Health and Disability Ethics Committees

Northern A Health and Disability Ethics Committee

Annual Report 2024

This document is available on the New Zealand Health and Disability Ethics Committee website: www.ethics.health.govt.nz

Contents

About this report

This report is a summary of the activities of the Northern A 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 Northern A 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 Northern A 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 Northern A HDEC is registered (number IRB00008714) 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

As the Chair of Northern A HDEC for the year ending June 2024, I am pleased to present this Annual Report summarising the work of the Committee. The Committee reviewed a total of 93 applications at full committee meetings. 257 submissions for amendment to previously approved studies were processed through the expedited pathway.

Northern A has functioned in accordance with the HRCEC's expectations for proper process and membership, the Guidelines for the Approval of Ethics Committees, and HDECs Standard Operating Procedures. The Committee has completed its role diligently throughout the year.

Over the past reporting year, Northern A has lost one non-lay member, who resigned due to heavy work commitments. The reappointment of existing members whose terms have expired, or appointment of new members is outstanding at the time of this report. Given this is the case on more than one committee, and the shared benefit of strong appointments, it would be useful to ensure a range of relevant skills are considered across the committees.

As was the case for the last reporting period, Northern A lay and non-lay members have also supported the other HDECs by regularly providing member support for meetings, to address gaps in appointment or absent members. Likewise, we have benefitted from members co-opted from other committees when needed. Ideally, appointments will be made of suitable members and in a timely way to reduce the burden on the Secretariat and existing members.

The number of applications at meetings varies, with a cap at 10. Any more than eight can be onerous, particularly in an online setting. All Northern A meetings continue to be held by Zoom on the third Tuesday of each month. Attendance by researchers is helpful and the norm and the trend towards having representatives of international Sponsors attend has continued. As noted in the last report, some refinement to the expectations of applicants (researchers) in assisting with the finalising of the agenda is worth considering, to give the Secretariat and the committee guidelines around applicants who do not confirm their attendance or non-attendance. A clear process for the implications of non-attendance would help the preparation of the agenda and also to avoid disjointed meetings.

The Committee has benefitted from closer working relationships with SCOTT and GTAC, following a meeting between the Chairs of the committees.

The Chairs of the four HDECS continue to meet by Zoom and this is a vital forum for ensuring the sharing of knowledge between the Chairs, as well as a way to receive updates on a variety of matters from the Secretariat. I support the continued, regular meeting of the Chairs. I would also encourage consideration of practical training for members in review requirements and meeting conduct, as well as broader training with content to current and emerging issues in the research ethics space.

The Secretariat has worked hard to continue to provide strong support, notwithstanding a period of significant uncertainty and a reduction in staff/positions, and I am grateful for their efforts.

I express my gratitude to all members and staff of the HDEC Secretariat for their hard work and support of me in my capacity as Chair, to non-lay members of other Committees who assist me with post approval reviews on behalf of NTA. It is my pleasure to serve as the Chair of Northern A and I look forward to the coming year.

Catherine Garvey

Chair – Northern A 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	28
No. of applications deferred (provisionally approved) at first review and subsequently approved	38
No. of applications deferred as at time of report	14
No. of applications that were declined because of no/insufficient consultation with appropriate Māori/whānau/iwi/hāpu	5
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.)	8
No. of applications which do not require ethics committee approval (across all four Committees that were deemed out of scope)	*773*
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	**93**

The Northern A HDEC did not review Expedited applications during the reporting period

Total number of applications received	**93**

Complaints and overdue application summary

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

Complaints received

There were no complaints received during the reporting period regarding Northern A matters.

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 34 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.

Northern A does not review expedited applications.

Appendix 1: Details of applications reviewed[1]

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 FULL 18830	A Phase 1, single-dose, open-label, randomized crossover study to evaluate the pharmacokinetics and safety of azelaprag in older adult healthy volunteers	Dr Susanna Abigail	3/10/2023	7/10/2023	Approved NSC	Approved	25/10/2023	Private Organisation	Infinity Consulting	BioAge Labs Inc.	19
2023 FULL 18787	A Phase 1b Multiple Ascending Dose (MAD) Study of EC5026 in Healthy Volunteers	Dr Cory Sellwood	2/10/2023	10/10/2023	Approved NSC	Approved	25/10/2023	Private Organisation	PPD, part of Thermo Fisher Scientific	EicOsis Human Health	19
2023 FULL 18428	Cognitive Improvement by early Restoration of cirCADian rhythms in very preterm Infants through Environmental Modification: The CIRCA DIEM Study	Dr Maria Saito-Benz	21/09/2023	8/10/2023	Approved NSC	Approved	25/10/2023	Te Whatu Ora locality, Tertiary Education Institution	Research Office, Centre of Clinical Excellence, Capital, Coast and Hutt Valley	Telethon Kids Institute	19
2023 FULL 18512	A Phase 3, Randomized, Double-blind, Placebo- and Active-Comparator-Controlled Clinical Study of Adjuvant V940 (mRNA-4157) Plus Pembrolizumab Versus Adjuvant Placebo Plus Pembrolizumab in Participants With Resected Stage II, IIIA,	Dr Tony Rahman	4/09/2023	5/09/2023	Approved NSC	Approved	27/09/2023	Private Organisation	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	20

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

	IIIB (N2) Non-small Cell Lung Cancer										
2023 FULL 18573	A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, SINGLE ASCENDING DOSE STUDY TO ASSESS THE SAFETY, TOLERABILITY, AND PHARMACOKINETICS OF INTRAVENOUSLY OR SUBCUTANEOUSLY ADMINSTERED REGN13335, A PLATELET-DERIVED GROWTH FACTOR-B ANTAGONIST, IN HEALTHY ADULT PARTICIPANTS	Dr Cory Sellwood	6/09/2023	18/09/2023	Approved NSC	Approved	27/09/2023	Private Organisation	ICON Clinical Research (New Zealand) Ltd	Regeneron Pharmaceuticals	20
2024 FULL 20202	A Sequential, Randomized, Double-Blind, Placebo-Controlled, Phase 1 Single and Multiple Ascending Dose Study of LTG-305 Administered Orally to Evaluate the Safety, Tolerability, and Pharmacokinetics in Healthy Male and Female Participants 18 to 55 Years of Age.	Dr Alexandra Cole	4/06/2024	12/06/2024	Approved NSC	Approved	27/06/2024	Private Organisation	PPD, Part of Thermo Fisher Scientific	Latigo Biotherapeutics, Inc.	20
2024 FULL 20128	Elucidating patterns of BCG vaccine-induced resistance to Mycobacterium tuberculosis strains in peripheral blood	Dr Gergely Toldi	3/04/2024	5/04/2024	Approved NSC	Approved	24/04/2024	Primary Health Care Centre, Tertiary Education Institution	University of Auckland		20
2023 EXP 18493	Exploring the early experiences of the assisted dying service in Aotearoa	Dr Jessica Young	7/09/2023	12/09/2023	Approved NSC	Approved	27/09/2023	Other	Victoria University of Wellington		20

2023 FULL 18075	He Kōwhiringa Hōu – A new primary care treatment pathway for whānau impacted by treatment-resistant depression	Director of Awa Associates Ms Suaree Borell	31/08/2023	12/09/2023	Declined	Declined	27/09/2023	Primary Health Care Centre			20
2024 FULL 19923	Towards elimination of tuberculosis (TB) for Māori in Aotearoa New Zealand (WHIRI TB)	Professor Philip Hill	3/04/2024	5/04/2024	Approved NSC	Approved	24/04/2024	Te Whatu Ora locality	University of Otago		20
2024 FULL 19553	Validation of the adolescent version of the Alimetry Gut-Brain Wellbeing Survey: A mental wellbeing scale for patients with chronic gastroduodenal symptoms	Dr Stefan Calder	27/03/2024	4/04/2024	Approved NSC	Approved	24/04/2024	Other	The University of Auckland		20
2024 FULL 18953	A 3D printed AFO for personalised form and function in patients with movement disorders	Dr Julie Choisne	23/05/2024	11/06/2024	Provisionally Approved	Provisionally Approved		Tertiary Education Institution	The University of Auckland		21
2024 FULL 20371	A Phase 1b Study to Evaluate the Safety, Pharmacokinetics, Pharmacodynamics, and Efficacy of Cavrotolimod Alone and in Combinations in Subjects with Chronic Hepatitis B Infection.	Professor Edward Gane	30/05/2024	12/06/2024	Approved NSC	Approved	27/06/2024	Private Organisation	Novotech (New Zealand) Limited	Bluejay Therapeutics, Inc.	21
2024 FULL 19567	A Phase 2b, Double-Blind, Randomized Extension Study to Evaluate the Long-Term Safety and Efficacy of PTC518 in Participants with Huntington's Disease	Professor Tim Anderson	29/05/2024	12/06/2024	Approved NSC	Approved	27/06/2024	Private Organisation	Harvest Integrated Research Organization New Zealand Ltd	PTC THERAPEUTICS, INC	21
2024 FULL 20183	AAA-Shape Pivotal Trial: Abdominal Aortic Aneurysm Sac Healing and Prevention of Expansion	Dr Andrew Holden	30/05/2024	12/06/2024	Provisionally Approved	Provisionally Approved		Te Whatu Ora locality	N/A - International sponsor	Shape Memory Medical Inc	21

2024 FULL 20016	Does iodine deficiency cause congenital hypothyroidism in preterm babies?	Dr Benjamin Albert	23/05/2024	11/06/2024	Provisionally Approved	Provisionally Approved		Te Whatu Ora locality	University of Auckland		21
2024 FULL 20396	Open label dose escalation study to evaluate safety, tolerability, pharmacokinetics, and pharmacodynamics of repeated daily oral dosing of YCT-529 for 28 days in healthy men	Dr Rohit Katial	4/06/2024	14/06/2024	Provisionally Approved	Provisionally Approved		Private Organisation	Research Associates Limited	YourChoice Therapeutics, Inc	21
2024 FULL 19738	Study of Paediatric Appendicitis Scores and Management Strategies	Professor Stuart Dalziel	22/05/2024	10/06/2024	Provisionally Approved	Provisionally Approved		Te Whatu Ora locality		Perth Children's Hospital	21
2024 FULL 18651	Elucidating patterns of BCG vaccine-induced resistance to Mycobacterium tuberculosis strains in peripheral blood	Dr Gergely Toldi	8/02/2024	12/02/2024	Declined	Declined	1/03/2024	Primary Health Care Centre, Tertiary Education Institution	University of Auckland		22
2024 EXP 19306	Is an AI neural network able to be trained to discriminate CT scans that are normal or with common age related changes from serious pathology?	Dr Ben McGuinness	2/02/2024	12/02/2024	Declined	Declined	1/03/2024		Te Whatu Ora Health New Zealand - Te Toka Tumai Auckland		22
2024 FULL 18446	The Children's Palliative Outcome Scale Validation Study	Dr Gemma Aburn	7/02/2024	15/02/2024	Approved NSC	Approved	1/03/2024	Te Whatu Ora locality	Te Whatu Ora Health New Zealand, Te Toka Tumai Auckland, Starship Child Health	King's College London	22
2023 FULL 18347	Towards elimination of tuberculosis (TB) for Māori in Aotearoa New Zealand (WHIRI TB)	Professor Philip Hill	20/12/2023	12/02/2024	Declined	Declined	1/03/2024	Te Whatu Ora locality	University of Otago		22
2023 EXP 17876	Protocol for a pilot to assess the effectiveness, acceptability and	Director Health Equity, Public Health Physician	20/12/2023	6/01/2024	Provisionally Approved	Approved	11/01/2024	Te Whatu Ora locality	Te Whatu Ora Northern Region		24

	feasibility of two models of verbal consent for Hepatitis C at community laboratory collection sites in the Northern Region	Karen Bartholomew									
2023 FULL 17956	Delivering optimal weight gain advice to pregnant women (DOT): a case study	Associate Professor Kirsten Coppell	17/11/2023	17/11/2023	Provisionally Approved	Approved	22/11/2023	Te Whatu Ora locality	University of Otago		24
2024 FULL 19409	A Phase 3, Randomized, Double-Blind, Placebo-Controlled Program to Evaluate the Efficacy and Safety of MK-7240 in Participants with Moderately to Severely Active Ulcerative Colitis	Dr Sriharan Selvaratnam	1/05/2024	12/05/2024	Provisionally Approved	Provisionally Approved		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	24
2023 FULL 17829	Paediatric Influence of Cooling duration on Efficacy in Cardiac Arrest Patients (P-ICECAP)	Dr John Beca	31/07/2023	1/08/2023	Provisionally Approved	Approved	25/08/2023	Te Whatu Ora locality		The University of Michigan Medicine	44
2023 FULL 16790	A Phase 3, Randomized, Double-Blind, Placebo- and Active-Comparator-Controlled Clinical Study of Adjuvant V940 (mRNA-4157) Plus Pembrolizumab Versus Adjuvant Placebo Plus Pembrolizumab in Participants With High-Risk Stage II-IV Melanoma	Dr Gareth Rivalland	8/08/2023	10/08/2023	Provisionally Approved	Approved	4/09/2023	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)	51
2023 FULL 13593	Novel white cap crowns for drill-free dental caries treatment in NZ children - Feasibility Study	Dr Joanne Jung Eun Choi	2/07/2023	22/07/2023	Provisionally Approved	Approved	28/07/2023	Te Whatu Ora locality	Te Whatu Ora Southern		49
2024 FULL 13562	The BEAD Feasibility Study: Baby Head Elevation device at full	Dr. Lynn Sadler	29/04/2024	1/05/2024	Provisionally Approved	Approved	6/05/2024	Te Whatu Ora locality	University of Auckland		26

	dilatation caesarean section										
2024 FULL 19718	An open label, single arm pilot study to investigate safety and tolerability of a single 300 mg intravenous dose of AVT16 in healthy adult subjects aged 18 to 55 years inclusive.	Dr Chris Wynne	5/03/2024	11/03/2024	Approved NSC	Approved	2/04/2024	Private Organisation	Infinity Consulting Ltd.	Alvotech Swiss AG Thurgauerstrasse 54	26
2024 FULL 19061	Assessing the feasibility of a new model of care in pharmacy for the self-management of asthma	Mrs Neera Rajballi-Naidoo	3/03/2024	11/03/2024	Declined	Declined	2/04/2024	Private Organisation			26
2024 FULL 19771	A Phase 1 Study Investigating the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Preliminary Antitumor Activity of BGB-B2033, Alone or in Combination With Tislelizumab, in Participants With Selected Advanced or Metastatic Solid Tumors	Prof Ed Gane	7/05/2024	7/05/2024	Provisionally Approved	Approved	15/05/2024	Te Whatu Ora locality	BeiGene		27
2023 EXP 18005	Evaluating the Efficacy of Positive Episodic Future Thinking (EFT-P) to Increase Positive Beliefs about the Future and Decrease Suicidal Ideation in University Students	Miss Rebecca Salzano	9/08/2023	13/08/2023	Provisionally Approved	Approved	6/09/2023	Tertiary Education Institution	University of Otago		51
2023 FULL 18139	A feasibility study of respiratory-gated non-invasive auricular vagus nerve stimulation in people with rheumatoid arthritis	Mr Ankit Parimal Parikh	27/10/2023	14/11/2023	Approved NSC	Approved	8/12/2023	Te Whatu Ora locality	Exsurgo Ltd		28
2023 FULL 18705	A Phase 3, Randomized, Double-Blind, Placebo-Controlled Multicenter	Dr Clinton Lewis	2/11/2023	13/11/2023	Approved NSC	Approved	8/12/2023	Te Whatu Ora locality	CARSL Consulting	Equillium, Inc	28

	Study of Itolizumab in Combination with Corticosteroids for the Initial Treatment of Acute Graft Versus Host Disease										
2023 FULL 19025	A Phase 3, Randomized, Double-blind, Placebo-controlled, Multicenter Study to Evaluate the Efficacy and Safety of Amyloid Depleter ALXN2220 in Adult Participants with Transthyretin Amyloid Cardiomyopathy (ATTR-CM)	Doctor Timothy Sutton	6/11/2023	15/11/2023	Approved NSC	Approved	8/12/2023	Te Whatu Ora locality		AstraZeneca Pty Ltd	28
2023 FULL 18497	Exclusive Enteral Nutrition (EEN) therapy in active luminal paediatric Crohn's disease: do specific additional foods affect therapy response?	Mrs Stephanie Brown	9/11/2023	13/11/2023	Declined	Declined	8/12/2023	Te Whatu Ora locality			28
2023 FULL 18720	How do teenage parents view hearing in early life?	Dr Andrew Wood	2/11/2023	16/11/2023	Approved NSC	Approved	8/12/2023	Other	The University of Auckland		28
2023 FULL 18359	Platform of Randomised Adaptive Clinical Trials in Critical Illness (PRACTICAL) Randomised Controlled Trial	Associate Professor Rachael Parke	29/10/2023	14/11/2023	Approved NSC	Approved	8/12/2023	Te Whatu Ora locality	Te Whatu Ora Te Toka Tumai Auckland	University Health Network	28
2023 FULL 18069	A Phase 2 Study of Oral Decitabine/Cedazuridine in Combination With Magrolimab for Previously Untreated Subjects With Intermediate- to Very High-Risk Myelodysplastic Syndromes (MDS)	Dr Merit Hanna	4/07/2023	15/07/2023	Provisionally Approved	Provisionally Approved		Te Whatu Ora locality	IQVIA	Astex Pharmaceuticals, Inc.	29

2023 FULL 18844	Streptococcus pneumoniae induced haemolytic uraemic syndrome in Aotearoa, New Zealand (NZ) in the era of pneumococcal vaccination 14 years experience	Dr Alex Humphrey	3/11/2023	0/01/1900	Provisionally Approved	Declined	14/11/2023	Te Whatu Ora locality			29
2023 FULL 18214	A Double-Blind, Randomized, Placebo-Controlled, Single and Multiple Dose Study Evaluating the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of AB-101, an Oral PD-L1 Inhibitor, in Healthy Subjects and Subjects with Chronic HBV Infection	Prof Edward Gane	5/07/2023	12/07/2023	Approved NSC	Approved	4/08/2023	Private Organisation	PPD, part of Thermo Fisher Scientific	Arbutus Biopharma Corparation	29
2023 FULL 18275	An exploration of the effectivess, feasability and acceptability of a DBT in schools (STEPS-A) programme in Aotearoa New Zealand	Dr Liesje Donkin	6/07/2023	12/07/2023	Declined	Declined	4/08/2023	Te Whatu Ora locality	Tu Whatu Ora Waitematā		29
2023 FULL 17793	Anticoagulation for Stroke Prevention In patients with Recent Episodes of perioperative Atrial Fibrillation after noncardiac surgery - The ASPIRE-AF trial	Professor Harvey White	5/07/2023	10/07/2023	Approved NSC	Approved	4/08/2023	Te Whatu Ora locality		Population Health Research Institute	29
2023 FULL 18268	Double-blind, placebo controlled, first in human study to evaluate safety, tolerability, pharmacokinetics, and pharmacodynamics of single ascending oral doses of YCT-529	Dr Alexandra Cole	5/07/2023	13/07/2023	Approved NSC	Approved	4/08/2023	Private Organisation	Novotech (New Zealand) Limited	YourChoice Therapeutics, Inc	29
2023 FULL 13151	Registry Of Pregnancy And Cardiac disease	Dr Chethan Kasargod	6/07/2023	11/07/2023	Provisionally Approved	Provisionally Approved		Te Whatu Ora locality			29

2024 FULL 19577	Aquablation theraPy outcomes in pRostate Cancer patienTs	Professor Peter Gilling	7/06/2024	10/06/2024	Provisionally Approved	Approved	17/06/2024	Private Organisation		PROCEPT BioRobotics Corporation	30
2023 FULL 13126	Ipilimumab and nivolumab combination therapy in patients with selected immunotherapy sensitive advanced rare cancers	Dr Jane So	26/07/2023	27/07/2023	Provisionally Approved	Approved	7/08/2023	Te Whatu Ora locality		Olivia Newton-John Cancer Research Institute	31
2024 FULL 20067	A Phase 2 trial to evaluate the efficacy and safety of WZTL-002 in patients with relapsed or refractory large B-cell lymphoma (ENABLE-2)	Dr. Philip George	4/06/2024	11/06/2024	Provisionally Approved	Approved	17/06/2024	Te Whatu Ora locality	Malaghan Institute of Medical Research		31
2023 FULL 16735	Mifepristone versus placebo to increase the rate of spontaneous labour in women with a prior caesarean: A double blind randomised controlled trial	Senior Lecturer, Consultant Meghan Hill	6/12/2023	12/12/2023	Provisionally Approved	Approved	19/12/2023	Te Whatu Ora locality	Department of Obstetrics and Gynaecology, School of Medicine		31
2023 FULL 19342	A Phase 2, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy, Safety, and Tolerability of ATB1651 in Adults with Mild to Moderate Onychomycosis	Doctor Cory Sellwood	19/12/2023	17/01/2024	Approved NSC	Approved	12/02/2024	Private Organisation	Novotech (New Zealand) Limited c/o Novotech (Australia) Pty	AmtixBio Co., Ltd	31
2023 FULL 16720	A Prospective Randomized Multicenter Single Blinded Study to Assess the Safety and Effectiveness of the SELUTION SLR™ 014 Drug Eluting Balloon in the Treatment of Below-the-Knee (BTK) Atherosclerotic Disease in Patients with Chronic Limb Threatening Ischemia (CLTI)	Dr Andrew Holden	1/08/2023	8/08/2023	Approved NSC	Approved	4/09/2023	Te Whatu Ora locality		MedAlliance LLC	31

2023 FULL 16788	A single-arm intervention study of the feasibility of endoscopic ultrasound-guided pancreatic cyst chemoablation (EUS-PCA) using gemcitabine and paclitaxel for intraductal papillary mucinous neoplasms (IPMN) in two New Zealand tertiary interventional endoscopy centres.	Associate Professor Michael Jameson	30/11/2023	12/01/2024	Approved NSC	Approved	12/02/2024	Te Whatu Ora locality	University of Auckland		31
2023 FULL 15602	ANZMACS. Australia and New Zealand Mechanical and Circulatory Support Registry	Dr. Cara Wasywich	3/08/2023	8/08/2023	Declined	Declined	4/09/2023	Te Whatu Ora locality			31
2023 FULL 15434	Effectiveness and safety of a lignocaine eluting intraperitoneal implant for pain relief in elective laparoscopic colectomy	Professor Andrew Hill	31/07/2023	8/08/2023	Declined	Declined	4/09/2023	Te Whatu Ora locality	The University of Auckland; Te Whatu Ora - Counties Manukau		31
2023 FULL 15488	FAST study: Feasibility ASessment of circulating Tumour DNA (ctDNA) in the diagnosis of advanced lung cancer	Dr Annie Wong	27/07/2023	9/08/2023	Declined	Declined	4/09/2023	Te Whatu Ora locality			31
2023 FULL 18972	Healthy ageing needs for adults with cerebral palsy: a qualitative study across New Zealand and Australia	Dr Sian Williams	30/11/2023	13/01/2024	Approved NSC	Approved	12/02/2024	Te Whatu Ora locality	The University of Auckland		31
2023 FULL 19337	Open-label, phase 1b, single ascending dose study to evaluate the safety of VERVE-102 administered to patients with heterozygous familial hypercholesterolemia or premature coronary artery disease who require additional	Professor Russell Scott	18/12/2023	16/01/2024	Provisionally Approved	Provisionally Approved		Private Organisation	IQVIA RDS Pty Limited	Verve Therapeutics	31

	lowering of low-density lipoprotein cholesterol										
2023 FULL 18346	Pilot and randomised controlled trail of an Aotearoa-specific early autism support programme.	Dr. Hannah Waddington	2/08/2023	10/08/2023	Approved NSC	Approved	4/09/2023	Tertiary Education Institution	Te Herenga Waka - Victoria University of Wellington		31
2023 FULL 15270	A Phase 3, randomised, double-blind, parallel-group, event-driven, cardiovascular safety study with BI 456906 administered subcutaneously compared with placebo in participants with overweight or obesity with established cardiovascular disease (CVD) or chronic kidney disease, and/or at least two weight-related complications or risk factors for CVD.	Dr Andrew Edwards	16/10/2023	25/10/2023	Provisionally Approved	Approved	7/11/2023	Private Organisation, Te Whatu Ora locality	Boehringer Ingelheim (N.Z.) Limited	Boehringer Ingelheim Pty Ltd	32
2024 FULL 20359	A Phase 3, Randomized, Double-Blind, Placebo-Controlled Program to Evaluate the Efficacy and Safety of Tulisokibart in Participants with Moderately to Severely Active Crohn's Disease	Dr Sriharan Selvaratnam	8/05/2024	13/05/2024	Provisionally Approved	Provisionally Approved		Te Whatu Ora locality	Name: Merck Sharp & Dohme (New Zealand) Limited, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA Address:	Name: Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA Address:	32
2024 FULL 20353	GEO-TBI Global Epidemiology and Outcomes following Traumatic Brain Injury - An international registry for supporting care and research excellence in traumatic brain injury.	Professor Giles Critchley	7/05/2024	12/05/2024	Declined	Declined	11/06/2024	Te Whatu Ora locality	University of Otago	University of Cambridge	32
2024 FULL 19855	Paediatric pelvic reconstruction outcomes study	Dr James Hamill	4/05/2024	12/05/2024	Provisionally Approved	Provisionally Approved		Te Whatu Ora locality	Te Toka Tumai Auckland		32

2024 FULL 20088	Randomized phase III trial in MMR deficient endometrial cancer patients comparing chemotherapy alone versus Dostarlimab in first line advanced/metastatic setting: DOMENICA STUDY (GINECO-EN105b/ENGOT-en13 study)	Dr Michelle Wilson	1/05/2024	3/05/2024	Approved NSC	Approved	11/06/2024	Te Whatu Ora locality		Australia New Zealand Gynaecological Oncology Group (ANZGOG)	32
2024 FULL 19461	Respiratory sinus arrhythmia pacing post-CABG surgery in patients with HFrEF	A/Prof Martin Stiles	2/05/2024	12/05/2024	Provisionally Approved	Provisionally Approved		Te Whatu Ora locality	Avania Pty Ltd	Ceryxl Medical	32
2024 FULL 19582	A Phase 3, Randomized Study to Compare Nemtabrutinib Versus Comparator (Investigator's Choice of Ibrutinib or Acalabrutinib) in Participants With Untreated Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (BELLWAVE-011)	Dr Merit Hanna	18/04/2024	26/04/2024	Provisionally Approved	Approved	1/05/2024	Te Whatu Ora locality	MSD / GCTO-ANZ	Merck Sharp & Dohme LLC (hereafter called the Sponsor or MSD)	33
2024 FULL 20019	AR882-302: A Phase 3 Randomized, Double-blind, Multi-center, Placebo-controlled Study to Evaluate the Efficacy and Safety of AR882 in Participants with Gout	Dr Claire Thurlow	2/05/2024	12/05/2024	Provisionally Approved	Provisionally Approved		Private Organisation	IQVIA RDS Pty Limited	IQVIA RDS Pty Limited	33
2024 FULL 19845	GO45006: A PHASE III, RANDOMIZED, DOUBLE-BLIND STUDY OF TIRAGOLUMAB PLUS ATEZOLIZUMAB COMPARED WITH PLACEBO PLUS ATEZOLIZUMAB IN	Dr Aileen Ludlow	2/05/2024	15/05/2024	Provisionally Approved	Provisionally Approved		Te Whatu Ora locality	Roche Products (New Zealand) Limited	Roche	33

	PARTICIPANTS WITH COMPLETELY RESECTED STAGE IIB, IIIA, OR SELECT IIIB, PD-L1 POSITIVE, NON-SMALL CELL LUNG CANCER WHO HAVE RECEIVED ADJUVANT PLATINUM-BASED CHEMOTHERAPY										
2023 FULL 15261	A Phase 3, randomised, double-blind, parallel-group, 76-week, efficacy and safety study of BI 456906 administered subcutaneously compared with placebo in participants with overweight or obesity and type 2 diabetes mellitus	Prof Dean Quinn	13/10/2023	24/10/2023	Provisionally Approved	Approved	7/11/2023	Private Organisation, Te Whatu Ora locality	Boehringer Ingelheim (N.Z.) Limited	Boehringer Ingelheim Pty Ltd	34
2023 FULL 18725	A Phase 3 randomized, placebo-controlled, double-blind program to evaluate efficacy and safety of upadacitinib in adult and adolescent subjects with severe alopecia areata.	Dr Marius Rademaker	9/11/2023	14/11/2023	Provisionally Approved	Approved	27/11/2023	Private Organisation, Te Whatu Ora locality	AbbVie Ltd	AbbVie Ltd	35
2023 FULL 18838	BP16-101: A Randomized, Double-Blind, Parallel group, Comparative Phase I study for the assessment of Pharmacokinetics, Pharmacodynamics, Safety, tolerability and Immunogenicity of BP16 (Denosumab) versus US licensed - Prolia® and EU approved - Prolia® Following a Single dose (60mg/mL) Subcutaneous Administration in Healthy Male	Dr Paul Hamilton	30/10/2023	5/11/2023	Provisionally Approved	Approved	16/11/2023	Private Organisation	PPD, part of Thermo Fisher Scientific	CuraTeQ Biologics Private Ltd.	35

2024 FULL 18327	Wireless HOME monitoring of intracranial (BRAIN) PRESSURE - HOME BRAIN PRESSURE study	Dr Sarah-Jane Guild	15/01/2024	16/01/2024	Provisionally Approved	Approved	24/01/2024	Te Whatu Ora locality	The University of Auckland		36
2023 FULL 15258	A Phase 3, randomised, double-blind, parallel-group, 76-week, efficacy and safety study of BI 456906 administered	Prof Dean Quinn	13/10/2023	24/10/2023	Provisionally Approved	Approved	7/11/2023	Private Organisation, Te Whatu Ora locality	Boehringer Ingelheim (N.Z.) Limited	Boehringer Ingelheim Pty Ltd	38
2024 FULL 18151	An open label, single arm, extension trial to examine long-term safety of Iclepertin once daily in patients with schizophrenia who have completed previous Iclepertin Phase III trials. (CONNEX-X)	Assoc Prof Sylvester Wayne Miles	23/02/2024	28/02/2024	Provisionally Approved	Approved	1/03/2024	Te Whatu Ora locality		Boehringer Ingelheim Pty Ltd	38
2024 FULL 19214	CB06-036-102: A Randomized, Double-Blind, Placebo-controlled Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of Multiple Ascending Doses of CB06-036 in Subjects with Chronic Hepatitis B	Dr Paul Hamilton	26/02/2024	27/02/2024	Provisionally Approved	Approved	6/03/2024	Private Organisation	Fortrea	Shanghai Zhimeng Biopharma, Inc.	39
2023 FULL 15596	A PHASE Ib/II, OPEN-LABEL, MULTICENTER, RANDOMIZED PLATFORM STUDY EVALUATING THE EFFICACY AND SAFETY OF NEOADJUVANT IMMUNOTHERAPY COMBINATIONS IN PATIENTS WITH SURGICALLY RESECTABLE	Professor Edward Gane	3/07/2023	6/07/2023	Provisionally Approved	Approved	20/07/2023	Te Whatu Ora locality	Labcorp New Zealand Limited	Genetech	40

	HEPATOCEULLULAR CARCINOMA (MORPHEUS-NEO HCC)										
2023 FULL 11995	COMBINEd Ischemia and Vulnerable Plaque Percutaneous INTERVENtion to Reduce Cardiovascular Events	Dr Scott Andrew Harding	9/10/2023	12/10/2023	Provisionally Approved	Approved	19/10/2023	Te Whatu Ora locality	Research Office	DIAgnostic Research And Management (DIAGRAM) B.V	40
2024 FULL 19860	BW-00163-1002: A Phase I, Randomized, Double-Blind, Placebo-Controlled, Single Ascending Dose Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of Subcutaneously Administered BW-00163 in Healthy Subjects and Subjects with Mild Hypertension	Dr Paul Hamilton	9/04/2024	11/04/2024	Provisionally Approved	Approved	26/04/2024	Private Organisation	IQVIA RDS PTY. Limited	Argo Biopharma Australia Pty Ltd	42
2024 FULL 19857	Co-designing a family-centered group intervention for children with neurodevelopmental delay and testing its feasibility.	Dr Parimala Kanagasabai	12/06/2024	17/06/2024	Provisionally Approved	Approved	24/06/2024	Te Whatu Ora locality	University of Otago		42
2023 FULL 15628	Understanding Child Abuse Victim, Caregiver and Clinician Trauma Focused Cognitive Behavioural Therapy (TF-CBT) Treatment Experience	Mrs Audrey Kusasira-Sutton	19/07/2023	21/07/2023	Provisionally Approved	Approved	7/08/2023	Private Organisation, Te Whatu Ora locality			44
2024 FULL 18387	A Prospective angiOtensin vs. noRadrenaline Trial for Hypotension management to reduce length Of hospital stay in Cardiac Surgery (The PORTHOS study)	Dr Daniel Frei	2/02/2024	8/02/2024	Provisionally Approved	Approved	20/02/2024	Te Whatu Ora locality			44

2024 FULL 19219	A Phase 3, Randomized, Open-label Study of MK-5684 Versus Alternative Abiraterone Acetate or Enzalutamide in Participants with Metastatic Castration-resistant Prostate Cancer (mCRPC) That Progressed On or After Prior Treatment with One Next-generation Hormonal Agent (NHA)	Dr Carmel Jacobs	1/05/2024	6/05/2024	Provisionally Approved	Approved	17/05/2024	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	45
2024 FULL 19940	DBQ103CT: A phase 1C, randomized, double-blind, placebo-controlled, multicenter study to evaluate the safety, pharmacokinetics, immunogenicity, and biological effects of DONQ52 in celiac disease patients with gluten challenge	Dr Dean Quinn	7/06/2024	20/06/2024	Provisionally Approved	Approved	5/07/2024	Private Organisation	ICON Clinical Research NZ	Chugai Pharmaceutical Co. Ltd	46
2024 FULL 18331	Surgical Ablation of Atrial Fibrillation Efficacy trial	Dr Shay McGuinness	20/06/2024	30/06/2024	Provisionally Approved	Approved	5/07/2024	Te Whatu Ora locality		Hamilton Health Sciences Corporation	46
2023 FULL 18754	Paediatric Rehabilitation Priority Setting Partnership	Dr Jimmy Chong	14/11/2023	15/11/2023	Provisionally Approved	Approved	13/12/2023	Te Whatu Ora locality	Auckland University of Technology		47
2023 FULL 18508	An Open-Label, Multicenter, Phase 1/2 Trial of GEN3014 (HexaBody® -CD38) in Relapsed or Refractory Multiple Myeloma and Other Hematologic Malignancies	Dr Sophie Leitch	14/11/2023	15/11/2023	Provisionally Approved	Approved	13/12/2023	Te Whatu Ora locality	Syneos Health New Zealand Limited	Genmab US, Inc.	48
2024 FULL 18182	Ex-vivo assessment of interactions between fibre and inflammation using 3-D cultured biopsies	PROFESSOR ANDREW DAY	8/04/2024	9/04/2024	Provisionally Approved	Approved	26/04/2024	Te Whatu Ora locality, Tertiary Education Institution	Director, Research & Enterprise, University of Otago		48

2023 FULL 18195	Recommendations for school-based health and wellbeing interventions for young people in the Wairarapa	Mr. Joshua James	15/08/2023	18/08/2023	Provisionally Approved	Approved	4/09/2023	Te Whatu Ora locality	Te Whatu Ora		48
2024 FULL 19255	A Phase 3 Randomized, Open-label Study of MK-5684 Versus Alternative Abiraterone Acetate or Enzalutamide in Participants With Metastatic Castration-resistant Prostate Cancer (mCRPC) Previously Treated With Next-generation Hormonal Agent (NHA) and Taxane-based Chemotherapy	Dr Orlaith Heron	21/03/2024	22/03/2024	Provisionally Approved	Approved	10/04/2024	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	49
2024 FULL 18421	PACE-NODES: A phase III randomised trial of 5 fraction prostate SBRT versus 5 fraction prostate and pelvic nodal SBRT.	Dr Jerusha Padayachee	23/04/2024	28/04/2024	Provisionally Approved	Approved	23/05/2024	Te Whatu Ora locality		The institute of Cancer Research	50
2023 FULL 17967	Paediatric Eosinophilic Gastrointestinal Diseases Database	Prof Andrew S Day	8/11/2023	14/11/2023	Provisionally Approved	Approved	13/12/2023	Te Whatu Ora locality	Te Whatu Ora Waitaha, Research Office		52
2024 FULL 18694	CAMBRIA-2: A Phase III, Open-Label, Randomised Study to Assess the Efficacy and Safety of Camizestrant (AZD9833, a Next-Generation, Oral Selective Estrogen Receptor Degrader) Versus Standard Endocrine Therapy (Aromatase Inhibitor or Tamoxifen) as Adjuvant Treatment for Patients with ER+/HER2- Early Breast Cancer and an Intermediate-High or	Dr/ Medical Oncologist Marion Kuper-Hommel	3/04/2024	4/04/2024	Provisionally Approved	Approved	26/04/2024	Te Whatu Ora locality	Breast Cancer Trials	Astra Zeneca Pharma Poland	53

	High Risk of Recurrence Who Have Completed Definitive Locoregional Treatment and Have No Evidence of Disease.										
2024 FULL 19501	Multicenter, PrOspective, Randomized, Controlled Trial Comparing GenIcular Artery EmbOlization Using Embosphere Microspheres to Corticosteroid iNjections for the Treatment of Symptomatic Knee Osteoarthritis: MOTION Study	Dr Rahul Bera	12/04/2024	20/04/2024	Provisionally Approved	Declined	15/05/2024	Te Whatu Ora locality	not applicable	Merit Medical Systems, Inc.	53
2024 FULL 15231	The NEOgrads playgroup study: Improving developmental motor outcomes through intensive Early Intervention in preterm infants: A feasibility study.	Dr Nusratnaaz Shaikh	11/03/2024	15/03/2024	Provisionally Approved	Approved	5/04/2024	Private Organisation	Auckland University of Technology		55
2023 FULL 18407	Safety and Feasibility Dose Escalation Study for Evaluation of RT-310 for Treatment of Lower Urinary Tract Symptoms (LUTS) Secondary to Benign Prostatic Hyperplasia (BPH)	Professor Peter Gilling	8/09/2023	12/09/2023	Provisionally Approved	Approved	11/10/2023	Private Organisation, Te Whatu Ora locality		Resurge Therapeutics Inc	62
2024 FULL 19532	A PHASE 1/2 DOSE-EXPLORATION AND DOSE-EXPANSION STUDY TO EVALUATE THE SAFETY AND EFFICACY OF BEAM-302 IN ADULT PATIENTS WITH ALPHA-1 ANTITRYPSIN DEFICIENCY (AATD)-ASSOCIATED LUNG	Dr Jeffery Garrett	9/05/2024	16/05/2024	Provisionally Approved	Approved	31/07/2024	Private Organisation, Te Whatu Ora locality	Medpace Australia Pty Ltd.	BEAM Therapeutics, Inc.	63

	DISEASE AND/OR LIVER DISEASE.										
2024 FULL 18702	OPTIMA: Optimal Personalised Treatment of early breast cancer using Multi-parameter Analysis (A multi-site partially blinded randomised international clinical trial with a non-inferiority endpoint and adaptive design)	Dr Marion Kuper-Hommel	24/05/2024	3/06/2024	Provisionally Approved	Approved	5/07/2024	Te Whatu Ora locality	Breast Cancer Trials ANZ (National sponsor)	University College London	65
2024 FULL 18645	Pilot randomised controlled trial for small drop administration of phenylephrine and cyclopentolate in preterm infants for retinopathy of prematurity eye examinations	Dr Lisa Kremer	16/01/2024	17/01/2024	Provisionally Approved	Approved	23/02/2024	Te Whatu Ora locality	University of Otago		65
2024 FULL 19089	A Phase 2 Randomized, Double-blind, Placebo-controlled Study to Evaluate the Effect of EDG-5506 on Safety, Biomarkers, Pharmacokinetics, and Functional Measures in Adults and Adolescents with Becker Muscular Dystrophy	Dr. Richard Roxburgh	23/04/2024	27/04/2024	Provisionally Approved	Approved	6/06/2024	Private Organisation	Medpace Australia Pty Ltd.	Edgewise Therapeutics	73