healthy Volunteers and Patients with Chronic Hepatitis B | Prof. Edward Gane | 29/07/2021 | 10/09/2021 | Approved | Approved | 10/09/2021 | Auckland Clinical Studies, New Zealand Clinical Research Ltd., New Zealand Clinical Research Ltd., Novotech (New Zealand) Limited | Auckland Clinical Studies, New Zealand Clinical Research Ltd., New Zealand Clinical Research Ltd., Novotech (New Zealand) Limited |
| 2021 EXP 11471 | Amendment Decline Test 2 | | 7/10/2021 | 7/10/2021 | Decline | Declined | 7/10/2021 | | |
| 2021 EXP 11244 | An investigation of particle production whilst using nasal high flow and a surgical mask in adult volunteers to inform the risk of infection to healthcare workers | Mr Matthew Payton | 2/12/2021 | 9/11/2021 | Provisionally Approve | Approved | 14/12/2021 | University of Auckland, University of Auckland | University of Auckland, University of Auckland |
| 2021 FULL 11004 | ASLAN004-003: Study of Efficacy and Safety of | Dr Marius Rademaker | 17/12/2021 | 10/11/2021 | Provisionally Approve | Approved | 28/01/2022 | Clinical Trials New Zealand Ltd, Clinical Trials New | Clinical Trials New Zealand Ltd, Clinical Trials New |

| | ASLAN004 in Adult Patients with Moderate-to-Severe Atopic Dermatitis | | | | | | | Zealand Ltd, ASLAN Pharmaceuticals Pte. Ltd., IQVIA | Zealand Ltd, ASLAN Pharmaceuticals Pte. Ltd., IQVIA |
|-----------------|---|--|------------|------------|--------------------------|----------|------------|---|---|
| 2021 FULL 11709 | AVT03-GL-P01: A Study to Compare AVT03 and Prolia® in Healthy Male Participants | Doctor Chris Wynne | 1/12/2021 | 11/02/2022 | Approved | Approved | 11/02/2022 | New Zealand Clinical Research, New Zealand Clinical Research, Alvotech Swiss AG, IQVIA RDS Pty Limited | New Zealand Clinical Research, New Zealand Clinical Research, Alvotech Swiss AG, IQVIA RDS Pty Limited |
| 21/CEN/200 | BALANCED LT | Dr Douglas Campbell | 22/07/2021 | 30/09/2021 | Approved | Approved | 30/09/2021 | ADHB, Auckland District Health Board, Auckland District Health Board, Auckland District Health Board | ADHB, Auckland District Health Board, Auckland District Health Board, Auckland District Health Board |
| 2022 EXP 12037 | Barriers to kidney transplantation for Pasifika patients with end stage renal disease | Dr Amelia Tekiteki | 6/05/2022 | 18/02/2022 | Provisionally Approve | Approved | 17/05/2022 | ADHB, Research Investment Manager for Health Delivery at HRC NZ | ADHB, Research Investment Manager for Health Delivery at HRC NZ |
| 2022 EXP 11682 | Beating Prediabetes Study | Associate Professor of Pathophysiology Kay Rutherfurd Markwick | 7/06/2022 | 28/06/2022 | Approved | Approved | 28/06/2022 | Massey University, Massey University, Massey University | Massey University, Massey University, Massey University |
| 2022 FULL 12670 | BGB-A317-210 (TIRHOL: Tislelizumab in Patients with Relapsed or Refractory Classical Hodgkin Lymphoma) | Dr Leanne Berkahn | 11/05/2022 | 3/06/2022 | Approved | Approved | 3/06/2022 | Auckland City Hospital, Auckland City Hospital, BeiGene Aus Pty Ltd | Auckland City Hospital, Auckland City Hospital, BeiGene Aus Pty Ltd |
| 2021 EXP 11207 | Biochemical Markers for Photodamage in Skin | Mr Ira Mautner | 13/10/2021 | 2/11/2021 | Approved | Approved | 2/11/2021 | The University of Auckland, University of Auckland | The University of Auckland, University of Auckland |
| 2022 FULL 12093 | BP42233: A Phase 1 Study Evaluating Safety and Pharmacokinetics of RO7425781 in Relapsed or Refractory Multiple Myeloma | Dr. Peter Browett | 8/03/2022 | 29/03/2022 | Approved | Approved | 29/03/2022 | New Zealand Clinical Research Ltd., New Zealand Clinical Research Ltd., Roche Products (New Zealand) Ltd | New Zealand Clinical Research Ltd., New Zealand Clinical Research Ltd., Roche Products (New Zealand) Ltd |
| 2021 FULL 11634 | BRN-002-HV-102: A Study to Assess the Safety of Multiple Doses of BRN-002 in Healthy Participants | Doctor Paul Hamilton | 10/11/2021 | 3/12/2021 | Approved | Approved | 3/12/2021 | New Zealand Clinical Research, New Zealand Clinical Research, Beren Therapeutics, P.B.C., Novotech (New Zealand) Limited | New Zealand Clinical Research, New Zealand Clinical Research, Beren Therapeutics, P.B.C., Novotech (New Zealand) Limited |
| 2022 FULL 11753 | Bronchiolitis KT Sustainability Study | Professor Stuart R Dalziel | 18/03/2022 | 11/02/2022 | Provisionally Approve | Approved | 30/03/2022 | Auckland District Health Board | Auckland District Health Board |

| 21/CEN/177 | CAMERA2 case-control retrospective study | Dr Genevieve Walls | 1/07/2021 | 19/07/2021 | Approved | Approved | 19/07/2021 | Counties Manukau Health, National Centre for Infectious Diseases | Counties Manukau Health, National Centre for Infectious Diseases |
|-----------------|--|---|------------|------------|--------------------------|----------|------------|---|---|
| 2022 EXP 11055 | Cancer in Pregnancy Study (INCIP) | Dr Rita Sasidharan | 5/04/2022 | 18/02/2022 | Provisionally Approve | Approved | 12/04/2022 | Auckland District Health Board, Auckland City Hospital, Universitaire Ziekenhuizen Leuven (UZ Leuven) | Auckland District Health Board, Auckland City Hospital, Universitaire Ziekenhuizen Leuven (UZ Leuven) |
| 2022 EXP 12106 | Cancer of the head and neck in New Zealand | Research Associate Professor Brian Cox | 8/03/2022 | 28/02/2022 | Provisionally Approve | Approved | 12/04/2022 | University of Otago, University of Otago | University of Otago, University of Otago |
| 2021 EXP 11465 | Carbon dioxide changes during a breath-hold freedive | Dr Tom Scott | 2/12/2021 | 14/12/2021 | Approved | Approved | 14/12/2021 | Auckland District Health Board, University of Auckland, University of Auckland | Auckland District Health Board, University of Auckland, University of Auckland |
| 2022 EXP 11992 | Changes in precise force control under stress | Dr Rebekah Blakemore | 2/03/2022 | 24/03/2022 | Approved | Approved | 24/03/2022 | University of Otago | University of Otago |
| 2021 EXP 11172 | Chinese in NZ and Their Attitudes Toward and Experiences of Psychotherapy/Mental Health in NZ | Miss Luyu Qiu | 28/09/2021 | 13/10/2021 | Decline | Declined | 13/10/2021 | Massey University | Massey University |
| 2021 EXP 11512 | Chinese in NZ and Their Attitudes Towards and Experiences of Psychotherapy/Mental Health in NZ | Miss Luyu Qiu | 28/10/2021 | 22/11/2021 | Approved | Approved | 22/11/2021 | Massey University, Massey University | Massey University, Massey University |
| 21/CEN/182 | COG ANBL19P1 | Dr Andrew Wood | 7/07/2021 | 16/08/2021 | Approved | Approved | 16/08/2021 | Starship Children's Hospital, Auckland District Health Board, Auckland District Health Board, Children's Oncology Group | Starship Children's Hospital, Auckland District Health Board, Auckland District Health Board, Children's Oncology Group |
| 21/CEN/181 | COG ARST1921 | Dr Andrew Wood | 7/07/2021 | 16/08/2021 | Approved | Approved | 16/08/2021 | Starship Hospital, Auckland District Health Board, Auckland District Health Board, Children's Oncology Group (COG) | Starship Hospital, Auckland District Health Board, Auckland District Health Board, Children's Oncology Group (COG) |
| 2021 EXP 11451 | Comparison of glucose monitoring technologies and self-care practices | Dr. Hamish Crocket | 1/11/2021 | 15/10/2021 | Provisionally Approve | Approved | 17/11/2021 | University of Waikato | University of Waikato |
| 2021 FULL 11157 | Comparison of two buprenorphine patches. | Dr Noelyn Hung | 11/11/2021 | 6/12/2021 | Approved | Approved | 6/12/2021 | Zenith Technology Corporation Ltd, Zenith | Zenith Technology Corporation Ltd, Zenith |

| | | | | | | | | Technology Corporation Limited, Juno Pharmaceuticals Pty Ltd, Zenith Technology Corporation Limited | Technology Corporation Limited, Juno Pharmaceuticals Pty Ltd, Zenith Technology Corporation Limited |
|-----------------|---|--|------------|------------|--------------------------|----------|------------|--|--|
| 2021 EXP 11189 | Continuous Lignocaine Infusion Pharmacokinetics in the Perioperative Period (CLIPP) | Dr Daniel Chiang | 21/10/2021 | 18/11/2021 | Approved | Approved | 18/11/2021 | Waitemata District Health Board, The University of Auckland, Ethics and Integrity Department | Waitemata District Health Board, The University of Auckland, Ethics and Integrity Department |
| 2021 EXP 11581 | COPPER Study | Prof John Windsor | 28/10/2021 | 22/11/2021 | Approved | Approved | 22/11/2021 | The University of Auckland, University of Auckland | The University of Auckland, University of Auckland |
| 21/CEN/215 | COSI-2 | Dr Arun Nair | 29/07/2021 | 14/12/2021 | Approved | Approved | 14/12/2021 | Telethon Kids Institute, Waikato District Health Board, Telethon Kids Institute | Telethon Kids Institute, Waikato District Health Board, Telethon Kids Institute |
| 2021 FULL 11043 | Digital Inclusion for Maori and Non-Maori Older People | Dr Kathy Peri | 21/12/2021 | 15/11/2021 | Provisionally Approve | Approved | 28/01/2022 | University of Auckland | University of Auckland |
| 2022 FULL 11695 | Does nebulised acetylcysteine improve oxygenation in intubated patients with thick or high volume secretions? | Doctor Simon Gordon | 21/05/2022 | 11/03/2022 | Provisionally Approve | Approved | 30/05/2022 | Waikato district health board | Waikato district health board |
| 2021 EXP 11490 | ECMT-154 for the Topical Treatment of Eczema v2 | Dr Gabby Shortt | 14/10/2021 | 3/12/2021 | Approved | Approved | 3/12/2021 | Medical Research Institute of New Zealand, Manuka Bioscience | Medical Research Institute of New Zealand, Manuka Bioscience |
| 2022 FULL 12496 | ECMT-154,¢ for the Topical Treatment of Eczema in children | Dr Gabby Shortt | 16/05/2022 | 5/05/2022 | Provisionally Approve | Approved | 30/06/2022 | Medical Research Institute of New Zealand, Manuka Bioscience | Medical Research Institute of New Zealand, Manuka Bioscience |
| 2022 EXP 12330 | Effect of collagen hydrolysate on muscle recovery | Associate Professor Matthew Barnes | 12/05/2022 | 5/05/2022 | Provisionally Approve | Approved | 17/05/2022 | Massey University, Massey University | Massey University, Massey University |
| 2021 EXP 11475 | EMPOWER Health Study | Dr Rebecca Slykerman | 19/11/2021 | 18/11/2021 | Provisionally Approve | Approved | 30/11/2021 | The University of Auckland, The University of Auckland | The University of Auckland, The University of Auckland |
| 2021 EXP 11251 | END DM-1 | Associate Professor Richard Roxburgh | 2/11/2021 | 22/11/2021 | Approved | Approved | 22/11/2021 | The University of Auckland, The University of Auckland, Virginia Commonwealth University, The University of Auckland | The University of Auckland, The University of Auckland, Virginia Commonwealth University, The University of Auckland |
| 2022 EXP 12616 | Endometriosis Novel Diagnostic Opportunities (ENDO Study) | Dr Claire Henry | 17/05/2022 | 5/05/2022 | Provisionally Approve | Approved | 31/05/2022 | University of Otago, University of Otago | University of Otago, University of Otago |
| 2022 EXP 11991 | Ethnic disparities in survival for Head & Neck Ca | Dr Abigail Weaver | 14/02/2022 | 28/02/2022 | Decline | Declined | 28/02/2022 | Hawkes Bay District Health Board, Hawkes Bay DHB | Hawkes Bay District Health Board, Hawkes Bay DHB |

| 2022 FULL 11800 | Evaluation of Dissociative Symptom Assessment | Dr. Martin Dorahy | 12/04/2022 | 11/03/2022 | Provisionally Approve | Approved | 16/06/2022 | University of Canterbury, University of Canterbury | University of Canterbury, University of Canterbury |
|-----------------|--|-----------------------------|------------|----------------|--------------------------|----------|------------|--|--|
| 21/CEN/219 | Evaluation of Dissociative Symptom Assessments | Prof. Martin Dorahy | 9/08/2021 | No Approval | Decline | Declined | 10/09/2021 | University of Canterbury, University of Canterbury, University of Canterbury | University of Otago, Christchurch, University of Otago, Christchurch, University of Otago, Christchurch |
| 21/CEN/207 | EVERGREEN | Dr Simon Carson | 29/07/2021 | 10/11/2021 | Approved | Approved | 10/11/2021 | Southern Clinical Trials, Southern Clinical Trials Ltd - Christchurch, Southern Clinical Trials Ltd - Christchurch, IQVIA RDS Pty Limited | Southern Clinical Trials, Southern Clinical Trials Ltd - Christchurch, Southern Clinical Trials Ltd - Christchurch, IQVIA RDS Pty Limited |
| 21/CEN/205 | exciteBCI rehabilitation: Determining optimal dose | Prof Denise Taylor | 2/08/2021 | 30/03/2022 | Approved | Approved | 30/03/2022 | Auckland University of Technology, AUT University, AUT University, Auckland University of Technology | Auckland University of Technology, AUT University, AUT University, Auckland University of Technology |
| 2022 EXP 12248 | Exploration of inherited propensity for codeine misuse and dependence | Dr Rhys Ponton | 11/04/2022 | 5/05/2022 | Approved | Approved | 5/05/2022 | University of Auckland, School of Pharmacy, University of Auckland | University of Auckland, School of Pharmacy, University of Auckland |
| 21/CEN/211 | Faecal microbiome transfer (FMT) to improve gut issues in autism | Prof Wayne S Cutfield | 4/08/2021 | 10/09/2021 | Approved | Approved | 10/09/2021 | Liggins Institute, University of Auckland, University of Auckland, The University of Auckland | Liggins Institute, University of Auckland, University of Auckland, The University of Auckland |
| 21/CEN/180 | Feasibility of implementing Ballistic Strength Training to improve mobility outcomes in inpatients with Traumatic Brain Injury | Mrs Izel Gilfillan | 1/07/2021 | 16/08/2021 | Decline | Declined | 16/08/2021 | ABI Rehabilitation, ABI Rehabilitation, ABI Rehabilitation | AUT, AUT, AUT, AUT |
| 2022 EXP 11621 | Fetal RHD Genotyping | Dr Sarah Morley | 22/03/2022 | 18/02/2022 | Provisionally Approve | Approved | 30/03/2022 | New Zealand Blood Service, New Zealand Blood Service | New Zealand Blood Service, New Zealand Blood Service |
| 2021 EXP 11521 | Fetal Visual Perception | Professor Vincent Reid | 12/11/2021 | 25/11/2021 | Approved | Approved | 25/11/2021 | University of Waikato | University of Waikato |
| 2021 EXP 11484 | Genetic markers in Ovarian Cancer in New Zealand - NOVel | Dr Bryony Simcock | 16/11/2021 | 11/02/2022 | Approved | Approved | 11/02/2022 | Canterbury District Health Board/ University of Otago | Canterbury District Health Board/ University of Otago |
| 2022 EXP 12532 | GENIUS- Genomic Feasibility study | Dr Michelle Wilson | 12/04/2022 | 4/05/2022 | Approved | Approved | 4/05/2022 | ADHB, ADHB | ADHB, ADHB |
| 2022 FULL 11285 | Getting ready for MinDArT | Ms Emma Febvre- Richards | 20/05/2022 | 11/03/2022 | Provisionally Approve | Approved | 31/05/2022 | Massey University, Massey University; | Massey University, Massey University; |

| 2021 FULL 10994 | Glory Days study | Dr Kay Shannon | 13/10/2021 | 10/11/2021 | Decline | Declined | 10/11/2021 | Auckland University of Technology | Auckland University of Technology |
|-----------------|--|---|------------|------------|--------------------------|----------|-----------------|--|--|
| 2022 EXP 11638 | GS-US-356-5413: A Study of Females Exposed to Eleclazine | Prof. Edward Gane | 9/02/2022 | 11/01/2022 | Provisionally Approve | Approved | 18/02/2022 | New Zealand Clinical Research Ltd., New Zealand Clinical Research Ltd., Gilead Sciences, Inc., ICON Clinical Research (New Zealand) Ltd | New Zealand Clinical Research Ltd., New Zealand Clinical Research Ltd., Gilead Sciences, Inc., ICON Clinical Research (New Zealand) Ltd |
| 21/CEN/212 | Gut Bugs for Anorexia Nervosa | Professor Justin O'Sullivan | 4/08/2021 | 10/09/2021 | Approved | Approved | 10/09/2021 | University of Auckland, University of Auckland, University of Auckland, The University of Auckland | University of Auckland, University of Auckland, University of Auckland, The University of Auckland |
| 2022 EXP 11122 | GUTFIT Cohort study | Dr Amber Milan | 8/03/2022 | 18/02/2022 | Provisionally Approve | Approved | 24/03/2022 | AgResearch Limited / The University of Auckland, The University of Auckland, The University of Auckland | AgResearch Limited / The University of Auckland, The University of Auckland, The University of Auckland |
| 2021 EXP 11344 | Head and neck cancer in NZ | Associate Professor David McBride | 2/11/2021 | 22/11/2021 | Decline | Declined | Not approved | University of Otago, University of Otago | University of Otago, University of Otago |
| 2021 FULL 11023 | Head COOLing in iscHaemic stroke patients undergoing EndovAscular thrombectomy: a feasibility stuDy (COOLHEAD-2) | Professor Alan Barber | 29/10/2021 | 14/10/2021 | Provisionally Approve | Approved | 14/12/2021 | University of Auckland | University of Auckland |
| 2021 FULL 10992 | HeadSMART II | Professor Mark Richards | 23/11/2021 | 10/11/2021 | Provisionally Approve | Approved | 28/01/2022 | Christchurch Heart Institute, Emergency Care Foundation, BRAINBox Solutions Inc., Research and Enterprise, University of Otago | Christchurch Heart Institute, Emergency Care Foundation, BRAINBox Solutions Inc., Research and Enterprise, University of Otago |
| 2022 EXP 12312 | Health Implications of a Vegan Diet | Professor Pamela von Hurst | 31/03/2022 | 16/05/2022 | Approved | Approved | 16/05/2022 | Massey University, Massey University, Massey University | Massey University, Massey University, Massey University |
| 21/CEN/227 | Healthy donor blood for immunotherapies | Dr Rachel Perret | 9/08/2021 | 26/08/2021 | Approved | Approved | 26/08/2021 | MALAGHAN INSTITUTE OF MEDICAL RESEARCH, Malaghan Institute of Medical Research, Malaghan Institute of Medical Research, Malaghan Institute of Medical Research | MALAGHAN INSTITUTE OF MEDICAL RESEARCH, Malaghan Institute of Medical Research, Malaghan Institute of Medical Research, Malaghan Institute of Medical Research |
| 2022 EXP 12240 | High-Intensity Exercise Benefits to Blood Glucose | Professor David Rowlands | 8/04/2022 | 23/03/2022 | Provisionally Approve | Approved | 10/05/2022 | Massey University, Massey University, School of Sport, | Massey University, Massey University, School of Sport, |

| | Control Is the Milk-Sugar Lactose better than Sucrose? | | | | | | | Exercise, and Nutrition, Massey University | Exercise, and Nutrition, Massey University |
|-----------------|---|--|------------|------------|--------------------------|----------|-----------------|---|---|
| 2021 EXP 11450 | HIV behavioural surveillance 2022 | Dr Peter Saxton | 22/10/2021 | 15/10/2021 | Provisionally Approve | Approved | 9/11/2021 | University of Auckland, University of Auckland | University of Auckland, University of Auckland |
| 2021 FULL 11022 | HMGCR myositis in New Zealand | Dr Ke Chow | 22/10/2021 | 14/10/2021 | Provisionally Approve | Approved | 13/12/2021 | Canterbury Health Laboratories | Canterbury Health Laboratories |
| 2022 EXP 12201 | Human response to neck treatment following concussion | Associate Professor Steven Tumilty | 21/04/2022 | 13/04/2022 | Provisionally Approve | Approved | 12/05/2022 | University of Otago, University of Otago, School of Physiotherapy, University of Otago | University of Otago, University of Otago, School of Physiotherapy, University of Otago |
| 2021 FULL 11148 | HV-101: A Study to Assess BRN-002 in Healthy Participants | Doctor Paul Hamilton | 14/09/2021 | 14/10/2021 | Approved | Approved | 14/10/2021 | New Zealand Clinical Research, New Zealand Clinical Research, Beren Therapeutics, P.B.C., Novotech (New Zealand) Limited | New Zealand Clinical Research, New Zealand Clinical Research, Beren Therapeutics, P.B.C., Novotech (New Zealand) Limited |
| 21/CEN/208 | HYPERION - A Phase 3 Study of Sotatercept in Newly Diagnosed | Henry Gallagher | 29/07/2021 | 18/11/2021 | Approved | Approved | 18/11/2021 | University of Auckland, Waikato District Health Board, Waikato District Health Board, PPD - acting as local sponsor | University of Auckland, Waikato District Health Board, Waikato District Health Board, PPD - acting as local sponsor |
| 2022 FULL 12696 | Hypermobile Ehlers-Danlos Syndrome and Hypermobility Spectrum Disorder - Assessing Criteria and Their Modification in Clinical Practice. | Dr Fraser Burling | 11/05/2022 | 3/06/2022 | Decline | Declined | Not approved | Rheumatology and Musculoskeletal Clinic, The Ehlers-Danlos Society | Rheumatology and Musculoskeletal Clinic, The Ehlers-Danlos Society |
| 2021 EXP 11280 | IDP® for enhancing the gut barrier | Dr Matthew Barnes | 26/10/2021 | 22/11/2021 | Approved | Approved | 22/11/2021 | Massey University, Massey University | Massey University, Massey University |
| 2022 EXP 12068 | Imaging the optic nerve sheath: a dynamic pressurised compartment | Dr Jesse Gale | 13/06/2022 | 4/05/2022 | Provisionally Approve | Approved | 27/06/2022 | University of Otago (Wellington) | University of Otago (Wellington) |
| 2021 FULL 11070 | IMG-7289-CTP- 202_Bomedemstat Extension Study | Dr James Liang | 13/10/2021 | 10/11/2021 | Approved | Approved | 10/11/2021 | Counties Manukau Health, Middlemore Clinical Trials, Imago BioSciences, Inc., Syneos Health New Zealand Limited | Counties Manukau Health, Middlemore Clinical Trials, Imago BioSciences, Inc., Syneos Health New Zealand Limited |
| 2022 EXP 11553 | Impact of a switch from tocilizumab to upadacitinib in a cohort of patients with rheumatoid arthritis in routine clinical practice | Dr Douglas White | 18/04/2022 | 12/04/2022 | Provisionally Approve | Approved | 10/05/2022 | Waikato DHB, Waikato DHB | Waikato DHB, Waikato DHB |

| 2022 FULL 11318 | Impact of caregiver brain injury on their children | Mrs Audrey McKinlay | 26/01/2022 | 10/11/2021 | Provisionally Approve | Approved | 15/03/2022 | University of Canterbury, University of Canterbury, University of Canterbury | University of Canterbury, University of Canterbury, University of Canterbury |
|-----------------|--|--|------------|------------|--------------------------|----------|------------|--|--|
| 21/CEN/218 | IMU-935 Double-Blind, Placebo-controlled, phase 1/1b Part C study in Psoriasis Patients | Dr Dean Quinn | 5/08/2021 | 10/09/2021 | Approved | Approved | 10/09/2021 | P3 Research, P3 Research, , Avance Clinical | P3 Research, P3 Research, , Avance Clinical |
| 21/CEN/213 | InPUT study | Ms Yan Chen | 4/08/2021 | 23/09/2021 | Approved | Approved | 23/09/2021 | Auckland District Health Board, Auckland District Health Board, Auckland District Health Board | Auckland District Health Board, Auckland District Health Board, Auckland District Health Board |
| 2022 EXP 11438 | Investigating the effectiveness of a novel foot scanning device to early identify foot complications | Associate Professor Suranga Nanayakkara | 6/04/2022 | 22/02/2022 | Provisionally Approve | Approved | 12/04/2022 | The University of Auckland, | The University of Auckland, |
| 2022 EXP 11457 | Investigation of the effects of patient antibodies on therapeutic drugs | Dr barry hock | 8/03/2022 | 3/03/2022 | Provisionally Approve | Approved | 12/04/2022 | University of Otago, Christchurch, Research and Enterprise, University of Otago | University of Otago, Christchurch, Research and Enterprise, University of Otago |
| 2022 FULL 12681 | KN056-A-101: A Study to Assess KN056 in Healthy Participants | Principal Investigator Alexandra Cole | 11/05/2022 | 3/06/2022 | Approved | Approved | 3/06/2022 | New Zealand Clinical Research, New Zealand Clinical Research, Suzhou Alphamab Co., Ltd., Novotech | New Zealand Clinical Research, New Zealand Clinical Research, Suzhou Alphamab Co., Ltd., Novotech |
| 2021 FULL 11250 | LIBerate-OLE | Professor Russell Scott | 5/11/2021 | 3/12/2021 | Approved | Approved | 3/12/2021 | New Zealand Clinical Research (NZCR), New Zealand Clinical Research (NZCR), LIB Therapeutics, LLC, Clinical and Regulatory Services (CARSL) Consulting | New Zealand Clinical Research (NZCR), New Zealand Clinical Research (NZCR), LIB Therapeutics, LLC, Clinical and Regulatory Services (CARSL) Consulting |
| 2022 EXP 12513 | LINK study | Dr Nicola Gillies | 27/04/2022 | 27/05/2022 | Approved | Approved | 27/05/2022 | University of Auckland, University of Auckland, Ethics and Integrity department | University of Auckland, University of Auckland, Ethics and Integrity department |
| 21/CEN/184 | Long term outcomes following posterior malleolus ankle fractures | Dr Swee Liang (Leo) Chong | 5/07/2021 | 2/08/2021 | Approved | Approved | 2/08/2021 | Midcentral DHB, , | Midcentral DHB, , |
| 2022 EXP 12566 | Lung Cancer Epigenetics and Genetics Study | Dr Ben Brockway | 30/06/2022 | 5/05/2022 | Provisionally Approve | Approved | 6/07/2022 | University of Otago, University of Otago, University of Otago | University of Otago, University of Otago, University of Otago |

| 2022 EXP 11383 | Lung Cancer Genetics and Epigenetics study | Dr Ben Brockway | 14/01/2022 | 11/02/2022 | Decline | Declined | Not approved | University of Otago, University of Otago, University of Otago | University of Otago, University of Otago, University of Otago |
|-----------------|---|----------------------------------|------------|------------|--------------------------|----------|-----------------|--|--|
| 2022 EXP 12634 | Mamaku effects on blood glucose response | Dr John Monro | 11/05/2022 | 5/05/2022 | Provisionally Approve | Approved | 17/05/2022 | Plant and Food Research, High Value Nutrition | Plant and Food Research, High Value Nutrition |
| 2022 FULL 11179 | MAOB Feasibility Study | Lead Clinician Ronald Sluiter | 7/02/2022 | 10/11/2021 | Provisionally Approve | Approved | 28/02/2022 | Orthodontix Cashmere, Align Technology, Inc | Orthodontix Cashmere, Align Technology, Inc |
| 2021 FULL 11622 | MAX-40070-001: A Study to Evaluate MAX-40070 in Healthy Participants | Doctor Cory Sellwood | 9/11/2021 | 3/12/2021 | Approved | Approved | 3/12/2021 | New Zealand Clinical Research Ltd. , New Zealand Clinical Research Ltd. , Maxinovel Pty. Ltd., IQVIA RDS Pty Limited | New Zealand Clinical Research Ltd. , New Zealand Clinical Research Ltd. , Maxinovel Pty. Ltd., IQVIA RDS Pty Limited |
| 2022 EXP 12042 | Microsimulation of personalised breast cancer screening | Dr Nokuthaba Sibanda | 16/06/2022 | 28/06/2022 | Approved | Approved | 28/06/2022 | Victoria University of Wellington, Victoria University of Wellington | Victoria University of Wellington, Victoria University of Wellington |
| 2021 FULL 10983 | Mindfulness-Based Cognitive Therapy for family carers of relatives living with dementia- An intervention study | Dr Emme Chacko | 4/11/2021 | 14/10/2021 | Provisionally Approve | Approved | 21/01/2022 | The University of Auckland, The University of Auckland | The University of Auckland, The University of Auckland |
| 2021 FULL 11173 | MK-6482-016 | Dr Jane Yeojeong So | 6/10/2021 | 10/11/2021 | Approved | Approved | 10/11/2021 | Auckland City Hospital, Auckland City Hospital, Merck Sharpe and Dohme (MSD) | Auckland City Hospital, Auckland City Hospital, Merck Sharpe and Dohme (MSD) |
| 2022 FULL 11906 | MK-8591A 033-02 Doravirine/Islatravir (DOR/ISL) Rollover | Dr Alan Pithie | 12/04/2022 | 11/03/2022 | Provisionally Approve | Approved | 13/04/2022 | Canterbury District Health Board, Canterbury District Health Board, Merck Sharp & Dohme (Australia) Pty Ltd, a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA | Canterbury District Health Board, Canterbury District Health Board, Merck Sharp & Dohme (Australia) Pty Ltd, a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA |
| 21/CEN/201 | Neurosteroids and Catamenial Epilepsy | Dr Rachael Sumner | 21/07/2021 | 27/08/2021 | Approved | Approved | 27/08/2021 | The University of Auckland, | The University of Auckland, |
| 21/CEN/198 | Nutritional beverages in hospitalised older adults | Dr Andrea Braakhuis | 20/07/2021 | 23/09/2021 | Approved | Approved | 23/09/2021 | The University of Auckland, , , Fonterra Co-operative Group Limited | The University of Auckland, , , Fonterra Co-operative Group Limited |
| 21/CEN/231 | Objective measurement of supraglottic constriction | Miss Elizabeth Cross | 19/08/2021 | 20/09/2021 | Provisionally Approve | Approved | 10/11/2021 | University of Canterbury, University of Canterbury Rose Centre for Stroke Recovery and Research, University of Canterbury Rose Centre for Stroke Recovery and Research | University of Canterbury, University of Canterbury Rose Centre for Stroke Recovery and Research, University of Canterbury Rose Centre for Stroke Recovery and Research |

| 2021 EXP 11680 | Ocular and systemic effects of inversion | Dr Jesse Gale | 30/11/2021 | 14/12/2021 | Approved | Approved | 14/12/2021 | University of Otago Wellington | University of Otago Wellington |
|-----------------|---|---|------------|------------|--------------------------|----------|-----------------|---|---|
| 2022 FULL 11865 | Ocular Rehabilitation after Eye Damage in Aotearoa New Zealand | Dr Stuti Misra | 19/04/2022 | 29/03/2022 | Provisionally Approve | Approved | 24/05/2022 | The University of Auckland, University of Auckland | The University of Auckland, University of Auckland |
| 2022 FULL 11013 | Optimal Post rtPA-IV Monitoring in Ischemic Stroke (OPTIMISTmain) | Dr. Arindam Kar | 11/05/2022 | 3/06/2022 | Decline | Declined | Not approved | Middlemore Hospital, The George Institute for Global Health | Middlemore Hospital, The George Institute for Global Health |
| 21/CEN/174 | Optimising lung cancer screening for Māori: A study of comparative invitation processes | Professor Sue Crengle | 30/06/2021 | #REF! | #REF! | Approved | #REF! | , University of Otago, , Waitemata District Health Board and Auckland District Health Board | , University of Otago, , Waitemata District Health Board and Auckland District Health Board |
| 2022 EXP 12056 | Orthotopic liver transplant Acid base | Dr Vanessa Beavis | 19/01/2022 | 11/02/2022 | Approved | Approved | 11/02/2022 | Auckland District Health Board, Auckland District Health Board, ADHB | Auckland District Health Board, Auckland District Health Board, ADHB |
| 2022 FULL 11671 | Outcomes Following Peritonectomies in New Zealand 2008 to 2020 | Mr Jasen Ly | 13/01/2022 | 18/02/2022 | Approved | Approved | 18/02/2022 | Waikato District Health Board University of Auckland | Waikato District Health Board University of Auckland |
| 2022 EXP 11681 | oVRcome - self guided virtual reality for social anxiety disorder | Assoc Prof Cameron Lacey | 9/03/2022 | 18/02/2022 | Provisionally Approve | Approved | 24/03/2022 | University of Otago, Christchurch, University of Otago, Christchurch | University of Otago, Christchurch, University of Otago, Christchurch |
| 21/CEN/183 | PDPH Database | Dr Yvonne Wagner | 8/07/2021 | 30/07/2021 | Decline | Declined | 30/07/2021 | ADHB, Auckland District Health Board, | WDHB, , |
| 2021 EXP 11281 | Ph+ve ALL: A multi-site retrospective study | Dr Peter Bradbeer | 18/10/2021 | 15/10/2021 | Provisionally Approve | Approved | 2/11/2021 | Auckland District Health Board, Starship Hospital | Auckland District Health Board, Starship Hospital |
| 2022 FULL 11149 | Phantom | Dr Doug Campbell | 14/06/2022 | 1/07/2022 | Approved | Approved | 1/07/2022 | Auckland District Health Board, Auckland District Health Board, East Metropolitan Health Service trading as Royal Perth Hospital, ADHB | Auckland District Health Board, Auckland District Health Board, East Metropolitan Health Service trading as Royal Perth Hospital, ADHB |
| 2021 FULL 11676 | Phase 1 study of safety and efficacy of KUR-101 in healthy adult participants. | Dr Chris Wynne | 11/11/2021 | 3/12/2021 | Approved | Approved | 3/12/2021 | New Zealand Clinical Research, New Zealand Clinical Research, Atai Life Sciences, Infinity Consulting Ltd | New Zealand Clinical Research, New Zealand Clinical Research, Atai Life Sciences, Infinity Consulting Ltd |
| 2021 FULL 11848 | Phase 1 study of safety of VIS171 in healthy volunteers | Principal Investigator Alexandra Cole | 2/12/2021 | 11/02/2022 | Approved | Approved | 11/02/2022 | New Zealand Clincial Research, New Zealand Clinical Research, Visterra, Inc. 275 2nd Avenue, 4th Floor Waltham, MA 02451 | New Zealand Clincial Research, New Zealand Clinical Research, Visterra, Inc. 275 2nd Avenue, 4th Floor Waltham, MA 02451 |

| 2021 FULL 11037 | Phase 3 open-label, multicenter, extension study to evaluate the long-term safety and efficacy of pegcetacoplan in subjects with geographic atrophy secondary to age- related macular degeneration- (GALE) | Doctor Stephen Guest | 12/10/2021 | 10/11/2021 | Approved | Approved | 10/11/2021 | Hamilton Eye Clinic, Clinical Trials New Zealand, Apellis Pharmaceuticals Inc, Labcorp New Zealand | Hamilton Eye Clinic, Clinical Trials New Zealand, Apellis Pharmaceuticals Inc, Labcorp New Zealand |
|-----------------|---|--|------------|------------|--------------------------|----------|-----------------|---|--|
| 2022 FULL 12134 | Phase 3 Study of Pembrolizumab Versus Placebo as Adjuvant Therapy Following Surgery and Radiation in Participants with High-risk Locally Advanced Squamous Cell Carcinoma of the Skin (KEYNOTE-630) | Principal Investigator Catherine Han | 9/02/2022 | 11/03/2022 | Approved | Approved | 11/03/2022 | New Zealand Clinical Research, New Zealand Clinical Research, Merck, Sharp & Dohme (Australia) Pty Ltd, Merck Sharp & Dohme (Australia) Pty Ltd Authorising on behalf of Merck Sharp & Dohme (New Zealand) Limited (MSD) | New Zealand Clinical Research, New Zealand Clinical Research, Merck, Sharp & Dohme (Australia) Pty Ltd, Merck Sharp & Dohme (Australia) Pty Ltd Authorising on behalf of Merck Sharp & Dohme (New Zealand) Limited (MSD) |
| 21/CEN/233 | Pilot study: Can a dairy based protein complex (IDP) enhance immune responses after influenza vaccination? | Associate Professor Rachel Page | 19/08/2021 | 10/11/2021 | Approved | Approved | 10/11/2021 | Massey University, Massey University, Massey University, Massey University, Quantec Ltd, Massey University | Massey University, Massey University, Massey University, Massey University, Quantec Ltd, Massey University |
| 2022 FULL 12358 | Placebo-controlled study to evaluate the efficacy of mRNA-1345 vaccine | Dr Michael Williams | 6/05/2022 | 29/03/2022 | Provisionally Approve | Approved | 8/06/2022 | Lakeland Clinical Trials, ModernaTX, Inc., PPD Global Limited | Lakeland Clinical Trials, ModernaTX, Inc., PPD Global Limited |
| 2022 FULL 11171 | PPB Registry: The International Pleuropulmonary Blastoma /DICER1 Registry (for PPB, DICER1 and Associated Conditions) | Dr Karen Tsui | 18/03/2022 | 11/03/2022 | Provisionally Approve | Approved | 16/05/2022 | Starship Hospital, Starship Hospital, Children's Minnesota | Starship Hospital, Starship Hospital, Children's Minnesota |
| 2022 FULL 11965 | Pregnancy-related abdominal wall neuropathy (PRAWN): a case series | Dr Emily Twidale | 18/03/2022 | 12/04/2022 | Provisionally Approve | Declined | Not approved | Waikato DHB | Waikato DHB |
| 2022 EXP 12034 | Preventing subsequent injuries: A feasibility study | Dr Helen Harcombe | 13/05/2022 | 12/04/2022 | Provisionally Approve | Approved | 31/05/2022 | University of Otago, University of Otago | University of Otago, University of Otago |
| 2021 FULL 11054 | Proof of concept and dose- finding study of danicopan in patients with Geographic Atrophy secondary to AMD | Professor Anthony P Wells | 9/09/2021 | 14/10/2021 | Decline | Declined | 14/10/2021 | Capital Eye Specialists, PPD, Alexion Pharmaceuticals Inc, PPD New Zealand | Capital Eye Specialists, PPD, Alexion Pharmaceuticals Inc, PPD New Zealand |
| 2022 EXP 11007 | Prospective study on Ocular Melanocytic Lesions in Aotearoa/New Zealand | Professor Charles McGhee | 19/01/2022 | 9/11/2021 | Provisionally Approve | Approved | 18/02/2022 | University of Auckland | University of Auckland |

| 2021 EXP 11804 | PROTO-KNEE External Validation Study: New Zealand | Dr Michael English | 1/12/2021 | 14/12/2021 | Approved | Approved | 14/12/2021 | Northland District Health Board | Northland District Health Board |
|-----------------|--|----------------------------|------------|------------|--------------------------|----------|------------|---|---|
| 2022 EXP 11206 | Rakeiora Tertiary Care Pathfinder | Professor Cristin Print | 10/05/2022 | 10/03/2022 | Provisionally Approve | Approved | 7/06/2022 | University of Auckland, University of Auckland | University of Auckland, University of Auckland |
| 2021 FULL 11498 | Rapid Avastin Treat and Extend Trial | Dr Vidit Singh | 30/11/2021 | 11/02/2022 | Decline | Declined | 11/02/2022 | MidCentral DHB | MidCentral DHB |
| 2022 EXP 11590 | Real World Data Collection Among Pediatric Neuroblastoma Patients Treated with Lorlatinib Through Expanded Access Program | Dr Andrew Wood | 16/03/2022 | 11/02/2022 | Provisionally Approve | Approved | 4/05/2022 | Starship Hospital / University of Auckland, Starship Hospital, Pfizer Global Clinical R&D Oncology | Starship Hospital / University of Auckland, Starship Hospital, Pfizer Global Clinical R&D Oncology |
| 2021 EXP 11116 | Reboot Kids €" A randomised controlled trial of a behavioural medicine intervention to prevent obesity and metabolic complications in young cancer survivors recently treatment (New Zealand pilot). | Dr Amy Lovell | 30/11/2021 | 11/02/2022 | Decline | Declined | 11/02/2022 | The University of Auckland | The University of Auckland |
| 2022 FULL 12345 | SafePass 3 | Dr Sanjeevan Pasupati | 19/04/2022 | 29/03/2022 | Provisionally Approve | Approved | 3/06/2022 | Waikato District Health Board, Waikato Cardiology Clinical Trials, Emboline, Inc. | Waikato District Health Board, Waikato Cardiology Clinical Trials, Emboline, Inc. |
| 2021 FULL 11095 | Safety and Efficacy of Tideglusib in Congenital Myotonic Dystrophy | Dr Gina O'Grady | 16/09/2021 | 14/10/2021 | Approved | Approved | 14/10/2021 | New Zealand Clinical Research and Starship Hospital (ADHB), New Zealand Clinical Research, AMO Pharma Ltd, Novotech (NZ) Ltd | New Zealand Clinical Research and Starship Hospital (ADHB), New Zealand Clinical Research, AMO Pharma Ltd, Novotech (NZ) Ltd |
| 2021 FULL 11146 | SCFAs and Tregs in neonates | Dr Gergely Toldi | 10/09/2021 | 14/10/2021 | Decline | Declined | 14/10/2021 | University of Auckland, Ethics and Integrity, University of Auckland | University of Auckland, Ethics and Integrity, University of Auckland |
| 2022 FULL 12313 | Shared decision-making for older patients with colorectal cancer considered for surgery | Dr Alison Jackson | 11/05/2022 | 3/06/2022 | Approved | Approved | 3/06/2022 | Waikato DHB | Waikato DHB |
| 2021 FULL 11657 | Short chain fatty acids and Tregs in neonates | Dr Gergely Toldi | 13/12/2021 | 3/12/2021 | Provisionally Approve | Approved | 28/01/2022 | University of Auckland, Ethics and Integrity, University of Auckland | University of Auckland, Ethics and Integrity, University of Auckland |
| 21/CEN/226 | Small Incision Sternoplasty for Pectus Deformity | Dr Fangbo Lin | 9/08/2021 | 25/08/2021 | Approved | Approved | 25/08/2021 | CMDHB, , | CMDHB, , |

| 21/CEN/188 | SP-104-02: A Study of SP-104 Compared to Immediate Release Naltrexone Capsules | Dr. Bridget Maher | 9/07/2021 | 16/08/2021 | Approved | Approved | 16/08/2021 | New Zealand Clinical Research, New Zealand Clinical Research, New Zealand Clinical Research, Inclin | New Zealand Clinical Research, New Zealand Clinical Research, New Zealand Clinical Research, Inclin |
|-----------------|---|--------------------------------------|------------|------------|--------------------------|----------|------------|--|--|
| 2022 FULL 12641 | STRIDE-3- V116 in Pneumococcal Vaccine- naÃ- ve Adults | Dr Jackie Kamerbeek | 13/04/2022 | 5/05/2022 | Approved | Approved | 5/05/2022 | P3 Research, P3 Research, Merck Sharp & Dohme (Australia) Pty Ltd (MSD), Merck Sharp & Dohme (Australia) Pty Ltd, Authorising on behalf of Merck Sharp & Dohme (New Zealand) Limited (MSD) | P3 Research, P3 Research, Merck Sharp & Dohme (Australia) Pty Ltd (MSD), Merck Sharp & Dohme (Australia) Pty Ltd, Authorising on behalf of Merck Sharp & Dohme (New Zealand) Limited (MSD) |
| 2021 EXP 11241 | Supportive care needs in prostate cancer (SUPPRO) | Professor David Baxter | 30/09/2021 | 15/10/2021 | Decline | Declined | 15/10/2021 | University of Otago | University of Otago |
| 2021 FULL 11093 | Tai Kaumatuatanga Survey | Professor Chris Cunningham | 6/09/2021 | 25/11/2021 | Decline | Declined | 25/11/2021 | Family Centre Social Policy Research Unit, Family Centre | Family Centre Social Policy Research Unit, Family Centre |
| 2021 EXP 11853 | Tai Kaumatuatanga: Older MÄ• ori Wellbeing and Participation: Present and Future Focus | Professor Chris Cunningham | 6/12/2021 | 14/12/2021 | Approved | Approved | 14/12/2021 | Family Centre Social Policy Research Unit, Family Centre | Family Centre Social Policy Research Unit, Family Centre |
| 2022 FULL 11080 | tDCS in Spinocerebellar Ataxia type 1 (SCA1) | Mrs Julie Rope | 4/02/2022 | 3/12/2021 | Provisionally Approve | Approved | 24/03/2022 | Auckland University of Technology, Auckland University of Technology | Auckland University of Technology, Auckland University of Technology |
| 2022 EXP 11725 | Te Tauwhiro Turi mĕ te RongoÄ: Knee Care for Arthritis through Pharmacy Study | Associate Professor Ben Darlow | 23/03/2022 | 12/04/2022 | Approved | Approved | 12/04/2022 | University of Otago, University of Otago | University of Otago, University of Otago |
| 21/CEN/237 | Telerehabilitation discrete choice survey | Dr Paul Brown | 21/08/2021 | 14/01/2022 | Approved | Approved | 14/01/2022 | AUT, Auckland University of Technology, | AUT, Auckland University of Technology, |
| 2022 FULL 12778 | Test Application | Baron Matthew Poulsen | 5/05/2022 | 5/05/2022 | Approved | Approved | 5/05/2022 | мон | мон |
| 2021 FULL 11864 | Testing new brain stimulation technique for improving memory and function. | Professor Dirk De Ridder | 30/11/2021 | 11/02/2022 | Approved | Approved | 11/02/2022 | University of Otago, University of Otago | University of Otago, University of Otago |
| 2021 EXP 11089 | The acute effects of dried kiwifruit on sleep onset, metabolites and cognition in men | Mr Alexander Kanon | 27/10/2021 | 24/11/2021 | Approved | Approved | 24/11/2021 | Massey University, School of Health Sciences, College of Health, Massey University, School of Health Sciences, College | Massey University, School of Health Sciences, College of Health, Massey University, School of Health Sciences, College |

| | | | | | | | | of Health, Massey University | of Health, Massey University |
|-----------------|---|--|------------|------------|--------------------------|----------|------------|---|---|
| 21/CEN/175 | The COASTAL study: Zandelisib and Rituxumab versus standard immunotherapy in relapsed Indolent Non-Hodgkins Lymphoma (iNHL) | Dr Wei-Hsun (Blake) Hsu | 1/07/2021 | #REF! | #REF! | Approved | #REF! | CDHB, Canterbury District Health Board, Christchurch Hospital, CDHB, Pharmaceutical Solutions Ltd | CDHB, Canterbury District Health Board, Christchurch Hospital, CDHB, Pharmaceutical Solutions Ltd |
| 2021 EXP 11372 | The DURESS Project - Day Surgery Sleep Survey | Dr Daniel Ramsay | 24/11/2021 | 18/11/2021 | Provisionally Approve | Approved | 30/11/2021 | CCDHB, CCDHB Department of Anaesthesia | CCDHB, CCDHB Department of Anaesthesia |
| 2021 FULL 11018 | The effect of a positive pressure treadmill training in adolescents with cerebral palsy | Dr. Pablo Ortega- Auriol | 13/10/2021 | 10/11/2021 | Decline | Declined | 10/11/2021 | University of Auckland, The University of Auckland | University of Auckland, The University of Auckland |
| 2021 FULL 11871 | The effect of a positive pressure treadmill training in young people with cerebral palsy. | Dr. Pablo Ortega- Auriol | 1/12/2021 | 11/02/2022 | Decline | Declined | 11/02/2022 | University of Auckland, The University of Auckland | University of Auckland, The University of Auckland |
| 2022 EXP 11625 | The Guillain-Barre Syndrome (GBS) phenotype in Aotearoa/New Zealand | Dr Eileen Mc Manus | 22/03/2022 | 30/03/2022 | Approved | Approved | 30/03/2022 | Waikato DHB | Waikato DHB |
| 2022 EXP 11081 | The Impact of Diabetes in Early Adulthood: TIDE Study | Mr Tyler Elliott | 19/05/2022 | 1/06/2022 | Approved | Approved | 1/06/2022 | University of Auckland, The University of Auckland | University of Auckland, The University of Auckland |
| 21/CEN/199 | The Impact of Methamphetamine on Orthopaedic Admissions | Mr Michael Hanlon | 20/07/2021 | 25/08/2021 | Approved | Approved | 25/08/2021 | /, Domain Orthopaedic Surgeons, Auckland City Hospital | /, Domain Orthopaedic Surgeons, Auckland City Hospital |
| 2022 EXP 13099 | The influence of mediating variable on ethnic dPisapgaeri t1ie os ff o1r6 mortality and survival for NZ head & neck cancer patients | Dr Abigail Weaver | 28/06/2022 | 14/07/2022 | Approved | Approved | 14/07/2022 | Hasting's hospital | Hasting's hospital |
| 2021 FULL 11264 | The Lungs4Life PIE Study - Process and Implementation Evaluation | Associate Professor Catherine Byrnes | 17/12/2021 | 6/12/2021 | Provisionally Approve | Approved | 31/01/2022 | The University of Auckland, Middlemore Clinical Trials | The University of Auckland, Middlemore Clinical Trials |
| 21/CEN/244 | The Microbiome in Colorectal Cancer Development | Associate Professor Tim Eglintion | 21/08/2021 | 16/05/2022 | Approved | Approved | 16/05/2022 | University of Otago, University of Otago, University of Otago | University of Otago, University of Otago, University of Otago |
| 2021 EXP 11363 | The predictive value of using radiology for patients with sleep disturbance undergoing surgical management | Dr Oliver Dugena | 10/11/2021 | 9/11/2021 | Provisionally Approve | Approved | 25/11/2021 | Capital Coast District Health Board | Capital Coast District Health Board |

| 2022 EXP 12993 | Transport-related serious injury in New Zealand | Ms Siobhan Isles | 22/06/2022 | 4/07/2022 | Approved | Approved | 4/07/2022 | National Trauma Network | National Trauma Network |
|-----------------|--|--|------------|------------|--------------------------|----------|------------|---|---|
| 21/CEN/203 | TRAS-GB Trial | Dr Swee Tan | 27/07/2021 | 10/09/2021 | Approved | Approved | 10/09/2021 | Gillies McIndoe Research Institute, Gillies McIndoe Research Institute, Gillies McIndoe Research Institute (GMRI), Gillies McIndoe Research Institute (GMRI) | Gillies McIndoe Research Institute, Gillies McIndoe Research Institute, Gillies McIndoe Research Institute (GMRI), Gillies McIndoe Research Institute (GMRI) |
| 2022 EXP 12456 | Trial for the Prevention of Stroke (TIIPS) | Associate Professor Rita Krishnamurthi | 18/05/2022 | 1/06/2022 | Approved | Approved | 1/06/2022 | Auckland University of Technology, Auckland University of Technology | Auckland University of Technology, Auckland University of Technology |
| 2022 EXP 11707 | T-TRAC Study - Time to recover after concussion study | Mrs Rebekah Miller | 3/05/2022 | 11/03/2022 | Provisionally Approve | Approved | 7/06/2022 | University of Otago | University of Otago |
| 2021 FULL 11170 | Umbilical catheterisation assistive device | Dr. Matthew Wallenstein | 12/10/2021 | 10/11/2021 | Approved | Approved | 10/11/2021 | Canterbury District Health Board | Canterbury District Health Board |
| 21/CEN/191 | Understanding the normal biology and the causes of pathogenesis in musculoskeletal and joint tissues | Dr Raewyn Poulsen | 13/07/2021 | 25/08/2021 | Approved | Approved | 25/08/2021 | University of Auckland, The University of Auckland, The University of Auckland, The University of Auckland | University of Auckland, The University of Auckland, The University of Auckland, The University of Auckland |
| 2022 FULL 12726 | Use of home blood pressure monitors for remote optimisation of cardiac medications (Home MED Study) | Dr Tze Vun Liew | 11/05/2022 | 3/06/2022 | Decline | Declined | 3/06/2022 | Waikato DHB, Waikato Medical Research Foundation | Waikato DHB, Waikato Medical Research Foundation |
| 2022 EXP 12872 | Validity testing of head injury prognostic calculators | Dr Harini Ravi | 20/05/2022 | 14/06/2022 | Decline | Declined | 14/06/2022 | Waikato DHB | Waikato DHB |
| 2022 FULL 11877 | Visualising the Immunology of Rheumatic Heart Valves (VIV- Study) | Associate Professor Nikki Moreland | 7/04/2022 | 11/02/2022 | Provisionally Approve | Approved | 30/05/2022 | The University of Auckland | The University of Auckland |
| 2022 FULL 12523 | VLS-01-101: A Study to Assess Two Formulations of VLS-01 (VLS-01-BU and VLS- 01-IV) in Healthy Participants | Dr Christian Schwabe | 12/04/2022 | 5/05/2022 | Approved | Approved | 5/05/2022 | New Zealand Clinical research, New Zealand Clinical Research, Viridia Life Sciences, Inc, Novotech (New Zealand) Limited | New Zealand Clinical research, New Zealand Clinical Research, Viridia Life Sciences, Inc, Novotech (New Zealand) Limited |
| 2022 FULL 11654 | Whaioranga te PÄ• Harakeke €" PaeÄ• rahi intervention for injury prevention and recovery for older Māori | Dr Joanna Hikaka | 25/01/2022 | 3/12/2021 | Provisionally Approve | Approved | 18/03/2022 | The University of Auckland, The University of Auckland | The University of Auckland, The University of Auckland |
| 2022 EXP 11487 | What is the normal anatomy of cervical and thoracic spinal | Dr Mohammad Gharib | 9/03/2022 | 14/12/2021 | Provisionally Approve | Approved | 12/04/2022 | Counties Manukau district health board | Counties Manukau district health board |

| | canal in Māori and Pasifika adult in New Zealand | | | | | | | | |
|-----------------|--|---------------------------|------------|------------|--------------------------|----------|------------|--|--|
| 2022 FULL 11728 | WN42444: A study to evaluate the efficacy and safety of gantenerumab in participants at risk for or at the earliest stages of Alzheimer's disease | Professor Tim Anderson | 9/05/2022 | 11/02/2022 | Provisionally Approve | Approved | 31/05/2022 | University of Otago, New Zealand Brain Research Institute, Roche Products (New Zealand) Ltd. | University of Otago, New Zealand Brain Research Institute, Roche Products (New Zealand) Ltd. |
| 2021 FULL 11370 | WP42873: A Study that Compares a Single Injection of Pertuzumab and Trastuzumab Under the Skin Given Either by a Needle and Syringe or by an Injection Device, in Healthy Male Volunteers | Doctor Chris Wynne | 11/10/2021 | 10/11/2021 | Approved | Approved | 10/11/2021 | New Zealand Clinical Research, New Zealand Clinical Research, Roche Products (New Zealand) Ltd | New Zealand Clinical Research, New Zealand Clinical Research, Roche Products (New Zealand) Ltd |
| 2022 EXP 11964 | Zone IV extensor tendon prospective observational study | Ms Amy Wang | 20/05/2022 | 17/05/2022 | Provisionally Approve | Approved | 31/05/2022 | Counties Manukau Health, Counties Manukau Health Tupu Research Fund | Counties Manukau Health, Counties Manukau Health Tupu Research Fund |