



**Health and
Disability Ethics
Committees**

**Southern Health and Disability
Ethics Committee**

**Annual Report
2024**

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About this report

This report is a summary of the activities of the Southern Health and Disability Ethics Committees (HDEC) for the period of 01 July 2023 – 30 June 2024. 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.

About the committee

The Southern 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 standards](#).

Approvals and registrations

The Southern 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](#).

The Southern HDEC is registered (number IRB00008713) 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

It is with pleasure that I present the annual report of the Southern HDEC for the year ending 30 June 2024.

The committee has been light on numbers for some of the year and we have been lucky to have the support of the other HDECs when it comes to co-opting their members to satisfy quorum requirements and/or lighten the workload on the committee members.

Our committee has a broad range of experience, and we have continued to make real progress with a number of research organisations in respect to compliance with ethical standards and in particular how the NEAC ethical standards apply to their studies. However, there still does remain a broad lack of understanding and/or knowledge of the HDEC website and templates available for researchers to assist with their applications.

I would like to end this by thanking the Secretariat staff who have been a huge help across the board. I want to recognise the significant resourcing constraints the Secretariat have increasingly faced over the last year. I commend them on their work despite the trying circumstances with only being a secretariat of 3 people to support almost 40 members and the volumes that have been laid out in these reports.

Nga mihi nui,

Dominic Fitchett

Chair – Southern 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 at first review	0
No. of applications approved subject to conditions / pending at first review	29
No. of applications deferred (provisionally approved) at first review and subsequently approved	38
No. of applications deferred as at time of report	5
No. of applications that were declined because of no/insufficient consultation with appropriate Māori/whānau/iwi/hāpu	1
No. of applications that were declined because of no/insufficient consultation with appropriate cultural group	0
No. of applications declined (this excludes those with no/insufficient consultation with appropriate Māori/whānau/iwi/hāpu/cultural group.)	6
<i>No. of applications which do not require ethics committee approval (across all four Committees that were deemed out of scope)</i>	<i>773</i>
No. of studies withdrawn by researcher	0
No. of studies terminated by sponsor	0
No. of studies transferred to another EC	0
Total number of applications received by full EC	79

Summary of applications received under expedited / low risk review.

(All outcomes refer to outcome of first review.)

No. of applications approved	10
No. of applications approved subject to conditions / pending at first review	14
No. of applications deferred at first review and subsequently approved	35
No. of applications deferred as at time of report	6
No. of applications declined	9
Total number of applications received under expedited / low risk review	74

Total number of applications received

153

Complaints and overdue application summary

This section outlines complaints about decisions made by the Committee during 2024.

Complaints received

Complaint one

Type of complaint: Wrongful Death & Researcher Responsiveness

Date resolved: 20 March 2024

Complaint received: 31 December 2023

Nature of complaint:

A participant in a device trial had died, and the daughter of the participant attributed the participation to the death and wanted to contact the research team for compensation. The nature of their complaint was around the timeliness and response of the research team to their query. The research team had already advised the HDECs of this death and advised they were investigating it and would provide the findings once they were available.

Actions taken:

The Secretariat followed up with the research team on behalf of the participant to ensure responsiveness was done in a timely manner. The Chair was also advised of the complaint.

Outcome:

The research team responded immediately and said it would be speaking with the family once the post-mortem investigation was complete as it was still under investigation. After follow-up, the post-mortem signaled kidney failure, which could have been attributed to participation, but these were also patients who were unwell. The complainant received the outcome of the post-mortem and sought compensation from the study which was arranged by them.

Overdue review

Average review times take into account 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 31 days for expedited applications. Target timeframe for expedited applications is 15 calendar days ([Standard Operating Procedures for Health and Disability Ethics Committees](#), para 9-102). The reason for this average being higher than the target was due to limited resourcing, Secretariat delays in being able to process the letters following review by the sub-committee, and the busy schedule of the Chair which limits his availability to complete reviews.

Average review time was 31 days for full applications. Target timeframe for full applications is 35 days. ([Standard Operating Procedures for Health and Disability Ethics Committees](#), para 54-59). There were no notable exceptions outside of the target timeframe for the reporting period.

Appendix 1: Details of applications reviewed¹

Applications reviewed by the committee

Review reference	Formal title	Coordinating investigator	Date received	Date of first review	Outcome of first review	Status at time of report	Date of final status decision	Locality	Local sponsor	Global sponsor	Clock days
2023 EXP 13310	Vestibular stimulation to enhance postural control in people with bilateral vestibulopathy	Professor Denise Taylor	3/07/2023	9/07/2023	Approved	Approved	10/07/2023	Private Organisation , Tertiary Education Institution	Auckland University of Technology		5
2023 EXP 15624	A Minimal Intervention to Support Motivation for Pre-Arthroplasty Physical Activity Behaviour	Ms Jessica Calverley	15/08/2023	16/08/2023	Approved	Approved	22/08/2023	Te Whatu Ora locality	Dunedin School of Medicine and Te Whatu Ora Health New Zealand Southern		6
2023 FULL 18186	A Phase 2, Double-Blind, Randomized, Active-Control, Parallel Group Study to Assess the Pharmacokinetics, Pharmacodynamics, Immunogenicity, and Safety of INBRX-101 Compared to Plasma Derived Alpha1-Proteinase Inhibitor (A1PI) Augmentation Therapy in Adults with Alpha-1 Antitrypsin Deficiency (AATD) Emphysema	Dr Michelle Baker	9/08/2023	10/08/2023	Provisionally Approved	Approved	18/08/2023	Private Organisation , Te Whatu Ora locality		Inhibrx, Inc.	32
2023 EXP 15438	Design and validation of the Skin Lesion Awareness Personal Application - a comprehensive, patient-	Dr Anne Collins	24/07/2023	30/07/2023	Declined	Declined	7/08/2023	Te Whatu Ora locality			10

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

	centred skin cancer application										
2023 EXP 16771	Measuring the skin metabolome to determine menopause status	Dr Geraldine McLeod	7/08/2023	11/08/2023	Approved	Approved	18/08/2023	Private Organisation	Director Reserach and Enterprise		10
2023 EXP 15582	Intergenerational Conflict in immigrant Chinese families in New Zealand: A Qualitative Study of Mental Health Service Users	Dr Richard Yu	24/08/2023	25/08/2023	Provisionally Approved	Approved	4/09/2023	Primary Health Care Centre, Te Whatu Ora locality			11
2023 FULL 13454	Māori approaches to communication support: Living well with mate wareware (dementia)	Miss Megan Eustace	2/08/2023	8/08/2023	Provisionally Approved	Approved	17/08/2023	Other, Te Whatu Ora locality, Tertiary Education Institution	University of Canterbury (School of Psychology, Speech and Hearing)		43
2023 FULL 17925	MK-0616-017: A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of MK-0616 in Adults With Heterozygous Familial Hypercholesterolemia	Dr Rosamund Carey	16/08/2023	21/08/2023	Provisionally Approved	Approved	29/08/2023	Private Organisation	Merck Sharp & Dohme (New Zealand) Ltd a subsidiary of Merck & Co., Inc., Rahway, NJ, USA		40
2023 FULL 16764	A soft pressure-sensitive skin to measure lymphoedema treatment efficiency.	Dr Anna Rolleston	17/08/2023	21/08/2023	Provisionally Approved	Approved	31/08/2023	Private Organisation			44
2024 EXP 20214	Community-based screening and health promotion initiative for Type 2 diabetes	Dr Fulton Shannon	29/04/2024	5/05/2024	Approved	Approved	15/05/2024	Other, Private Organisation	Health Research Council of New Zealand		13
2023 EXP 16691	Improving the engagement of patients with low back pain to education and exercise advice to reduce recurrence	Dr Paul Marshall	27/07/2023	28/07/2023	Provisionally Approved	Approved	11/08/2023	Private Organisation	NZ Chiropractic College		14
2024 EXP 19500	Lupus Nephritis outcomes in tertiary referral hospitals in Aotearoa New Zealand; a retrospective case series	Professor Rebecca Grainger	19/04/2024	25/04/2024	Provisionally Approved	Approved	8/05/2024		Te Whatu Ora Capital Coast and Hutt Valley		38
2023 EXP 17867	Improving nutrition delivery in acute and chronic	Professor John Windsor	13/07/2023	24/07/2023	Declined	Declined	31/07/2023	Tertiary Education Institution	The University of Auckland		16

	diseases: A pilot volunteer study										
2023 EXP 19315	Neuronal intranuclear inclusion disease in New Zealand: A novel discovery and potential Polynesian founder effect	Dr Tony Zhang	23/11/2023	13/12/2023	Provisionally Approved	Provisionally Approved		Te Whatu Ora locality	Te Whatu Ora Te Toka Tumai Auckland		16
2023 EXP 18914	Vitamin E for preterm infants - A retrospective cohort study	Dr Barbara Cormack	28/11/2023	14/12/2023	Approved NSC	Approved	18/12/2023		The Liggins Institute		16
2023 EXP 19347	Exhaled breath as a marker of asthma control	Dr Amy Chan	6/12/2023	18/12/2023	Approved NSC	Approved	11/01/2024	Tertiary Education Institution	The University of Auckland		17
2023 EXP 19252	Health Coaching Pilot Study; a single-case experimental study with longitudinal follow-up	Mr Erik van den Top	11/12/2023	15/01/2024	Declined	Declined	18/01/2024	Private Organisation	Southern Cross Health Society		17
2023 EXP 17995	Investigation of hyper-excretion of cefazolin as a potential cause of treatment failure in patients with invasive bacterial infection	Dr Nicholas Douglas	21/12/2023	15/01/2024	Approved NSC	Approved	26/01/2024	Tertiary Education Institution	University of Otago		17
2023 EXP 18267	Understanding Māori and Pacific Perspectives of Anaesthesia Preadmission Clinic	Dr Vikrant Singh	5/10/2023	10/10/2023	Approved NSC	Approved	27/10/2023	Te Whatu Ora locality	Te Whatu Ora Health New Zealand - Te Toka Tumai Auckland		17
2023 EXP 18068	Clinical and histological diversity in hyperkeratotic flexural erythema – beyond granular parakeratosis?	Dr Anna Luo	19/07/2023	24/07/2023	Declined	Declined	7/08/2023				18
2024 EXP 19987	The impact of funding restrictions on the prescribing of Sodium-glucose co-transporter 2 inhibitors (SGLT2i) in adult patients admitted to Middlemore Hospital for heart failure (HF) management	Pre-Specialist Pharmacist - Cardiology Athena Sun	30/04/2024	16/05/2024	Provisionally Approved	Provisionally Approved			Te Whatu Ora Counties Manukau		18
2024 EXP 19247	Transabdominal Cervical Cerclage at Te Toka Tumai Auckland – A	Miss Sarah Latus	19/02/2024	20/02/2024	Provisionally Approved	Approved	21/02/2024		Liggins Institute		19

	Retrospective Observational Study										
2023 EXP 19124	Design and validation of the Skin Lesion Awareness Personal Application (SLAPA) Study – a comprehensive, patient-centred skin cancer mobile application	Dr Anne Collins	17/12/2023	10/01/2024	Approved NSC	Approved	23/01/2024	Te Whatu Ora locality			19
2023 EXP 17955	GLOBE: Effects of a glucoraphanin-containing vegetable soup on the composition and functional activities of blood extracellular vesicles	Dr Farha Ramzan	11/07/2023	17/07/2023	Provisionally Approved	Approved	31/07/2023	Tertiary Education Institution	University of Auckland		43
2024 FULL 19516	A Phase 1 Clinical Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Efficacy of ZN-A-1041 Enteric Capsules as a Single Agent or in Combination in Patients with HER2-Positive Advanced Solid Tumors	Dr. Yeo Jeong (Jane) So	28/02/2024	1/03/2024	Approved NSC	Approved	20/03/2024	Te Whatu Ora locality	PPD, part of Thermo Fisher Scientific	Suzhou Zanrong Pharma Limited	20
2024 FULL 19551	A Randomized, Blinded, Placebo-Controlled Dose-Ranging Phase 1b Study of the Safety, Pharmacokinetics, and Antiviral Activity of ABI-4334 in Subjects with Chronic Hepatitis B Virus Infection.	Professor Edward Gane	27/02/2024	6/03/2024	Approved NSC	Approved	20/03/2024	Private Organisation	PPD, part of Thermo Fisher Scientific; TMF Group	Assembly Biosciences, Inc	20
2023 EXP 18426	International validation of a prospective seizure prediction model in encephalitis from Wellington area	Dr Martin Punter	1/12/2023	15/12/2023	Provisionally Approved	Provisionally Approved					20
2023 EXP 19109	Optimising Nutritional Delivery in Acute and Chronic Diseases using a Smart Feeding Tube: A Pilot Healthy Volunteer Study	Professor John Windsor	31/10/2023	8/11/2023	Approved	Approved	22/11/2023	Tertiary Education Institution	The University of Auckland		20

2024 EXP 19249	The expression of p53 isoform ($\Delta 133p53$) and other potential biomarkers in colitis associated colorectal cancer	Dr Tamara Glyn	22/02/2024	14/03/2024	Approved	Approved	18/03/2024	Te Whatu Ora locality	University of Otago		20
2024 FULL 19569	The need for FASD intervention: Prevalence and Knowledge in Youth Justice	Dr Joanna Chu	23/02/2024	4/03/2024	Declined	Declined	20/03/2024	Other	University of Auckland		20
2023 FULL 19340	A parallel-arm comparison of three noise stimulation waveforms for modulation of tinnitus loudness and intrusiveness.	Professor Dirk De Ridder	30/11/2023	3/12/2023	Approved NSC	Approved	22/12/2023	Tertiary Education Institution	University of Otago		21
2023 FULL 19206	A phase 1, randomized, double-blind, placebo-controlled single ascending dose study to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of subcutaneously administered SGB-9768 in healthy volunteers	Dr Alex Cole	24/11/2023	5/12/2023	Approved NSC	Approved	22/12/2023	Private Organisation	Novotech New Zealand	Suzhou Sanegene Bio Inc.	21
2023 FULL 18861	A Phase 1, Single-Center Study Evaluating the Safety, Tolerability, and Biodistribution of RCT2100 with Single-Ascending Doses in Healthy Participants	Dr. Rohit Katial	24/11/2023	4/12/2023	Approved NSC	Approved	22/12/2023	Private Organisation	Novotech (New Zealand) Limited c/o Novotech (Australia) Pty	ReCode Therapeutics Inc.	21
2023 FULL 18960	A PHASE 1/2A DOSE-ESCALATING STUDY TO EVALUATE THE SAFETY, TOLERABILITY, PHARMACOKINETICS, AND PHARMACODYNAMICS OF ARO-DM1 IN SUBJECTS WITH TYPE 1 MYOTONIC DYSTROPHY WHO ARE ≥ 18 TO ≤ 65 YEARS	Dr Cory Sellwood	24/11/2023	6/12/2023	Approved NSC	Approved	22/12/2023	Private Organisation	Novotech (New Zealand) Limited	Arrowhead Pharmaceuticals Inc.	21
2023 EXP 18305	Hearing Loss Related Quality of Life Implications	Dr Ben Thomson	28/10/2023	8/11/2023	Declined	Declined	22/11/2023	Te Whatu Ora locality			21

	for Head and Neck Cancer Patients Receiving Cisplatin Chemotherapy in Te Tai Tokerau, Aotearoa										
2023 EXP 13401	Perioperative Management of New Antiplatelet Agents in patients presenting for Ophthalmic Surgery: a Retrospective Observational Cohort Study	Dr Phil Guise	4/08/2023	7/08/2023	Provisionally Approved	Approved	25/08/2023		Te Whatu Ora Health New Zealand - Te Toka Tumai Auckland		48
2023 EXP 18609	Retinoblastoma in New Zealand - A comprehensive, nationwide study including epidemiology, diagnosis, management and outcomes for all children with retinoblastoma over the last 20 years.	Dr Cheefoong Chong	17/09/2023	22/09/2023	Approved NSC	Approved	11/10/2023				21
2024 EXP 19756	Taimaha i rukiruki: A kaupapa Māori approach to pēpi loss	Dr. Kendall Stevenson	24/06/2024	9/07/2024	Approved NSC	Approved	18/07/2024	Other, Tertiary Education Institution	Te Herenga Waka, Victoria University of Wellington		21
2024 EXP 19259	The economic burden on parents of children who need glasses	Dr Justin Mora	19/03/2024	25/03/2024	Approved NSC	Approved	11/04/2024	Te Whatu Ora locality			21
2023 FULL 19042	A Phase 2 Study to Evaluate Patient Reported Preference for Subcutaneous Pembrolizumab Coformulated with Hyaluronidase (MK-3475A) Over Intravenous Pembrolizumab Formulation in Participants With Multiple Tumor Types (MK-3475A-F11)	Dr Peter Fong	26/10/2023	7/11/2023	Approved NSC	Approved	24/11/2023	Private Organisation, Te Whatu Ora locality	Merck Sharp & Dohme (New Zealand) Limited, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA	Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA	22
2024 FULL 18552	A Phase 2, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Tolerability of INCB000928 in	Dr. Patrick Yap	25/01/2024	7/02/2024	Approved NSC	Approved	23/02/2024	Te Whatu Ora locality	Syneos Health New Zealand Limited	Incyte Corporation	22

	Participants With FOP (PROGRESS)										
2023 FULL 1866 5	A Phase 3, Multi-centre, Randomized Withdrawal and Long-Term Extension Study of Amprexetine for the Treatment of Symptomatic Neurogenic Orthostatic Hypotension in Participants with Multiple System Atrophy	Prof Tim Anderson	1/11/2023	6/11/2023	Approved NSC	Approved	24/11/2023	Other	Calyx Bioconsulting Limited	Theravance Biopharma Ireland Limited	22
2024 FULL 1792 8	BerriQi for post-respiratory infection recovery in primary school age kids in Motueka, NZ	Dr. Starin Mckeen	22/01/2024	7/02/2024	Declined	Declined	23/02/2024	Other	Anagenix Ltd		22
2023 EXP 18385	Exploring the Acceptability, Feasibility, and Key Learnings from a New Iwiled Antenatal Hub	Ms Ngaire Kereru Sparkes	29/09/2023	9/10/2023	Approved NSC	Approved	27/10/2023	Primary Health Care Centre, Te Whatu Ora locality, Tertiary Education Institution	Dean of the Faculty of Health, Te Herenga Waka - Victoria University of Wellington		22
2024 FULL 1955 6	Impact of Dementia care wareware and solutions for Equity in Aotearoa	Professor Ngaire Kerse	25/01/2024	7/02/2024	Approved NSC	Approved	23/02/2024	Other			22
2024 FULL 1881 1	Improving Medication Safety in Emergency Department Resuscitations	Doctor Andrew Brainard	19/01/2024	6/02/2024	Declined	Declined	23/02/2024	Other	Te Whatu Ora Counties Manukau		22
2024 EXP 19383	Inpatient dermatology reviews in a New Zealand tertiary hospital: insight into resource allocation and service delivery.	Dr Harriet Bell	29/01/2024	9/02/2024	Approved NSC	Approved	21/02/2024		Te Whatu Ora Counties Manukau		22
2024 EXP 18966	Lived experience and meaning of occupational engagement for adults with sexual trauma related post-traumatic stress disorder in Aotearoa - New Zealand.	Mrs Tracey Partridge-Tricker	30/04/2024	16/05/2024	Provisionally Approved	Provisionally Approved		Other			22
2024 FULL 1889 3	Warfarin self testing and use of a patient portal for individuals living with rheumatic heart disease	Dr Miriam Wheeler	21/01/2024	6/02/2024	Declined	Declined	23/02/2024	Te Whatu Ora locality	Te Toka Tumai, Te Whatu Ora		22

	and mechanical valve replacement										
2024 EXP 19458	Testing a Faith-based Smoking Cessation Intervention for Muslims in Ramadan: A Pilot Randomised Controlled Trial.	Mr Abdullah (Dilla) Kalantan	1/02/2024	2/02/2024	Provisionally Approved	Approved	5/02/2024	Other			24
2023 EXP 19034	Demographics and Clinical Characteristics of patients presenting to Middlemore Hospital with Thyroid Emergencies	Doctor Abigail Swager	9/11/2023	13/11/2023	Approved NSC	Approved	4/12/2023				24
2023 FULL 17880	Evaluate the impact of noninvasive ventilation (NIV) with expiratory washout on respiratory rate of patients with acute hypercapnic respiratory failure. A prospective, randomized cross over pilot investigation	Dr William Good	25/07/2023	1/08/2023	Approved NSC	Approved	21/08/2023	Te Whatu Ora locality	Fisher and Paykel Healthcare		24
2023 FULL 18246	Evaluating the utility of the BioFire PCR panel in the diagnosis of joint infection	Dr Shivani Fox-Lewis	26/07/2023	1/08/2023	Approved NSC	Approved	21/08/2023	Te Whatu Ora locality	Research Office, Te Toka Tumai Auckland		24
2023 EXP 18924	GEO-TBI incidence - An international, prospective observational study on traumatic brain injury epidemiology	Professor Giles Critchley	10/11/2023	13/11/2023	Declined	Declined	4/12/2023		University of Otago	University of Cambridge	24
2023 EXP 18171	Long-term follow-up study of investigational gene-editing therapies in participants with or at high risk for cardiovascular disease	Dr. Patrick Gladding	7/09/2023	28/09/2023	Approved	Approved	2/10/2023	Private Organisation	IQVIA RDS Pty Limited	Verve Therapeutics	24
2023 FULL 17975	MK-0616-015: A Phase 3 Randomized, Placebo-Controlled Clinical Study to Evaluate the Efficacy and Safety of MK-0616 in Reducing Major Adverse Cardiovascular Events in	Dr Rosamund Carey	27/07/2023	2/08/2023	Approved NSC	Approved	21/08/2023	Private Organisation, Te Whatu Ora locality	Merck Sharp & Dohme (New Zealand) Limited (MSD)		24

	Participants at High Cardiovascular Risk										
2024 EXP 19363	Validation of days alive out of hospital as an outcome measure after admission to Intensive Care: a retrospective cohort study.	Dr Aislinn Brown	21/02/2024	26/02/2024	Approved	Approved	18/03/2024		Te Whatu Ora Health New Zealand - Te Toka Tumai Auckland		24
2023 FULL 18780	FAST study: Feasibility ASessment of circulating Tumour DNA (ctDNA) in the diagnosis of advanced lung cancer	Dr Annie Wong	20/12/2023	9/01/2024	Provisionally Approved	Approved	10/01/2024	Te Whatu Ora locality	University of Otago		25
2024 EXP 19803	Alcohol Related Liver Disease and Liver Transplantation in New Zealand	Doctor Hannah Giles	19/03/2024	25/03/2024	Provisionally Approved	Provisionally Approved			N/A		25
2023 EXP 18561	Anti-inflammatories and Physiotherapy for people with Knee Osteoarthritis: The AP-KO randomised controlled trial.	Dr Cathy Chapple	26/10/2023	7/11/2023	Approved NSC	Approved	24/11/2023	Primary Health Care Centre, Tertiary Education Institution	University of Otago		25
2023 EXP 18642	Does the pathway to elective surgery for benign general surgical conditions exacerbate health inequity for Māori?	Dr Jesse Fischer	13/09/2023	19/09/2023	Approved NSC	Approved	11/10/2023		University of Auckland		25
2023 EXP 11606	Friedreich Ataxia Global Clinical Consortium UNIFIED Natural History Study	Associate Professor Richard Roxburgh	11/10/2023	18/10/2023	Approved NSC	Approved	6/11/2023	Tertiary Education Institution	University of Auckland	Friedreich's Ataxia Research Alliance (FARA)	25
2023 EXP 13961	Cell-free nucleic acids biomarkers of recurrence in colorectal cancer (CRC)	Dr Tamara Glyn	13/12/2023	18/12/2023	Provisionally Approved	Approved	19/12/2023	Te Whatu Ora locality, Tertiary Education Institution	Director, Research and Enterprise		26
2024 EXP 13966	oVRcome - self guided virtual reality for panic disorder with agoraphobia. A randomised controlled trial.	Associate Professor Cameron Lacey	13/05/2024	16/05/2024	Provisionally Approved	Approved	24/05/2024	Other	University of Otago		26
2024 FULL 19210	Pregabalin for the Treatment of CANVAS Associated Chronic Cough	Associate Professor Richard Roxburgh	10/01/2024	12/01/2024	Provisionally Approved	Approved	15/01/2024	Tertiary Education Institution	The University of Auckland		26

2023 FULL 18550	A Phase 3, Open-Label, Randomized Study of Sonrotoclax (BGB-11417) Plus Zanubrutinib (BGB-3111) Compared With Venetoclax Plus Obinutuzumab in Patients With Previously Untreated Chronic Lymphocytic Leukemia	Doctor Robert Weinkove	31/08/2023	7/09/2023	Approved NSC	Approved	26/09/2023	Te Whatu Ora locality	BeiGene		26
2023 FULL 18408	A PHASE III, RANDOMIZED, OPEN-LABEL STUDY EVALUATING EFFICACY AND SAFETY OF GIREDESTRANT COMPARED WITH FULVESTRANT, BOTH COMBINED WITH A CDK4/6 INHIBITOR, IN PATIENTS WITH ESTROGEN RECEPTOR-POSITIVE, HER2-NEGATIVE ADVANCED BREAST CANCER WITH RESISTANCE TO PRIOR ADJUVANT ENDOCRINE THERAPY	Dr Richard Isaacs	31/08/2023	6/09/2023	Approved NSC	Approved	26/09/2023	Te Whatu Ora locality		Roche Products (New Zealand) Limited	26
2023 FULL 18681	Abortion is a Human Right and Health Issue: Disabled People's Experiences of Abortion Services in Aotearoa New Zealand	Associate Professor Brigit Mirfin-Veitch	29/08/2023	7/09/2023	Approved NSC	Approved	26/09/2023	Other, Private Organisation			26
2023 FULL 15571	Clinical Evaluation of Safety and Effectiveness for Acuity 200™ (fluoroxxyfocon A) Orthokeratology Contact Lens for Overnight Wear	Dr. Jagrut Lallu	26/08/2023	5/09/2023	Declined	Declined	26/09/2023	Private Organisation		Acuity Polymers, Inc.	26
2023 FULL 15478	Ultra-Early, minimally inVasive intraCerebral haemorrhage evaCUAtion versus standard trEatment (EVACUATE)	Dr. Martin Punter	30/08/2023	7/09/2023	Approved NSC	Approved	26/09/2023	Te Whatu Ora locality		The University of Melbourne	26
2024 EXP 18826	Asia Pacific Lupus Collaboration - The SLE	Dr Kristine (Pek Ling) Ng	18/01/2024	19/01/2024	Provisionally Approved	Approved	24/01/2024	Te Whatu Ora locality	Te Whatu Ora Waitemata		27

	Outcomes Study -SOS: Determinants of Long Term Outcomes in Systemic Lupus Erythematosus										
2023 EXP 15077	He Oranga mō te Whānau: Improving outcomes for people with hip and/or knee osteoarthritis and co-morbidities	Associate Professor Kirsten Coppell	31/10/2023	2/11/2023	Provisionally Approved	Approved	2/11/2023	Primary Health Care Centre, Private Organisation	University of Otago		27
2023 EXP 15305	The effects of hyperthyroidism and hypothyroidism on the eye	Dr Stuti Misra	2/11/2023	8/11/2023	Declined	Declined	1/12/2023	Other, Te Whatu Ora locality, Tertiary Education Institution	The University of Auckland		27
2024 FULL 19519	A Pilot Phase 2A Study to Examine the Preliminary Efficacy, Safety and PK of TAVO101 in Patients with Severe Atopic Dermatitis (AD)	Dr Penelope Montgomery	29/02/2024	1/03/2024	Provisionally Approved	Approved	8/03/2024	Private Organisation	Pharmaceutical Solutions Ltd	Tavotek Lab Inc	28
2024 FULL 19068	AttaCH: A Phase 2, Multicenter, Long-Term, Open Label Extension Trial Evaluating Safety, Tolerability, and Efficacy of Subcutaneous Doses of TransCon CNP Administered Once Weekly in Children and Adolescents with Achondroplasia	Prof Paul Hofman	25/01/2024	25/01/2024	Provisionally Approved	Approved	2/02/2024	Private Organisation, Tertiary Education Institution	Pharmaceutical Solutions Ltd	Ascendis Pharma	28
2024 EXP 19197	Auditory Perception of the Foetus	Professor Vincent Reid	27/03/2024	2/04/2024	Provisionally Approved	Approved	8/04/2024	Te Whatu Ora locality	University of Waikato - Te Whare Wananga o Waikato		28
2024 FULL 18956	Clinical Evaluation of Safety and Effectiveness for Acuity 200™ (fluoroxfocon A) Orthokeratology Contact Lens for Overnight Wear	Dr. Jagrut Lallu	11/01/2024	16/01/2024	Provisionally Approved	Approved	19/01/2024	Private Organisation	Visique Rose Optometrists	Acuity Polymers, Inc.	28
2024 EXP 19080	Ngāi Tai ki Tāmaki Hauora Strategy Development -	Dr Byron Rangiwai	8/03/2024	9/03/2024	Provisionally Approved	Approved	18/03/2024	Other			28

	Ngā Kanohi Kitea Development Grant										
2024 EXP 19081	Ngāi Tai ki Tāmaki Health Research Project - Ngā Kanohi Kitea Project Grant	Dr Byron Rangiwai	4/03/2024	5/03/2024	Provisionally Approved	Approved	6/03/2024	Other			28
2024 FULL 18545	WHY ARE NEUTROPHILS UNABLE TO KILL BACTERIA IN THE AIRWAYS OF CHILDREN WITH CYSTIC FIBROSIS?	Dr Nina Dickerhof	22/03/2024	22/03/2024	Provisionally Approved	Approved	28/03/2024	Te Whatu Ora locality	Research and Enterprise, University of Otago		28
2023 FULL 18622	A pivotal in vivo bioequivalence study comparing betamethasone ointment (Nova Chem, Australia) to Diprosone® ointment (Organon, Australia), using the ED50 for Diprosone® ointment calculated from the pilot dose duration-response study and using 90 responders with the expectation to have 40-60 participants who meet the responder and detector criteria ("evaluable").	Dr Noelyn Hung	26/10/2023	6/11/2023	Approved NSC	Approved	24/11/2023	Private Organisation	Zenith Technology Corporation Limited	Nova Chem Australasia Pty Ltd	28
2023 FULL 18624	A pivotal in vivo bioequivalence study comparing betamethasone OV ointment (Nova Chem, Australia) to Diprosone® OV ointment (Organon, Australia), using the ED50 for Diprosone® OV ointment calculated from the pilot dose duration-response study and using 90 responders with the expectation to have 40-60 subjects who meet the responder and detector criteria ("evaluable").	Dr Noelyn Hung	26/10/2023	6/11/2023	Approved NSC	Approved	24/11/2023	Private Organisation	Zenith Technology Corporation Limited	Nova Chem Australasia Pty Ltd	28
2024 FULL 19816	An Open-label, Randomized Phase 3 Study of MK-2870 as a Single Agent and in	Dr. Soizick Mesnage	30/04/2024	6/05/2024	Provisionally Approved	Provisionally Approved		Te Whatu Ora locality	Merck Sharp & Dohme (New Zealand) Limited (MSD),	Merck & Co. Inc.	28

	Combination with Pembrolizumab Versus Treatment of Physician's Choice in Participants with HR+/HER2- Unresectable Locally Advanced or Metastatic Breast Cancer								a subsidiary of Merck & Co., Inc., Rahway, NJ, USA		
2023 FULL 1888 7	Effect of Mild Cognitive Impairment and Alzheimer's Disease on oculomotor response, perception, and cognition	Professor Steven Dakin	26/10/2023	7/11/2023	Approved NSC	Approved	24/11/2023	Other, Tertiary Education Institution	The University of Auckland		28
2024 FULL 1983 7	A Phase 3, Randomized, Double-blind, Multicentre Study of MK-1084 in combination With Pembrolizumab Compared With Pembrolizumab Plus Placebo as First-line Treatment of Participants With KRAS G12C-Mutant, Metastatic NSCLC With PD-L1 TPS ≥50%	Dr Daisy Wing-San Mak	24/04/2024	8/05/2024	Approved NSC	Approved	31/05/2024	Te Whatu Ora locality	Merck Sharp & Dohme (New Zealand) Limited (MSD)	Merck & Co., Inc	29
2024 FULL 2008 6	A phase 3b, randomized, open label, multi-country, multi-center, extension and crossover vaccination study to evaluate the immunogenicity and safety of different revaccination schedules and persistence of a single dose of the RSVPreF3 OA vaccine in adults aged 60 years and above who participated in the RSV OA=ADJ-006 study	Dr Mathanki Vivekananda	24/04/2024	7/05/2024	Approved NSC	Approved	31/05/2024	Private Organisation , Te Whatu Ora locality		GSK	29
2024 FULL 1964 6	BIOTRONIK – Safety and Clinical Performance of the Drug Eluting Resorbable Coronary MAGnesium Scaffold System (Freesolve®) in the Treatment of Subjects with de Novo Lesions in Native Coronary Arteries:	Dr Jithendra Somaratne	26/04/2024	6/05/2024	Provisionally Approved	Provisionally Approved		Te Whatu Ora locality		BIOTRONIK Australia Pty Ltd	29

2024 FULL 1939 4	GEO-TBI incidence - An international, prospective observational study on traumatic brain injury epidemiology	Professor Giles Critchley	22/03/2024	4/04/2024	Declined	Declined	26/04/2024	Te Whatu Ora locality	University of Otago	University of Cambridge	29
2024 FULL 2002 8	Improving Medication Safety in Emergency Department Resuscitations	Doctor Andrew Brainard	20/03/2024	28/03/2024	Approved NSC	Approved	26/04/2024	Other	Te Whatu Ora Counties Manukau		29
2024 FULL 1959 4	MK-0616-019: A Phase 3, Open-label Extension Study to Evaluate the Safety and Efficacy of MK-0616 in Adults With Hypercholesterolemia	Dr Michael (Mike) Williams	20/03/2024	3/04/2024	Approved NSC	Approved	26/04/2024	Private Organisation	Merck Sharp & Dohme (New Zealand) Ltd a subsidiary of Merck & Co., Inc., Rahway, NJ, USA		29
2024 FULL 1980 5	MK-5684-01A Substudy: A Phase 1/2 Umbrella Substudy of MK-5684-U01 Master Protocol to Evaluate the Safety and Efficacy of MK-5684-based Treatment Combinations or MK-5684 Alone in Participants With Metastatic Castration-resistant Prostate Cancer (mCRPC)	Dr Peter Fong	25/03/2024	5/04/2024	Approved NSC	Approved	26/04/2024	Te Whatu Ora locality	Merck Sharp & Dohme (Australia) Pty Ltd (MSD), Authorising on behalf of Merck Sharp & Dohme (New Zealand) Limited (MSD)	Merck Sharp & Dohme (Australia) Pty Ltd (MSD)	29
2024 FULL 1926 0	R-MINI-CHOP versus R-MINI-CHP in combination with polatuzumab-vedotin, as primary treatment for patients with diffuse large B-cell lymphoma, ≥ 80 years, or frail ≥ 75 years - an open label randomized Nordic Lymphoma Group phase III trial	Doctor Henry Ngu	26/04/2024	8/05/2024	Provisionally Approved	Provisionally Approved		Te Whatu Ora locality		Australasian Leukaemia and Lymphoma Group	29
2024 FULL 2032 4	Uplifting the mana of Pacific young people	Ms Rupi Riley	1/05/2024	7/05/2024	Provisionally Approved	Provisionally Approved		Other			29
2024 FULL 1951 3	A Prospective, Multicenter, Randomized, Masked, Controlled Study to Evaluate the Safety, Efficacy, and Dose-response of the	Dr. Dean Corbett	19/04/2024	22/04/2024	Provisionally Approved	Approved	29/04/2024	Private Organisation		SpyGlass Pharma, Inc.	30

	Bimatoprost Implant System Used in Combination With the SpyGlass IOL Compared to Timolol Maleate Ophthalmic Solution, USP, 0.5%										
2024 FULL 19064	A Randomized, Double-blind, Placebo-controlled, Phase 2/3 Study to Assess the Efficacy, Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of Obeticholic Acid Compared to Placebo in Pediatric Subjects with Biliary Atresia, Post-hepatoporoenterostomy	Dr Helen Evans	20/02/2024	21/02/2024	Provisionally Approved	Approved	1/03/2024	Te Whatu Ora locality	Syneos Health New Zealand Limited	Intercept Pharmaceuticals Inc.	30
2024 FULL 19228	A Randomized, Double-Blind, Placebo-Controlled, Phase 2 Dose-Ranging Study to Evaluate the Efficacy and Safety of TAK-101 for the Prevention of Gluten-Specific T Cell Activation in Subjects with Celiac Disease on a Gluten-Free Diet.	Dr. Nah Yeon Baik	4/05/2024	6/05/2024	Provisionally Approved	Approved	15/05/2024	Primary Health Care Centre, Private Organisation, Te Whatu Ora locality	IQVIA RDS Pty Limited	Takeda Development Center Americas, Inc.	31
2023 FULL 18646	A randomised, double blind placebo-controlled trial evaluating the medical food synbiotic SBD121, versus placebo for the clinical dietary management of early Rheumatoid Arthritis	Dr. Penelope Jane Montgomery	5/10/2023	5/10/2023	Provisionally Approved	Approved	11/10/2023	Primary Health Care Centre, Private Organisation	Research Associates Limited	Solarea Bio	32
2024 FULL 19211	Assessing the effects of LSD microdosing in menstruating persons with and without Premenstrual Syndrome/Premenstrual Dysphoric Disorder	Associate Professor Suresh Muthukumaraswamy	7/02/2024	9/02/2024	Provisionally Approved	Approved	20/02/2024	Tertiary Education Institution	The University of Auckland		32
2023 EXP 16747	Co-designing whānau stories to reduce opioid use for chronic pain in Aotearoa	Dr Hemakumar Devan	11/12/2023	18/12/2023	Provisionally Approved	Approved	19/12/2023	Primary Health Care Centre, Te Whatu Ora	University of Otago		32

								locality, Tertiary Education Institution			
2023 EXP 11084	Preserving brain health after surgery: does light general anaesthesia reduce postoperative delirium and cognitive decline compared with deep general anaesthesia in older adults? The Balanced-2 randomised controlled trial	Dr Carolyn Deng	21/10/2023	24/10/2023	Provisionally Approved	Approved	6/11/2023	Te Whatu Ora locality	Te Whatu Ora Te Toka Tumai Auckland		32
2024 EXP 18813	The effect of head-mounted AR/VR goggles on time-series features collected from wearable data of normal gait.	Professor Mark Billingham	8/02/2024	9/02/2024	Provisionally Approved	Approved	20/02/2024	Other, Tertiary Education Institution	University of Auckland	Meta Inc.	32
2023 EXP 18277	A Kaupapa Māori Response to Covid	Miss Beverly Te Huia	29/10/2023	30/10/2023	Provisional Approval	Approved	10/11/2023	Other			33
2024 EXP 19184	Digital Twins for the management of chronic metabolic disease	Prof Merryn Tawhai	10/05/2024	16/05/2024	Provisionally Approved	Approved	24/05/2024	Tertiary Education Institution	University of Auckland		33
2023 FULL 18502	High flow nasal oxygen therapy versus conventional oxygen therapy in patients undergoing bronchoscopy and the effect on oxygenation: a randomised controlled trial	Dr Georgia Burton	7/12/2023	14/12/2023	Provisionally Approved	Approved	20/12/2023	Te Whatu Ora locality	Te Whatu Ora Waitaha Canterbury		33
2023 EXP 16657	Māori and Pacific Womens Views of Endometrial Cancer Microbiome Research	Mrs. Roimata Tipene	17/11/2023	20/11/2023	Provisionally Approved	Approved	4/12/2023	Te Whatu Ora locality	Te Whatu Ora, Waitemata		33
2024 FULL 20643	A Phase 3, Multicenter, Randomised, Double-blind, Placebo-controlled Study Comparing the Efficacy and Safety of Golcadomide Plus R-CHOP Chemotherapy vs Placebo Plus R-CHOP Chemotherapy in	Dr Henry Ngu	20/06/2024	4/07/2024	Approved NSC	Approved	31/07/2024	Te Whatu Ora locality	Bristol Myers Squibb	Bristol Myers Squibb	33

	Participants with Previously Untreated High-risk Large B-cell Lymphoma										
2024 FULL 20423	AN OPEN-LABEL, PHASE I/II STUDY TO EVALUATE THE SAFETY, PHARMACOKINETICS AND PRELIMINARY ANTI-TUMOR ACTIVITY OF ENGLUMAFUSP ALFA (RO7227166, A CD19 TARGETED 4-1BB LIGAND) IN COMBINATION WITH OBINUTUZUMAB AND IN COMBINATION WITH GLOFITAMAB FOLLOWING A PRE-TREATMENT DOSE OF OBINUTUZUMAB ADMINISTERED IN PARTICIPANTS WITH RELAPSED/REFRACTORY B-CELL NON-HODGKIN'S LYMPHOMA	Dr Leanne Berkahn	25/06/2024	2/07/2024	Approved NSC	Approved	31/07/2024	Te Whatu Ora locality		Roche Products (New Zealand) Limited	33
2024 FULL 20707	Assessing the feasibility of a new model of care in pharmacy for the self-management of asthma	Mrs Neera Rajballi-Naidoo	23/06/2024	1/07/2024	Provisionally Approved	Provisionally Approved		Private Organisation			33
2024 FULL 20712	Does Paracetamol decrease reperfusion injury to patients presenting with acute ST-elevation myocardial infarction when given prior to primary percutaneous intervention.	Dr Adrian Owen	24/06/2024	1/07/2024	Approved NSC	Approved	31/07/2024	Te Whatu Ora locality	Te Whatu Ora Waikato		33
2024 EXP 20607	ECMM Candida IV study: Antifungal tolerance, resistance, and clinical outcomes on candidemia caused by non-albicans Candida	Dr Arthur Morris	10/06/2024	17/06/2024	Approved	Approved	18/07/2024		Te Whatu Ora, Te Toka Tumai Auckland	Medical University of Graz	33
2023 EXP 18735	Investigating the immune cell landscape in coronary artery disease	Dr Kirsty Danielson	7/09/2023	19/09/2023	Approved NSC	Approved	11/10/2023	Te Whatu Ora locality, Tertiary	University of Otago		33

								Education Institution			
2023 FULL 13824	Use of home blood pressure monitors for remote optimisation of cardiac medications (Home MED Study)	Dr Tze Vun Liew	1/08/2023	1/08/2023	Provisionally Approved	Approved	4/09/2023	Te Whatu Ora locality			64
2023 FULL 19076	A Phase 1, randomized, double-blind, placebo-controlled, single and multiple ascending dose study to determine the safety, tolerability, immunogenicity and pharmacokinetic properties of LASN01 in healthy subjects and in patients with pulmonary fibrosis or thyroid eye disease	Dr Jeremy Krebs	19/12/2023	19/12/2023	Provisionally Approved	Approved	11/01/2024	Te Whatu Ora locality	Novotech (New Zealand) Limited	Lassen Therapeutics 1	34
2023 EXP 15326	Risk estimation for aspiration pneumonia from known physiological risk factors.	Miss Laura Strevens	27/09/2023	6/10/2023	Provisionally Approved	Approved	16/10/2023	Primary Health Care Centre, Private Organisation, Te Whatu Ora locality	UC Rose Centre for Stroke Recovery and Research		34
2024 EXP 19373	Combined interscalene and anterior suprascapular nerve block for shoulder surgery. A survey study	Dr Tin Lun Chiu	1/02/2024	9/02/2024	Approved	Approved	20/02/2024	Te Whatu Ora locality	Te Whatu Ora Health New Zealand - Te Toka Tumai Auckland		35
2024 EXP 19143	Effect of manual therapy on selected biomechanical outcomes of gait in people with knee osteoarthritis	Mr Sarfaraz Alam	2/04/2024	2/04/2024	Provisionally Approved	Approved	11/04/2024	Tertiary Education Institution	University of Otago		35
2024 EXP 18943	Improving communication access in stroke care	Associate Professor Clare McCann	21/02/2024	21/02/2024	Provisionally Approved	Approved	5/03/2024	Te Whatu Ora locality	University of Auckland		35
2024 FULL 20065	The need for FASD intervention: Prevalence and Knowledge in Youth Justice	Dr Joanna Chu	2/05/2024	8/05/2024	Provisionally Approved	Approved	9/05/2024	Other	University of Auckland		35
2023 EXP 18102	Provision of Rural Palliative Care in the Waikato Region	Doctor Rowan Beaumont Bell	11/10/2023	12/10/2023	Provisionally Approved	Approved	27/10/2023	Other	Hospice Waikato		36

	of New Zealand: Perceptions of caregivers										
2024 FULL 18620	The Chronic kidney disease Adaptive Platform Trial Investigating Various Agents for Therapeutic Effect.	Assoc Prof Janak de Zoysa	29/05/2024	31/05/2024	Provisionally Approved	Approved	17/06/2024	Te Whatu Ora locality	Te Whatu Ora Waitemata	The George Institute for Global Health	36
2024 EXP 19723	An Aoteara-New Zealand multi-centre study of acute pancreatitis management and outcomes	Dr Nejo Joseph	27/04/2024	1/05/2024	Provisionally Approved	Approved	15/05/2024	Te Whatu Ora locality	The University of Auckland		37
2023 EXP 18706	Comparing community antibiotic prescribing to dispensing:	Dr Max Bloomfield	16/11/2023	16/11/2023	Provisionally Approved	Approved	4/12/2023		Te Whatu Ora Capital, Coast & Hutt Valley		37
2024 FULL 19945	Effects of Liraglutide on Body Surface Gastric Mapping	Dr Charlotte Daker	14/06/2024	17/06/2024	Provisionally Approved	Approved	24/06/2024	Private Organisation	Alimetry Limited		37
2024 FULL 19344	He Rapunga Hauora mō te Mate Wareware: A Prevalence Study	Dr Makarena Dudley	4/01/2024	16/01/2024	Provisionally Approved	Approved	25/01/2024	Other	The University of Auckland		37
2023 EXP 18656	Histological diversity in hyperkeratotic flexural erythema	Dr Anna Luo	21/09/2023	22/09/2023	Provisionally Approved	Approved	11/10/2023				37
2024 EXP 15186	New Zealand Breast Device Registry - Te Rehita Taputapu Uma o Aotearoa	Associate Professor Michelle Locke	24/06/2024	1/07/2024	Provisionally Approved	Approved	18/07/2024	Private Organisation , Te Whatu Ora locality	University of Auckland Department of Surgery		37
2024 EXP 18664	The effect of a bitter hop-based appetite suppressant on weight loss and appetite in a cohort of obese males and females.	Dr Edward Walker	10/04/2024	14/04/2024	Provisionally Approved	Approved	26/04/2024	Other	The New Zealand Institute for Plant and Food Research		37
2024 EXP 19597	The effects of hyperthyroidism and hypothyroidism on the eye	Associate Professor Stuti Misra	24/05/2024	30/05/2024	Provisionally Approved	Approved	11/06/2024	Other, Te Whatu Ora locality, Tertiary Education Institution	The University of Auckland		37
2023 FULL 17941	A Phase 3 Program to Evaluate the Safety and Efficacy of Upadacitinib in Subjects with Moderately to	Dr Mark Sapsford	28/07/2023	27/08/2023	Declined	Declined	4/09/2023	Te Whatu Ora locality	Abbvie	Abbvie	37

	Severely Active Systemic Lupus Erythematosus.										
2023 FULL 1394 4	Effectiveness of intensive, app-based swallowing skill rehabilitation vs. usual dysphagia management for post-stroke dysphagia in hospital and community settings: A Randomized Controlled Trial.	PhD student Ruth FLYNN	4/09/2023	11/09/2023	Provisionally Approved	Approved	13/10/2023	Primary Health Care Centre, Te Whatu Ora locality	The University of Canterbury Rose Centre for Stroke Recovery and Research		61
2023 EXP 19166	Early dysphagia rehab in Critical Care: the effect of Expiratory Muscle Strength Training on swallowing, voice and cough outcomes	Associate Professor Anna Miles	5/12/2023	12/12/2023	Provisionally Approved	Approved	18/12/2023	Te Whatu Ora locality	The University of Auckland		38
2023 EXP 18578	Marginalism, racism, and tokenism: The experiences of Māori Dietitians	Ms Hannah Rapata	1/11/2023	2/11/2023	Provisionally Approved	Approved	7/11/2023	Private Organisation	Health Research Council New Zealand		38
2023 FULL 1664 9	A randomised, open-label study to compare the bioavailability of 1 x 6.3 mg rosuvastatin orally disintegrating tablet (ODT) taken sublingually (Aspen) versus 1 x 10 mg Crestor® oral tablet (Menarini, Australia) in healthy participants under fasting conditions.	Dr Noelyn Hung	27/09/2023	6/10/2023	Provisionally Approved	Approved	6/11/2023	Private Organisation	Zenith Technology Corporation Limited	Aspen Pharmacare Australia Pty Ltd	66
2024 EXP 20224	Effects of Glucagon-like peptide-1 receptor agonist on residual gastric volume on gastric ultrasound after standard fasting: A prospective, observational study.	Dr Chooi Ling Wong	7/06/2024	13/06/2024	Provisionally Approved	Provisionally Approved		Te Whatu Ora locality	Te Whatu Ora Health New Zealand - Te Toka Tumai Auckland		38
2024 FULL 1881 5	A Phase III Randomised, Parallel-Group, Double-Blind, Placebo-Controlled, Two-Arm Study to Evaluate the Efficacy and Safety of Elafibranor 80 mg on Long-Term Clinical Outcomes in Adult Participants with	Dr Jeffrey Ngu	22/03/2024	27/03/2024	Provisionally Approved	Approved	10/04/2024	Te Whatu Ora locality	ICON Clinical Research (New Zealand) Ltd	Ipsen Bioscience, Inc	39

	Primary Biliary Cholangitis (PBC).										
2024 EXP 19836	Community-based screening and health promotion initiative for Type 2 diabetes	Dr Fulton Shannon	28/03/2024	2/04/2024	Provisionally Approved	Declined	15/04/2024	Other, Private Organisation	Health Research Council of New Zealand		39
2024 EXP 18822	Gender Minority Communities and Forensic Science: The use of CRISPR technology for the detection of forensically relevant body fluids	Dr Rachel Fleming	23/04/2024	24/04/2024	Provisionally Approved	Approved	15/05/2024	Other	Institute of Environmental Science and Research Ltd		39
2024 FULL 20023	Tandem Freedom Feasibility Trial #1	A/Prof Martin de Bock	3/05/2024	7/05/2024	Provisionally Approved	Approved	15/05/2024	Te Whatu Ora locality, Tertiary Education Institution	University of Otago	Tandem Diabetes Care, Inc.	39
2024 FULL 17987	The effect of cannabidiol (CBD) on recovery from contusion injury in healthy males	Dr Matthew Barnes	12/06/2024	17/06/2024	Provisionally Approved	Approved	24/06/2024	Tertiary Education Institution	Massey University		39
2024 EXP 18763	An Investigation into the Frequency Spectrum of the Lung	Mrs. Sarla Kumari	9/01/2024	9/01/2024	Provisionally Approved	Declined	23/01/2024	Tertiary Education Institution	AUT		40
2024 FULL 18728	CardioVascular Disease Risk Assessment by Pharmacy in secondary care for high-risk ethnicities (CVD RAP)	Cardiology Pharmacist Team Leader Kaihautu Ope Ro Ev Tolerton	22/05/2024	28/05/2024	Provisionally Approved	Approved	11/06/2024	Te Whatu Ora locality	Te Whatu Ora		40
2024 FULL 19041	A Pilot study of the Drug-Eluting Coronary Spur StEnt System as a Primary trEatment for In-stent Restenosis of the CORONARY Arteries (DEEPER CORONARY).	Dr Scott Harding	23/01/2024	24/01/2024	Provisionally Approved	Approved	16/02/2024	Te Whatu Ora locality	Reflow Medical, Inc	Reflow Medical, Inc	41
2023 FULL 11224	Advanced MRI for Characterisation of Hemodynamic Changes in Brain Associated with Early Stages of Dementia	Dr Soroush Safaei	29/09/2023	5/10/2023	Provisionally Approved	Approved	16/10/2023	Te Whatu Ora locality	University of Auckland		41
2023 FULL 18467	A randomized, parallel-group, double-blind, placebo controlled,	Doctor Nigel Gilchrist	25/10/2023	25/10/2023	Provisionally Approved	Approved	10/11/2023	Private Organisation		Novartis Pharmaceutical	42

	multicenter Phase III trial to investigate the efficacy and safety of secukinumab 300 mg and 150 mg administered subcutaneously versus placebo, in combination with a glucocorticoid taper regimen, inpatients with giant cell arteritis (GCA) (GCAptAIN)									s Australia Pty Limited	
2024 FULL 19431	Colorectal Anastomosis and Bacterial Eradication (CABE) Trial: The effect of pre-operative antibiotics on the colonic microbiome in Colorectal Surgery	Dr John Woodfield	18/06/2024	4/07/2024	Provisionally Approved	Approved	12/07/2024	Te Whatu Ora locality, Tertiary Education Institution	Research and enterprise University of otago		42
2024 EXP 18955	The role of Patient and Healthcare Service Factors in Re-presentations and Readmissions Following Colorectal Cancer Resection in Northland, Aotearoa New Zealand: a qualitative analysis	Dr Scott McLaughlin	1/02/2024	5/02/2024	Provisionally Approved	Approved	20/02/2024	Te Whatu Ora locality	Whangarei Hospital, Te Whatu Ora - Te Tai Tokerau		44
2023 FULL 14037	A randomised multi-arm trial evaluating the role of antibiotic therapy or immunoglobulin to prevent infection in patients with acquired hypogammaglobulinemia secondary to haematological malignancies.	Dr Robert Weinkove	7/11/2023	9/11/2023	Provisionally Approved	Approved	8/01/2024	Te Whatu Ora locality		Monash University	68
2023 FULL 18565	A Phase 3 Multicenter Study to Evaluate Efficacy, Safety, and Pharmacokinetics of Upadacitinib with Open-Label Induction, Randomized, Double-Blind Maintenance and Open-Label Long- Term Extension in Paediatric Subjects with Moderately to Severely Active Ulcerative	Prof. Andrew Day	3/11/2023	9/11/2023	Provisionally Approved	Approved	23/11/2023	Te Whatu Ora locality	AbbVie Ltd	AbbVie Ltd	46

	Colitis and Inadequate Response, Intolerance, or Medical Contraindications to Corticosteroids, Immunosuppressants, and/or Biologic Therapy.										
2024 FULL 13734	The Tairāwhiti pilot study: a whole-body imaging-based pediatric study	Ms Leigh Potter	11/03/2024	2/04/2024	Provisionally Approved	Approved	5/04/2024	Private Organisation			46
2023 FULL 18325	A Multicenter, Double-Masked, Randomized, Vehicle-Controlled 12-Month (with a 12-month, Double-Masked Extension) Parallel Comparison of the Safety and Efficacy of 0.1% and 0.2% CBT-001 versus Vehicle, Dosed Twice-Daily, in Patients with Pterygium	Dr John Rawstron	19/09/2023	22/09/2023	Provisionally Approved	Approved	20/10/2023	Private Organisation, Te Whatu Ora locality	IQVIA RDS Pty Limited	Cloudbreak Therapeutics, LLC	53
2024 FULL 20075	BerriQi for post-respiratory infection recovery in primary school age kids in Motueka, NZ	Dr Starin Mckeen	21/06/2024	1/07/2024	Provisionally Approved	Approved	18/07/2024	Other	Anagenix Ltd		54
2023 FULL 13080	CIRCA NZ: Investigation and Research of Patients with Immune Dysfunction	Dr Ignatius Chau	16/11/2023	27/11/2023	Provisionally Approved	Approved	18/12/2023	Primary Health Care Centre, Tertiary Education Institution			55
2023 EXP 18988	The effect of differing modes of hot-water immersion on 24-h ambulatory blood pressure in patients with hypertension	Dr Brendon Roxburgh	21/11/2023	21/11/2023	Provisionally Approved	Approved	8/12/2023	Te Whatu Ora locality, Tertiary Education Institution	University of Otago		55
2023 FULL 15182	Investigating dual-task gait performance using Plantiga insole sensor technology in the management of concussion	Dr Nusratnaaz Shaikh	10/09/2023	19/09/2023	Provisionally Approved	Approved	13/10/2023	Private Organisation	Auckland University of Technology		56
2024 FULL 18383	Transcatheter Tricuspid Repair Utilizing the Versa Vascular Repair System in New Zealand	Professor Mark Webster	19/06/2024	21/06/2024	Provisionally Approved	Approved	22/07/2024	Te Whatu Ora locality	Occam Labs, Limited	Versa Vascular, Inc.	60

2024 FULL 1966 2	Get A Grip: Spinal stimulation for upper limb and respiratory function in tetraplegia	Mrs Julie Rope	12/06/2024	26/06/2024	Provisionally Approved	Approved	29/07/2024	Private Organisation	The Catwalk Spinal Cord Injury Trust T/A The CatWalk Trust		74
2024 FULL 1827 6	Tailored adjuvant therapy in POLE-mutated and p53-wildtype early stage endometrial cancer (TAPER)	Dr Bryony Simcock	29/05/2024	30/05/2024	Provisionally Approved	Approved	18/07/2024	Private Organisation, Te Whatu Ora locality	Australia New Zealand Gynaecological Oncology Group	Canadian Cancer Trials Group (CCTG)	78