



**Health and
Disability Ethics
Committees**

**Central Health and Disability
Ethics Committee**

**Annual Report
2024**

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Contents

About this report 1

About the committee..... 1

Chairperson’s report..... 2

Applications reviewed 3

Complaints and overdue application summary..... 4

 Complaints received.....4

 Overdue review4

Appendix 1: Details of applications reviewed..... 6

 Applications reviewed by the committee.....6

About this report

This report is a summary of the activities of the Central Health and Disability Ethics Committees (HDEC) for the period of 01 July 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 Central Health and Disability Ethics Committees (HDEC) is a Ministerial committee established under section 87 of the [Pae Ora \(Healthy Futures\) Act 2022](#). Its members are appointed by the Minister of Health through the public appointments process.

The primary function of the Committee is to provide independent ethical review of health research and innovative practice in order to safeguard the rights, health and wellbeing of consumers and research participants and, in particular, those persons with diminished autonomy by checking that it meets or exceeds established [ethical standards](#).

Approvals and registrations

The Central HDEC is approved by the Health Research Council Ethics Committee for the purposes of section 25(1)(c) of the [Health Research Council Act 1990](#).

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

Chairperson's report

The end of another very busy year for the Central Committee, as a consequence of the amazing research that occurs in New Zealand. Thank you to our researchers for enabling all this groundbreaking work to occur.

During Covid, New Zealand became a “go to” location for overseas companies as a consequence of our “almost healthy” population. We need to continue this trend as it enables access to treatments not usually funded here and financial benefit for New Zealand. But we need the support of the Ministry of Health (the Ministry) which has the HDEC Secretariat (‘Ministry’) to achieve this. Already a very small department administratively, in the last reshuffle we lost several staff members. To be able to maintain service to the Research Community this needs to be revisited. The Research Ethics Committees are paid significantly less than other Government Committees and have a large workload so please ensure that there is adequate administrative support in place.

The speed of scientific progress is huge with AI as an added impact, Ethics Committees consequently need to be supported by a good back up service and training to keep up to date with what “techniques” are becoming more and more available for researchers. The protection of personal information is crucial, which becomes harder by the day as new platforms are introduced.

A change to the review structure could also be beneficial to accommodate the volume of applications. We already have an expedited path, but a “low risk” expedited review could be added to take the pressure off the full committees.

The decision process for committees needs a slight change. Decisions are “approved, provisional approval, decline”. The provisional approval creates a problem if it is returned but not totally addressed. The only option for the reviewer is to decline. Another provisional option would be beneficial.

I would like to take this opportunity to thank the members of the Central Committee for their commitment to the huge ethics workload they cope with alongside their full-time jobs. Without you and your dedication and good humour all the huge advances achieved in Health would not be possible.

I would also like to extend this thanks to the other Committees that I have worked with during the year.

It is busy not only for the committee members but also for our administration team, they need a huge vote of thanks for coordinating all this for us and being there for advice when needed. As I have said earlier in this report, please ensure that the Ministry are recognising their worth and are giving them the full support necessary.

Helen Walker QSM, BSc, CMInstD (Retd)

Chair – Central HDEC

Applications reviewed

Summary of applications received by full EC.

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

No. of applications approved at first review	2
No. of applications approved subject to conditions / pending at first review	29
No. of applications deferred (provisionally approved) first review and subsequently approved	42
No. of applications deferred as at time of report	9
No. of applications that were declined because of no/insufficient consultation with appropriate Māori/whānau/iwi/hāpu	4
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.)	10
<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	96

Summary of applications received under expedited / low risk review.

(All outcomes refer to outcome of first review.)

No. of applications approved	16
No. of applications approved subject to conditions / pending at first review	37
No. of applications deferred at first review and subsequently approved	56
No. of applications deferred as at time of report	12
No. of applications declined	8
Total number of applications received under expedited / low risk review	129

Total number of applications received

225

Complaints and overdue application summary

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

Complaints received

Complaint one

Type of complaint: Scoping Error

Date resolved: 05 October 2023

Complaint received: 25 August 2023

Nature of complaint:

The Committee received a complaint about an Audit/QI substudy within an already approved application that was deemed out of scope by HDEC when submitted as a progress report, and the progress report was approved. However, a member on a governance group in the relevant field lodged a complaint about the approval of the substudy as it appeared not to have ethical review.

Actions taken:

The rationale behind the decision to out of scope the substudy was provided and the complainant was advised that this appears to be a locality-level governance issue as the progress report approval did not constitute ethical approval of the audit as this was an out-of-scope component for HDEC.

Outcome:

The rationale for the decision was provided and highlighted to be consistent with HDEC approval and scoping processes.

Complaint two

Type of complaint: Participant Safety

Date resolved: 05 September 2024

Complaint received: 27 February 2024

Nature of complaint:

The Committee received a complaint about an ongoing study testing ketamine to treat internalising disorders. The complaint raised concern about the inclusion/exclusion criteria, safety monitoring and follow-up in the study and ongoing use of ketamine after the study.

Actions taken:

The researcher met with the Committee to discuss the safety arrangements. The researcher and committee agreed future studies would place greater emphasis on reviewing the medical histories of potential participants to determine suitability and increased safety monitoring while on the trial. The researcher outlined to the committee the support provided to participants' GPs following the trial, if the participant benefited from ketamine and their GP wished to continue prescribing it.

Outcome:

The Committee was satisfied with the researcher's actions and the complaint was closed.

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 20 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 the average is higher than the target is that although a majority of expedited applications were under the target 15 days, there were a few exceptions which raised the average. This was due to either the submission receiving significant amendments following provisional approval and the time required by the Committee to review these or due to limited resourcing in the Secretariat which delayed processing the letters following review by the sub-committee.

Average review time was 23 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 17981	Prolonged PACU Stay at Waikato hospital; retrospective observational study: Risks and Consequences	Dr Timothy Starkie	19/12/2023	22/12/2023	Approved	Approved	8/01/2024				1
2023 EXP 19198	Computer vision for intraoperative cholangiography	Dr Saxon Connor	12/12/2023	17/12/2023	Approved NSC	Approved	18/12/2023		Te Whatu Ora Waitaha Canterbury, University of Otago Christchurch	St Vincents Hospital Melbourne	3
2024 EXP 11941	Healthcare access equity in childhood asthma in Aotearoa; a national retrospective observational study	Prof Stuart Dalziel	1/05/2024	3/05/2024	Provisionally Approved	Approved	6/05/2024		Te Toka Tumai, Te Whatu ora		16
2023 FULL 1887 1	Stepped Care Model for rehabilitation for people with persistent shoulder pain	Professor Gisela Sole	28/11/2023	1/12/2023	Approved NSC	Approved	4/12/2023	Private Organisation, Tertiary Education Institution	School of Physiotherapy		3

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

2023 EXP 19359	Ganglioneuroblastoma – the natural history and management of paediatric secondary scoliosis	Dr Katarina Sim	19/12/2023	20/12/2023	Provisionally Approved	Approved	8/01/2024				4
2023 EXP 18156	Economic burden of odontogenic infections at a single tertiary hospital in New Zealand. A pre, peri, and, post COVID comparison	Dr Linbei Ke	17/12/2023	22/12/2023	Approved	Approved	8/01/2024				4
2023 EXP 18553	Predictive value of 18F-FET PET in gliomas - a real world retrospective study	Dr Yuhan Wei	16/11/2023	20/11/2023	Provisionally Approved	Provisionally Approved			Te Whatu Ora Capital and Coast		4
2023 EXP 19370	Prevalence of MRI abnormalities in children presenting with back pain to Starship Hospital	Dr Wendy He	17/12/2023	22/12/2023	Approved	Approved	8/01/2024				4
2023 EXP 18100	To determine the long-term outcomes of cases with high grade precancerous discordant results, where the cases were discussed at colposcopy multidisciplinary meeting, and the cytology/histology results were 'down-graded' avoiding an excisional treatment.	MS Lauren Moore	7/09/2023	16/09/2023	Approved NSC	Approved	18/09/2023				4
2024 EXP 19401	Maungārongo: Exploring the end-of-life care needs of incarcerated New Zealanders REVISED	Professor Meryn Gott	15/04/2024	16/04/2024	Provisionally Approved	Approved	17/04/2024	Other	University of Auckland		5

2023 EXP 17903	Determining potential drivers of inequity in endometrial cancer service access, incidence and mortality using routinely collected health data in the Northern Region	Doctor Karen Bartholomew	3/10/2023	8/10/2023	Approved	Approved	11/10/2023		Te Whatu Ora Te Toka Tumai and Te Whatu Ora Waitematā		5
2023 EXP 13198	PC-PEP Phase 4: Predictors of Mental Health for Men with Prostate Cancer undergoing a Patient Empowerment Program	Mr. Peter Dickens	12/09/2023	15/09/2023	Provisionally Approved	Approved	18/09/2023	Private Organisation	Prostate Cancer Foundation of New Zealand	Nova Scotia Health / Dalhousie University	31
2024 EXP 20276	Current surgical management and outcomes of pyogenic granuloma of the hand and digits at Health New Zealand [Te Whatu Ora Counties Manukau	Professor Jon Mathy	6/05/2024	10/05/2024	Approved NSC	Approved	15/05/2024		Counties Manukau Health		6
2023 EXP 18908	Deaths at home study – Clinical characteristics of patients dying at home from diabetic ketoacidosis (DKA) – 12 year retrospective study	Dr Rui Qian (Ryan) Yeu	28/09/2023	8/10/2023	Approved	Approved	11/10/2023		Te Whatu Ora Te Toka Tumai Auckland		6
2023 EXP 18866	Determining the outcomes of extended three monthly Paliperidone depot (TRINZA)	Dr Alwyn Castelino	26/09/2023	8/10/2023	Declined	Declined	11/10/2023		Te Whatu Ora Counties Manukau		6
2024 EXP 20052	Dipeptidyl Peptidase 4 Inhibitor-related bullous pemphigoid between 2019 and 2024 in a New Zealand population	Dr Leah Jones	28/04/2024	3/05/2024	Approved NSC	Approved	8/05/2024		Te Whatu Ora Auckland		6

2023 EXP 18687	Host, Pathogen, and Environment in Childhood Bone and Joint infection	Dr Sarah Hunter	29/10/2023	3/11/2023	Declined	Declined	7/11/2023	Te Whatu Ora locality	Starship Hospital		6
2024 FULL 20343	NIU: Implementation and evaluation of a Pasifika intervention to increase uptake of urate lowering therapy for gout	Dr Samulea Ofanoa	6/06/2024	18/06/2024	Provisionally Approved	Provisionally Approved		Primary Health Care Centre, Tertiary Education Institution	University of Auckland		6
2023 EXP 18509	Sociodemographic and Spatio-temporal Distribution of Frequent Attendance in Three Emergency Departments in Te Whatu Ora Southern	Professor John Eastwood	29/09/2023	8/10/2023	Approved	Approved	11/10/2023		Te Whatu Ora Southern		6
2023 EXP 18980	Syntocinon - reduces rates of retained placenta in second trimester Medical Termination of Pregnancy	Dr Neha Patel	10/10/2023	17/10/2023	Declined	Declined	19/10/2023		Te-Whatu Ora - Waitemata		6
2023 FULL 18330	A pivotal in vivo bioequivalence study comparing betamethasone cream (Nova Chem, Australia) to Diprosone® cream (Organon, Australia), using the ED50 for Diprosone® cream 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	11/07/2023	20/07/2023	Approved NSC	Approved	4/08/2023	Private Organisation	Zenith Technology Corporation Limited	Nova Chem Australasia Pty Ltd	21
2023 EXP 19295	Understanding Menstrual Fluid Loss in Premenopausal Females	Dr Claire Badenhorst	8/12/2023	17/12/2023	Approved NSC	Approved	18/12/2023	Tertiary Education Institution	Massey University		6

2023 EXP 19296	Understanding upper tract urinary obstruction from malignancy – how do our patients do?	Mr Giovanni Losco	7/12/2023	17/12/2023	Approved	Approved	18/12/2023		Canterbury Urology Research Trust		6
2024 FULL 20198	Clinical characteristics and outcome of patients with prosthetic valve thrombosis in Auckland	Dr Danting Wei	10/05/2024	17/05/2024	Provisionally Approved	Provisionally Approved		Te Whatu Ora locality			7
2024 EXP 18820	Multicentre study on Liver Transplantation for Primary Sclerosing Cholangitis: Indications & outcomes	Dr Hannah Giles	6/02/2024	12/02/2024	Approved NSC	Approved	14/02/2024				7
2024 EXP 19983	Staphylococcus aureus bacteraemia at Middlemore Hospital: a retrospective review	Dr Genevieve Walls	28/03/2024	4/04/2024	Approved NSC	Approved	10/04/2024		Te Whatu Ora Counties Manukau		7
2023 EXP 13366	Understanding Anterior Cruciate Ligament Reconstruction Outcomes in New Zealand	Dr Sarah Ward	19/07/2023	21/07/2023	Provisionally Approved	Approved	27/07/2023	Tertiary Education Institution			23
2024 EXP 20034	Validation of days alive out of hospital as an outcome measure for patients who have experienced major trauma	Dr Luke Boyle	3/05/2024	9/05/2024	Approved	Approved	15/05/2024		Te Whatu Ora Health New Zealand - Te Toka Tumai Auckland		7

2024 EXP 19781	An investigation of the products of digestion of bovine hydrolysed collagen	Dr Katie Schradars	3/04/2024	4/04/2024	Provisionally Approved	Approved	10/04/2024	Tertiary Education Institution	Massey University		8
2024 EXP 18987	Combined tumour genomics and metabolomics of pheochromocytoma and paraganglioma	Dr Veronica Boyle	20/03/2024	20/03/2024	Provisionally Approved	Approved	22/03/2024	Te Whatu Ora locality	University of Auckland, Uniservices		8
2024 EXP 19351	A comparison of post meal glycaemic excursion after ingestion of konjac glucomannan rice, cauliflower rice and brown rice (control) in type 1 diabetes.	Dr Amber Parry Strong	21/02/2024	24/02/2024	Approved NSC	Approved	1/03/2024	Te Whatu Ora locality	Te Whatu Ora CCHV		8
2023 FULL 18059	Exploring how rider engagement within the therapeutic horse riding landscape can be optimised: a participatory action research approach	Dr Rachelle Martin	12/07/2023	23/07/2023	Declined	Declined	4/08/2023	Private Organisation			21
2024 EXP 19456	Community-based screening and health promotion initiative for Type 2 diabetes	Dr Fulton Shannon	9/01/2024	16/01/2024	Declined	Declined	17/01/2024	Other, Private Organisation	Health Research Council of New Zealand		8
2023 EXP 16746	In-Vitro Compatibility of Human Blood to Pig Cells	Dr. Ian Dittmer	9/08/2023	13/08/2023	Provisionally Approved	Approved	18/08/2023	Other, Te Whatu Ora locality	NZeno Limited		20

2023 EXP 18092	Retrospective review of blood glucose and temperature monitoring for patients receiving endovascular clot retrieval	Dr Jae Hyun Lee	25/10/2023	2/11/2023	Approved NSC	Approved	7/11/2023		Te Whatu Ora Health New Zealand - Te Toka Tumai Auckland		8
2023 EXP 18709	Identification of reliable CNP assays to Advance Clinical Science	Dr Timothy Prickett	14/11/2023	15/11/2023	Provisionally Approved	Approved	22/11/2023	Tertiary Education Institution	University of Otago Christchurch		9
2023 EXP 17909	The Association between Frailty Index and Severe/Critical Aortic Stenosis in New Zealand	Cardiology Research Fellow Timothy Oh	7/07/2023	11/07/2023	Provisionally Approved	Declined	18/07/2023				9
2023 EXP 18159	The SNaPP Study: Sugammadex, Neostigmine and Postoperative Pulmonary Complications	Dr Peter Xiang	19/09/2023	22/09/2023	Provisionally Approved	Approved	26/09/2023	Te Whatu Ora locality	Te Whatu Ora Te Toka Tumai Auckland	University of Melbourne	9
2023 FULL 19046	AN OPEN-LABEL, PARALLEL-GROUP PHASE I STUDY TO EVALUATE THE RELATIVE AND ABSOLUTE BIOAVAILABILITY OF SINGLE SUBCUTANEOUS DOSES OF NXT007 AMONG INJECTION SITES ABDOMEN, UPPER ARM, AND THIGH IN HEALTHY MALE PARTICIPANTS	Dr Rohit Katial	13/11/2023	24/11/2023	Approved NSC	Approved	8/12/2023	Private Organisation		Roche New Zealand	22
2024 EXP 19743	A Retrospective Analysis into the Haemorrhage Rate During Follow-Up Of High-Grade Intracranial Dural Arterio-Venous Fistulas - between 2016 - 2023 at a single centre (Auckland City Hospital)	Dr Ben McGuinness	7/03/2024	12/03/2024	Approved NSC	Approved	18/03/2024		Auckland District Health Board		9

2024 EXP 19647	Obstetric haemorrhage and need for blood transfusion: a retrospective cohort study	Senior Lecturer, Consultant Meghan Hill	23/02/2024	2/03/2024	Approved	Approved	6/03/2024		School of Medicine		9
2024 EXP 19472	Skeletal metastases in neuroendocrine neoplasms	Associate Professor Marianne Elston	5/01/2024	15/01/2024	Approved NSC	Approved	17/01/2024	Te Whatu Ora locality, Tertiary Education Institution	Te Whatu Ora Waikato		9
2024 EXP 18798	Sentinel lymph node mapping in presumed early stage endometrial cancer; retrospective clinical review 2020-2023 – Te Toka Tumai Auckland.	Dr. Tom De Greve	21/03/2024	25/03/2024	Provisionally Approved	Approved	28/03/2024				10
2024 EXP 19839	Analysis of the Endolymphatic sac	Doctor Phil Bird	5/06/2024	10/06/2024	Provisionally Approved	Provisionally Approved		Private Organisation, Te Whatu Ora locality			10
2023 EXP 18441	Mortality Associated with Rheumatoid Arthritis and Rheumatoid Arthritis Associated Interstitial Lung Disease in Canterbury, Aotearoa, New Zealand	Dr Hamish Farquhar	31/07/2023	10/08/2023	Approved	Approved	18/08/2023		University of Otago		10
2023 EXP 19246	Understanding circulatory control in postural orthostatic tachycardia syndrome	Associate Professor James Fisher	4/12/2023	16/12/2023	Approved NSC	Approved	18/12/2023	Tertiary Education Institution	University of Auckland		10

2024 EXP 15283	Understanding genetic modifiers of penetrance in familial focal segmental glomerulosclerosis with a TRPC6 mutation.	Professor Martin Kennedy	8/06/2024	18/06/2024	Provisionally Approved	Provisionally Approved		Te Whatu Ora locality, Tertiary Education Institution	University of Otago, Christchurch		10
2023 EXP 18843	Assessment of colonization and scalp quality parameter improvement by topical application of probiotic <i>Micrococcus luteus</i> Q24 in healthy adults.	Dr John Tagg	30/10/2023	2/11/2023	Provisionally Approved	Approved	7/11/2023	Other	Blis Technologies		11
2023 EXP 18978	Coblation intra-capsular tonsillectomy – A cost-benefit analysis	Dr Omid Ahmadi	9/11/2023	14/11/2023	Provisionally Approved	Approved	16/11/2023		Te Whatu Ora Waikato		11
2024 EXP 19764	Examining intentional medication nonadherence among people living with cancer	Dr Kate Perry	25/03/2024	27/03/2024	Provisionally Approved	Approved	28/03/2024	Other	Atlantis Health Group Ltd		11
2024 EXP 19678	Impact of the New Zealand pine bark extract (Enzogenol®) on sucrose metabolism and glycaemic responses in healthy adults – a single-blind, randomised, placebo-controlled, crossover trial	Dr Wen Xin Janice Lim	21/03/2024	25/03/2024	Provisionally Approved	Approved	28/03/2024	Tertiary Education Institution	ENZO Nutraceuticals Limited		11
2024 EXP 17862	Traumatic brain injury (TBI). Earlier recognition and diagnosis of treatable clinical syndromes following TBI, using correlations between advanced MRI and neuropsychiatric assessments.	Dr Guillaume Newburn	15/01/2024	16/01/2024	Provisionally Approved	Approved	16/01/2024	Primary Health Care Centre, Private Organisation, Te Whatu Ora locality			11

2023 EXP 18556	Understanding pain management education provided to patients undergoing orthopaedic surgery.	Mrs Leah Chen	26/11/2023	28/11/2023	Provisionally Approved	Approved	4/12/2023	Te Whatu Ora locality	Bay of Plenty Clinical Trials Unit		11
2024 FULL 19627	Verification of height estimation equations using different body segments in a New Zealand clinical population	Mrs Nicky Breiding	28/02/2024	1/03/2024	Provisionally Approved	Approved	6/03/2024	Te Whatu Ora locality	Te Whatu Ora		11
2024 EXP 18388	Visual fixation retraining: a potential treatment for visually induced dizziness	Dr Shikha Chaudhary	23/02/2024	23/02/2024	Provisionally Approved	Approved	26/02/2024	Private Organisation , Tertiary Education Institution	AUT		11
2023 EXP 17953	"Effect of novel functional connectivity neurofeedback training on pain and function in chronic low back pain- A pilot double blinded randomised placebo-controlled trial."	Professor Dirk De Ridder	14/07/2023	21/07/2023	Approved	Approved	27/07/2023	Tertiary Education Institution	University of Otago		11
2024 FULL 19988	A Phase 1, Randomized, Double-Blind, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of STC-004	Dr Chris Wynne	8/04/2024	20/04/2024	Approved NSC	Approved	6/05/2024	Private Organisation	Avance Clinical	SiteOne Therapeutics	24
2023 EXP 18413	Azole resistance in Aspergillus fumigatus	Dr Arthur Morris	1/08/2023	10/08/2023	Provisionally Approved	Provisionally Approved		Te Whatu Ora locality			11

2023 EXP 18892	Diagnosis of parathyroid adenomas using SPECT/CT - A histopathological correlation.	Dr Jason Yeoh	22/11/2023	29/11/2023	Approved NSC	Approved	4/12/2023		Te Whatu Ora		11
2023 EXP 19366	Diagnostic workup, management, and outcomes of Nutcracker Syndrome in New Zealand	Dr Sinead Gormley	6/12/2023	16/12/2023	Declined	Declined	19/12/2023	Te Whatu Ora locality	The University of Auckland		11
2024 EXP 20026	Fluid administration and fluid overload in the intensive care unit (FLUID-ICU) - Protocol for an international inception cohort study	Prof Paul Young	26/03/2024	4/04/2024	Approved NSC	Approved	8/04/2024		Medical Research Institute of New Zealand		11
2023 EXP 19203	How many hospice patients present to hospital and why - a retrospective observational study.	Dr Phillipa Tuckey	22/11/2023	29/11/2023	Approved	Approved	4/12/2023				11
2024 EXP 19609	Kōhanga Winter Preparedness: a feasibility study	Dr Samantha Marsh	24/01/2024	1/02/2024	Approved NSC	Approved	5/02/2024	Other	University of Auckland	FluLab	11
2023 EXP 15069	Persistent SARS- COV-2 infection (PSI): A Retrospective Descriptive Study of Patients in the Auckland Region	Dr Tim Cutfield	6/09/2023	8/09/2023	Approved	Approved	18/09/2023				11

2023 EXP 19244	Quality of Paediatric Resuscitation in a multicenter Collaborative: An observational study.	Dr Gabrielle Nuthall	21/11/2023	29/11/2023	Approved	Approved	4/12/2023			Children's Hospital of Philadelphia (CHOP)	11
2023 EXP 18670	The Utility of PET CT in the Preoperative Assessment of CT Stage IA Non Small Cell Lung Cancers.	Mr Richard Kelly	6/09/2023	16/09/2023	Approved NSC	Approved	18/09/2023		Te Whatu Ora Counties Manukau		11
2023 EXP 18674	Corneal Transplantation During the COVID-19 Pandemic	Dr Jie Zhang	25/10/2023	26/10/2023	Provisionally Approved	Approved	1/11/2023		Te Toka Tumai Auckland		12
2023 EXP 19279	Host, Pathogen, and Environment in Childhood Bone and Joint infection	Dr Sarah Hunter	17/12/2023	18/12/2023	Provisionally Approved	Approved	20/12/2023	Te Whatu Ora locality	Starship Hospital		12
2024 EXP 19435	IMPACTS: Ipsilateral Motor cortex Pathway Assessment from the Contralesional hemisphere using TMS in chronic Stroke	Professor Cathy Stinear	7/02/2024	9/02/2024	Provisionally Approved	Approved	12/02/2024	Tertiary Education Institution	The University of Auckland		12
2023 EXP 18849	Neurofeedback intervention for managing neuropathic-like pain experience in musculoskeletal conditions; a pilot-feasibility clinical trial.	Dr Jerin Mathew	30/10/2023	2/11/2023	Provisionally Approved	Declined	7/11/2023	Tertiary Education Institution	Department of Anatomy, School of Biomedical Sciences, University of Otago		12

2023 EXP 18625	The economic burden of childhood bone and joint infection	Dr Sarah Hunter	8/11/2023	14/11/2023	Provisionally Approved	Approved	16/11/2023				12
2023 EXP 18894	Thyroid status of patients who have received definitive therapy for a solitary toxic nodule	Associate Professor Marianne Elston	12/10/2023	16/10/2023	Provisionally Approved	Approved	20/10/2023	Te Whatu Ora locality	Te Whatu Ora Waikato		12
2024 EXP 19544	Virtual Reality Rehabilitation Programme for Complex Regional Pain Syndrome	Dr Nusratnaaz Shaikh	26/04/2024	3/05/2024	Approved NSC	Approved	8/05/2024	Tertiary Education Institution	Auckland University of Technology		12
2023 EXP 18825	Estimating the burden of undiagnosed Ureaplasma species and Mycoplasma hominis infection in lung and renal transplant patients, and determining the antimicrobial resistance profile of these organisms in Aotearoa New Zealand	Dr Andrew Fox-Lewis	30/10/2023	2/11/2023	Provisionally Approved	Approved	7/11/2023		Te Toka Tumai Auckland, Te Whatu Ora Health New Zealand		13
2023 EXP 18647	Testing rates for familial hyperaldosteronism type 1 in Aotearoa/New Zealand	Associate Professor Marianne Elston	12/10/2023	16/10/2023	Provisionally Approved	Approved	20/10/2023		Te Whatu Ora Waikato		13
2024 FULL 2009 1	The eating behaviour in metabolically healthy New Zealanders	Associate Professor Andrea Braakhuis Braakhuis	16/05/2024	17/05/2024	Provisionally Approved	Approved	24/05/2024	Tertiary Education Institution	The University of Auckland-Clinical Research Centre		13

2023 EXP 19329	Ageing well with diabetes technology: Insulin pumping in patients aged 65+	Clinical Associate Professor Helen Lunt	30/11/2023	16/12/2023	Approved NSC	Approved	18/12/2023	Private Organisation , Te Whatu Ora locality	Te Whatu Ora Waitaha, Research Office		13
2024 EXP 20401	Digital Papillary Adenocarcinoma: A New Zealand Experience	Dr Emma Littlehales	28/05/2024	4/06/2024	Approved NSC	Approved	11/06/2024		Health Research South		13
2023 EXP 18248	How Does the Digestible Indispensable Amino Acid Score (DIAAS) Influence Protein Turnover? The Efficacy Potential of Combinatorial Proteins in Humans	Professor David Rowlands	4/07/2023	12/07/2023	Approved NSC	Approved	18/07/2023	Tertiary Education Institution	Riddet Institute		13
2023 EXP 19021	Taonga Tuku Iho: National measurement of preterm birth outcomes	Professor Katie Groom	1/12/2023	16/12/2023	Approved	Approved	18/12/2023	Tertiary Education Institution	University of Auckland		13
2023 EXP 19024	Varicella in a Paediatric Intensive Care Unit in the vaccine era: 10-year review from Starship Children's Hospital, New Zealand	Dr Michael-John Fay	18/10/2023	26/10/2023	Approved NSC	Approved	1/11/2023				13
2024 EXP 18715	Assessing the safety and efficacy of Systane Ultra Preservative Free Lubricant Eye Drops (DEU894-I001)	Professor Jennifer Craig	4/04/2024	10/04/2024	Provisionally Approved	Approved	16/04/2024	Private Organisation , Tertiary Education Institution	ICON Plc	Alcon Research LCC	14

2024 EXP 20125	Clinical and imaging findings in a South Auckland cohort with Moyamoya	Dr Karim Mahawish	2/05/2024	3/05/2024	Provisionally Approved	Approved	6/05/2024		Counties Health		14
2024 EXP 19494	Does HRV Biofeedback minimise the impact of acute stress on gastric activity? An investigation using the Cold Pressor Test and Body Surface Gastric Mapping.	Dr Elizabeth Broadbent	16/04/2024	17/04/2024	Provisionally Approved	Approved	22/04/2024	Private Organisation	The University of Auckland		14
2023 EXP 18993	Early dysphagia rehab in Critical Care: the effect of Expiratory Muscle Strength Training on swallowing, voice and cough outcomes	Associate Professor Anna Miles	22/10/2023	25/10/2023	Provisionally Approved	Declined	1/11/2023	Te Whatu Ora locality	The University of Auckland		14
2024 EXP 19398	A longitudinal survey of fetal movements in late pregnancy	Professor John Thompson	24/05/2024	4/06/2024	Provisionally Approved	Provisionally Approved		Other, Te Whatu Ora locality	The University of Auckland		14
2024 EXP 19675	A review of the management and outcomes of 1200 patients with pituitary disease by a single neurosurgeon.	Dr Hector Law	12/02/2024	24/02/2024	Approved NSC	Approved	1/03/2024		Te Whatu Ora Health New Zealand - Te Toka Tumai Auckland		14
2024 EXP 19635	Looking for biomarkers of harm in healthy vaping participants: CT imaging and induced sputum	Dr Kelly Burrowes	8/02/2024	15/02/2024	Approved NSC	Approved	23/02/2024	Te Whatu Ora locality, Tertiary Education Institution	University of Auckland		14

2024 EXP 19783	Resistance exercise and artery function	Dr Blake Perry	27/05/2024	4/06/2024	Approved NSC	Approved	11/06/2024	Tertiary Education Institution	Massey University		14
2023 EXP 17971	Should pre-procedure oral vitamin C supplementation be considered in people with diabetes undergoing dental procedures?	Associate Professor Helen Lunt	3/09/2023	8/09/2023	Approved NSC	Approved	18/09/2023	Te Whatu Ora locality, Tertiary Education Institution	New Zealand Society for the Study of Diabetes		14
2024 EXP 19741	Surgical strategy for women with advanced malignant ovarian germ cell tumour: case series and review of the literature	Doctor Cecile Bergzoll	20/06/2024	28/06/2024	Approved NSC	Approved	5/07/2024		Te Whatu Ora - Te Toka Tumai		14
2023 EXP 18021	The LipoCre Study	Professor David Rowlands	1/07/2023	3/07/2023	Provisionally Approved	Approved	17/07/2023	Tertiary Education Institution	Massey University	Pharmako Biotechnologies	46
2023 EXP 18317	A comprehensive approach to address exercise-associated gastrointestinal syndrome: Evaluation and treatment strategies	Mrs. Rachel Scrivin	24/07/2023	24/07/2023	Provisional Approval	Approved	28/07/2023	Tertiary Education Institution			15
2024 EXP 20045	How patients' and companions' beliefs about radioiodine relate to treatment experience and adherence to post-dose distancing and hygiene requirements.	Professor Keith Petrie	2/05/2024	3/05/2024	Provisionally Approved	Approved	6/05/2024	Te Whatu Ora locality	University of Auckland		15

2024 EXP 18902	SEAL™ ME: Saccular Endovascular Aneurysm Lattice System Multicenter Enrollment Global Registry	Dr James Caldwell	14/03/2024	20/03/2024	Provisionally Approved	Approved	22/03/2024	Te Whatu Ora locality	Te Whatu Ora Te Toka Tumai Auckland	Galaxy Therapeutics, Inc	15
2024 FULL 19611	Tissue and organ donor demographics in Aotearoa New Zealand	Dr Natalie Allen	20/02/2024	22/02/2024	Provisionally Approved	Approved	26/02/2024	Tertiary Education Institution	University of Auckland		15
2024 FULL 19709	A PHASE I, OPEN-LABEL, SINGLE-DOSE STUDY TO EVALUATE THE EFFECT OF MILD OR MODERATE HEPATIC IMPAIRMENT ON THE PHARMACOKINETICS OF FENEPRUTINIB	Professor Edward Gane	10/04/2024	18/04/2024	Approved NSC	Approved	6/05/2024	Private Organisation	Fortrea New Zealand Limited	Genentech, Inc.	24
2023 EXP 19053	Utility of changes in magnetic resonance spectroscopic imaging (MRSI) as a biomarker of cancer related cognitive impairment in women with breast cancer: a case control prospective cohort study.	Dr Marta Seretny	30/11/2023	16/12/2023	Approved NSC	Approved	19/12/2023	Te Whatu Ora locality, Tertiary Education Institution	University of Auckland		15
2024 EXP 19389	Validation of the classification model for Pulmonary Atresia Intact Ventricular Septum	Dr Adrian Tarca	30/04/2024	7/05/2024	Approved NSC	Approved	15/05/2024		Starship Children's Hospital		15
2023 EXP 19103	Monitoring Colorectal Cancer QPIs at Taranaki Base Hospital – A Retrospective Cohort Review	Dr Jamie-Lee Rahiri	12/11/2023	14/11/2023	Provisionally Approved	Approved	22/11/2023		Te Whatu Ora Taranaki		16

2023 EXP 18471	Outcomes after valve surgery for adult patients with active Enterococcus faecalis endocarditis.	Dr Simon Briggs	7/11/2023	13/11/2023	Provisionally Approved	Approved	15/11/2023				16
2023 EXP 19082	Patient Experiences of Apronectomy for Excess Skin Removal following significant Weight Loss in Te Tairāwhiti – a Qualitative Analysis	Dr Jamie-Lee Rahiri	8/12/2023	12/12/2023	Provisionally Approved	Approved	18/12/2023	Te Whatu Ora locality	Te Whatu Ora Tairāwhiti		16
2024 EXP 20236	CRISP: Cold temperatures in patients with SePsis - an inception cohort study	Ms Bianca Crichton	31/05/2024	10/06/2024	Approved NSC	Approved	19/06/2024		Medical Research Institute of New Zealand		16
2024 FULL 20321	Efficacy of a VR-based Balance Training Program on Exercise Adherence, Balance, and Mobility of Older Adults: A Randomized Controlled Trial	Dr. Yanxin Zhang	18/06/2024	28/06/2024	Approved NSC	Approved	5/07/2024	Private Organisation, Tertiary Education Institution	University of Auckland		16
2024 EXP 19602	Temporary epicardial pacing in cardiac surgical patients in New Zealand: a survey and prospective observational study of current management	Doctor Thomas Barr	1/06/2024	10/06/2024	Approved NSC	Approved	20/06/2024		Te Whatu Ora Te Toka Tumai		16
2024 FULL 19663	A PHASE I, OPEN-LABEL, SINGLE-DOSE STUDY TO EVALUATE THE EFFECT OF SEVERE RENAL IMPAIRMENT ON THE PHARMACOKINETICS OF FENEPRUTINIB	Dr. Nick Cross	10/04/2024	18/04/2024	Approved NSC	Approved	6/05/2024	Private Organisation	Fortrea New Zealand Limited	Genentech, Inc.	24

2023 EXP 18477	An Investigation of gas flows during preoxygenation with nasal high flow in volunteers	Mr Matthew Payton	28/08/2023	7/09/2023	Approved NSC	Approved	18/09/2023	Private Organisation	University of Auckland		17
2023 EXP 18572	Perioperative oral nutritional supplementation in patients undergoing colorectal surgery: a pilot study for a randomised clinical trial	Associate Professor Andrea Braakhuis	24/08/2023	7/09/2023	Approved NSC	Approved	18/09/2023	Te Whatu Ora locality	The University of Auckland Clinical Research Centre		17
2023 FULL 18954	A Non-Interventional Study to Collect De-Identified Data from Patients Scheduled for Holmium Laser Enucleation of the Prostate (HoLEP) Procedures and a Retrospective Review of De-identified patient Medical Charts from Completed HoLEP Procedures	Professor Peter Gilling	1/12/2023	10/12/2023	Provisionally Approved	Approved	13/12/2023	Private Organisation		Andromeda Surgical	18
2024 EXP 19433	AFT-MXIV-14: Maxigesic IV PK Study: Single-centre, randomised, open label, single dose study to evaluate the pharmacokinetic parameters of different doses of Maxigesic® IV (intravenous paracetamol + intravenous ibuprofen) in healthy Japanese volunteers and Caucasian volunteers	Dr Paul Hamilton	24/01/2024	4/02/2024	Approved NSC	Approved	12/02/2024	Private Organisation	AFT Pharmaceuticals		18
2023 EXP 19281	Family Violence Victim-Survivors and Agency Case Records: Supporting or Undermining Safety?	Professor Julia Tolmie	28/11/2023	15/12/2023	Provisionally Approved	Provisionally Approved		Tertiary Education Institution	Faculty of Law, University of Auckland		18
2024 EXP 20329	Identifying Pro-inflammatory Biomarkers for Osteoarthritis	Dr. Adele Woolley	17/06/2024	20/06/2024	Provisionally Approved	Provisionally Approved		Tertiary Education Institution	Director of Research and Enterprise, University of Otago		18

2024 EXP 19932	The effect of high dose tranexamic acid on visual acuity during arthroscopic rotator cuff repair	Dr Jonathan Chan	16/06/2024	18/06/2024	Provisionally Approved	Provisionally Approved		Private Organisation, Te Whatu Ora locality	Taranaki Base Hospital		18
2024 EXP 19156	A New Zealand Medical Retinal Outcomes Registry: Observational Registry of Standard of Care Clinical Practice and Impact on Visual Outcomes and Disease Progression	Dr Narme Deva	8/01/2024	16/01/2024	Provisionally Approved	Approved	18/01/2024				19
2023 EXP 18153	Intentional non-adherence in patients receiving methotrexate for inflammatory arthritis	Dr Rachel Murdoch	18/08/2023	22/08/2023	Provisionally Approved	Approved	25/08/2023	Te Whatu Ora locality, Tertiary Education Institution	The University of Auckland		19
2024 EXP 18691	Kinematic analysis of the scapulothoracic articulation	Professor Thor Besier	7/05/2024	7/05/2024	Provisionally Approved	Approved	15/05/2024	Private Organisation	The University of Auckland		19
2024 EXP 19357	Streptococcus pneumoniae induced haemolytic uraemic syndrome in Aotearoa, New Zealand (NZ) in the era of pneumococcal vaccination 16 years experience (2008 - 2023)	Dr Alex Humphrey	14/05/2024	15/05/2024	Provisionally Approved	Approved	24/05/2024		Starship Children's Health		19
2023 EXP 18114	The Guillain-Barre Syndrome (GBS) phenotype in Aotearoa/New Zealand, a prospective study: how ethnicity, socioeconomic and infection influence GBS outcomes.	Dr Eileen Mc Manus	2/11/2023	3/11/2023	Provisionally Approved	Approved	7/11/2023	Te Whatu Ora locality			19

2024 EXP 19336	The Prevalence of Atopic Dermatitis in the Adults in Auckland	Dr. Paul Jarrett	23/02/2024	1/03/2024	Provisionally Approved	Approved	6/03/2024		Te Whatu Ora Counties Manukau		19
2023 EXP 18094	Patient Satisfaction and Timing of Quality of Life (QoL) Questionnaires in Salivary Gland Disorders	Dr. Saskia Boogaard	23/11/2023	28/11/2023	Provisionally Approved	Approved	4/12/2023	Te Whatu Ora locality			20
2024 EXP 20665	A feasibility study to evaluate the effect of Talking About Medicines: Video Guides for Healthy Hearts	Dr Nataly Martini	27/06/2024	10/07/2024	Provisionally Approved	Provisionally Approved		Te Whatu Ora locality	The University of Auckland		20
2023 EXP 15465	Patient perceptions of using faecal immunochemical test (FIT) in assessment of symptoms indicating possible underlying colorectal cancer - A mixed methods qualitative evaluation in the FIT for Symptomatic Pilot	Professor Ian Bissett	23/08/2023	28/08/2023	Provisionally Approved	Approved	1/09/2023	Te Whatu Ora locality	Chairperson of National Bowel Cancer Working Group. Te Whatu Ora - Waikato district.		21
2024 EXP 18942	Retrospective cohort study of outcomes for women treated for ovarian, tubal and peritoneal cancer in Auckland 2007-2020	Doctor Cecile Bergzoll	6/04/2024	10/04/2024	Provisionally Approved	Approved	19/04/2024		Te Whatu Ora - Te Toka Tumai		21
2024 FULL 19999	A PHASE I, RANDOMIZED, INVESTIGATOR/PARTICIPANT-BLIND, PARALLEL-GROUP, PLACEBO-CONTROLLED, SINGLE AND MULTIPLE ASCENDING DOSE STUDY TO DETERMINE THE SAFETY, TOLERABILITY, PHARMACOKINETICS, AND PHARMACODYNAMICS OF	Dr Millie Wang	10/04/2024	21/04/2024	Approved NSC	Approved	6/05/2024	Private Organisation		Roche Products (New Zealand) Ltd	24

	RO7504109 IN HEALTHY PARTICIPANTS.										
2024 FULL 19736	Addressing gaps in the surveillance and response to influenza-like illness: A community pharmacy-based feasibility study	Prof Alex Semprini	14/03/2024	22/03/2024	Approved NSC	Approved	8/04/2024	Other	Medical Research Institute of New Zealand		24
2023 EXP 18611	The Association between Frailty Index and Severe/Critical Aortic Stenosis in New Zealand	Cardiology Research Fellow Timothy Oh	14/09/2023	17/09/2023	Provisionally Approved	Provisionally Approved					21
2023 EXP 17984	The development of a device to allow the accurate estimation of the urine production rate and automatic dilution for the subsequent development of quantitative diagnostic tests for various urinary metabolites	Chief Scientist (Dr) Delwyn Cooke	19/09/2023	4/10/2023	Approved NSC	Approved	11/10/2023	Private Organisation	Science Haven Limited		21
2023 FULL 18667	The Role of Surgical Timing on Functional Outcomes of Traumatic Full-Thickness Rotator Cuff Tear Repair	Dr Michael van der Merwe	27/08/2023	7/09/2023	Approved NSC	Approved	18/09/2023	Private Organisation			21
2024 FULL 17901	Clinical efficacy of single dose (daily) IV antibiotics followed by two days oral antibiotics compared to three doses (daily) IV antibiotics for children with complicated urinary tract infections: a multicentre randomised trial.	Professor Stuart Dalziel	11/03/2024	20/03/2024	Provisionally Approved	Provisionally Approved		Te Whatu Ora locality		Royal Children's Hospital	24

2023 EXP 18564	Vascular risk equity for Aotearoa NZ- safe return of data to PHOs	Assoc Prof Sue Wells	15/09/2023	4/10/2023	Approved	Approved	11/10/2023	Tertiary Education Institution	University of Auckland		22
2024 EXP 18049	Young New Zealanders' experiences and views about media content, online behaviour, and the potential impacts on body image	Dr Phillipa (Pip) Aimer	27/02/2024	1/03/2024	Provisionally Approved	Approved	6/03/2024	Te Whatu Ora locality			24
2023 FULL 18969	New Techniques to Understand the Development of Diabetic Kidney Disease Amongst Māori and Pasifika	Associate Professor John Baker	12/10/2023	20/10/2023	Approved NSC	Approved	6/11/2023	Tertiary Education Institution	Middlemore Hospital		24
2024 FULL 19755	Safety and Efficacy of the Infinity Figure 8 balloon dilator for Improvement of Swallowing in Patients with Upper esophageal sphincter obstruction	Associate Professor Jacqui Allen	9/03/2024	20/03/2024	Declined	Declined	8/04/2024	Private Organisation , Te Whatu Ora locality	Te Whatu Ora Waitemata		24
2024 FULL 19823	Uplifting the mana of Pacific young people in Ōtepoti	Ms Rupi Riley	11/03/2024	21/03/2024	Declined	Declined	8/04/2024	Other			24
2023 FULL 18897	A Phase 1 Open-label, Parallel-Group, Single-Dose Study to Evaluate the Pharmacokinetics and Safety of Obeldesivir in Participants With Normal Renal Function and Renal Impairment	Dr Nick Cross	11/10/2023	22/10/2023	Approved NSC	Approved	6/11/2023	Private Organisation	Gilead Sciences Pty Ltd	Gilead Sciences, Inc	25

2024 FULL 1994 7	A Phase 1, Randomised. Double-Blind, Placebo-Controlled Study of the Safety, Tolerability, and Pharmacokinetics of ALN-ANG3 in Otherwise Healthy Adult Participants	Dr Jane Kerr	10/04/2024	20/04/2024	Approved NSC	Approved	6/05/2024	Private Organisation	ICON Clinical Research (New Zealand) Ltd	Regeneron Pharmaceuticals, Inc.	25
2023 FULL 1835 2	A Phase 3, Multinational, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of NTLA-2001 in Participants with Transthyretin Amyloidosis with Cardiomyopathy (ATTR-CM)	Dr Timothy Sutton	8/08/2023	18/08/2023	Approved NSC	Approved	4/09/2023	Private Organisation	CARSL Consulting (Clinical and Regulatory Services limited)	Intellia Therapeutics, Inc.	25
2023 FULL 1886 2	A Phase II, Multicenter Single-arm Study Evaluating the Efficacy, Safety, Pharmacokinetics and Pharmacodynamics of Crovalimab in Adult and Adolescent Participants With Atypical Hemolytic Uremic Syndrome (aHUS)	Professor Robert Walker	6/10/2023	17/10/2023	Approved NSC	Approved	6/11/2023	Private Organisation, Te Whatu Ora locality	Te Whatu Ora Southern University of Otago	Roche Products (New Zealand) Limited	25
2023 FULL 1829 7	A Sequential, Randomized, Double-Blind, Placebo-Controlled, Phase 1 Single and Multiple Ascending Dose Study of LTG-001 Administered Orally to Evaluate the Safety, Tolerability, and Pharmacokinetics in Healthy Male and Female Participants 18 to 55 Years of Age	Dr Alexandra Cole	7/08/2023	11/08/2023	Approved NSC	Approved	4/09/2023	Private Organisation	PPD, Part of Thermo Fisher Scientific	Latigo Biotherapeutics, Inc.	25
2023 FULL 1781 8	COG AOST2032: A Feasibility and Randomised Phase 2/3 Study of the VEGFR2/MET Inhibitor Cabozantinib in Combination with Cytotoxic Chemotherapy for Newly Diagnosed Osteosarcoma	Dr Tristan Pettit	11/10/2023	22/10/2023	Approved NSC	Approved	6/11/2023	Te Whatu Ora locality		Children's Oncology Group	25

2024 EXP 19649	Corneal Transplant Endothelial Cell Characteristics: a specular and confocal microscopy analysis	Dr Jie Zhang	12/04/2024	15/04/2024	Provisionally Approved	Approved	19/04/2024	Te Whatu Ora locality	University of Auckland		25
2023 EXP 16784	Parent Peer Support for Caregivers of Children with a Feeding Tube: A Pilot Survey	Dr Sarah Leadley (Doctoral Supervisor for Rae Padd)	25/08/2023	28/08/2023	Provisionally Approved	Approved	4/09/2023	Other	University of Auckland		25
2023 FULL 17990	Morphological awareness in children with hearing aids	Miss Caelyn Eades	25/09/2023	18/10/2023	Declined	Declined	6/11/2023	Other, Tertiary Education Institution	University of Canterbury		25
2023 FULL 18371	Phase 1/2a Dose-Escalating Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of ARO-DUX4 in Adult Patients with Facioscapulohumeral Muscular Dystrophy Type 1	Associate Professor Richard Roxburgh	3/08/2023	18/08/2023	Approved NSC	Approved	4/09/2023	Private Organisation	Novotech (New Zealand) Limited	Arrowhead Pharmaceuticals Inc.	25
2023 FULL 13989	Pilot Study- Assessment of FAPI PETCT in Neuroendocrine tumours with discordant disease at FDG PETCT	Dr Andrew Henderson	4/08/2023	18/08/2023	Approved NSC	Approved	4/09/2023	Private Organisation			25
2023 FULL 18299	Setting the research agenda for tertiary paediatric rehabilitation in Aotearoa New Zealand using a Priority Setting Partnership process	Dr Jimmy Chong	17/07/2023	8/08/2023	Declined	Declined	4/09/2023	Te Whatu Ora locality	Auckland University of Technology		25

2023 FULL 1677 6	The effect of a novel nasal mask on minute ventilation in adults with chronic respiratory failure: A pilot randomised cross-over trial.	Dr Julie Cook	7/08/2023	19/08/2023	Approved NSC	Approved	4/09/2023	Private Organisation , Te Whatu Ora locality	Fisher & Paykel Healthcare		25
2023 FULL 1825 7	Using codesign to create an early-life hearing health service which meets the needs of teenage parents.	Dr Andrew Wood	4/08/2023	15/08/2023	Declined	Declined	4/09/2023	Other			25
2023 FULL 1320 8	ZERO2 Precision Medicine for Every Child with Cancer	Dr Andrew Wood	14/12/2023	26/01/2024	Approved NSC	Approved	12/03/2024	Te Whatu Ora locality	Te Whatu Ora-Health New Zealand, Te Toka Tumai-Auckland	Australian and New Zealand Children's Haematology Oncology Group (ANZCHOG)	25
2023 FULL 1805 0	An Extension Study to Monitor Long-Term Safety of LUM-201 Treatment in Children with Idiopathic Growth Hormone Deficiency	Dr. Esko Wiltshire	8/08/2023	10/08/2023	Provisionally Approved	Approved	16/08/2023	Other	Novotech (New Zealand) Limited	Lumos Pharma	26
2024 FULL 1927 6	A First-in-Human, Phase 1, Double-Blind, Randomised, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of Ginger Tincture extract (Carelwon®; zingerone 12.5 mg/mL) in Healthy Volunteers.	Dr Alexander Semprini	9/01/2024	23/01/2024	Approved NSC	Approved	13/02/2024	Private Organisation	Evithé Biotechnology Pty Ltd		26
2023 FULL 1923 3	A PHASE 1/2A DOSE-ESCALATING STUDY TO EVALUATE THE SAFETY, TOLERABILITY, PHARMACOKINETICS, AND PHARMACODYNAMICS OF SINGLE AND MULTIPLE DOSES OF ARO-CFB IN ADULT HEALTHY VOLUNTEERS AND ADULT	Dr Christian Schwabe	21/12/2023	23/01/2024	Approved	Approved	13/02/2024	Private Organisation	Novotech (New Zealand) Pty Ltd.	Arrowhead Pharmaceuticals Inc.	26

	PATIENTS WITH COMPLEMENT-MEDIATED KIDNEY DISEASE										
2024 FULL 1898 6	A single blinded, parallel group, 2-arm randomised control trial investigating immunogenicity and reactogenicity of subcutaneous (SC) vs intramuscular (IM) administration of Pfizer COVID-19 vaccine in adults aged 18 – 75 years	Dr Gabby Shortt	9/02/2024	24/02/2024	Approved NSC	Approved	12/03/2024	Other	Medical Research Institute of New Zealand		26
2024 FULL 1810 9	Colorectal Anastomosis and Bacterial Eradication (CABE) Trial: The effect of pre-operative antibiotics on Anastomotic Leaks in Colorectal Surgery	DR John Woodfield	9/01/2024	27/01/2024	Approved NSC	Approved	13/02/2024	Te Whatu Ora locality	Research and enterprise University of Otago		26
2024 FULL 1959 6	Does Paracetamol decrease reperfusion injury to patients presenting with acute ST-elevation myocardial infarction when given prior to primary percutaneous intervention.	Dr Adrian Owen	8/05/2024	24/05/2024	Declined	Declined	11/06/2024	Te Whatu Ora locality	Te Whatu Ora Waikato		26
2024 EXP 19848	An online survey to define the prevalence, impact and treatment of primary dysmenorrhea, and exercise status of Aotearoa New Zealand women and those who menstruate	Miss Melissa Black	8/05/2024	15/05/2024	Provisionally Approved	Approved	24/05/2024	Private Organisation	Medical Research Institute of New Zealand		26
2024 FULL 2025 2	Double-Blind, Placebo-Controlled, Phase 3 Study to Evaluate the Efficacy and Safety of Plozasiran in Adults with Severe Hypertriglyceridemia (SHASTA-4 Study)	Prof Russell Scott	9/05/2024	24/05/2024	Provisionally Approved	Provisionally Approved		Primary Health Care Centre, Private Organisation	IQVIA RDS Pty. Ltd	Arrowhead Pharmaceuticals, Inc.	26

2024 FULL 1836 1	Evaluation of the safety and efficacy of 150mg and 300mg of OMG-100 cannabis for insomnia: a phase IIB/III, randomised, double-blind, placebo controlled study.	Dr Alex Semprini	12/02/2024	26/02/2024	Declined	Declined	12/03/2024	Other		Oz Medicann Group	26
2023 FULL 1941 8	He Kōwhiringa Hōu – A new primary care treatment pathway for whānau impacted by treatment-resistant depression	Director of Awa Associates Ms Suaree Borell	20/12/2023	23/01/2024	Declined	Declined	13/02/2024	Primary Health Care Centre			26
2024 FULL 2012 4	M20-465: A Phase 3 Multicenter, Randomized, Double-Blind Placebo-Controlled Study to Evaluate the Efficacy and Safety of Lutikizumab in Adult and Adolescent Subjects with Moderate to Severe Hidradenitis Suppurativa	Professor Marius Rademaker	9/05/2024	24/05/2024	Provisionally Approved	Provisionally Approved		Private Organisation, Te Whatu Ora locality	AbbVie Ltd	AbbVie Ltd	26
2024 FULL 2004 1	Phase 1 trial of intraperitoneal lignocaine eluting implant for postoperative analgesia in elective laparoscopic colectomy	Professor Andrew Hill	15/05/2024	24/05/2024	Provisionally Approved	Provisionally Approved		Te Whatu Ora locality	University of Auckland		26
2023 FULL 1918 1	Phase 1/2 Multicenter, Open-label Study to Evaluate Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of NTLA-3001 in Participants with Alpha-1 Antitrypsin Deficiency (AATD)-Associated Lung Disease	Dr Mark O'Carroll	15/12/2023	25/01/2024	Provisionally Approved	Provisionally Approved		Private Organisation	CARSL Consulting (Clinical and Regulatory Services Limited)	Intellia Therapeutics, Inc.	26
2024 FULL 1807 0	The PRECeDe Trial: Prevention of neonatal Respiratory distress with antenatal corticosteroids prior to Elective Caesarean section in women with diabetes – A Randomised Trial	Professor Katie Groom	13/05/2024	22/05/2024	Provisionally Approved	Provisionally Approved		Te Whatu Ora locality, Tertiary Education Institution	University of Auckland	The University of Melbourne	26

2023 FULL 1939 5	YST-162-102: A Multi-center, Randomized, Double-blind, Placebo-controlled Phase 1b Clinical Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of 162 with a Single Ascending Dose in Subjects with Chronic Hepatitis B Virus Infection	Dr Paul Hamilton	21/12/2023	25/01/2024	Approved NSC	Approved	13/02/2024	Private Organisation	Research Associates Ltd	Yangshengtang Co., Ltd	26
2024 FULL 1877 6	Evaluation of the Safety and Performance of the Zenith LAA Occlusion System and Procedure for the mechanical closure of the Left Atrial Appendage (LAA).	Dr Matthew O'Connor	11/01/2024	16/01/2024	Provisionally Approved	Approved	18/01/2024	Te Whatu Ora locality	Clinical Research Consulting Ltd	AuriGen Medical Ltd	27
2024 FULL 1918 8	Feasibility and Safety of PillBot™ - Remotely Controlled Capsule Endoscopy	Dr Cameron Schauer	21/02/2024	22/02/2024	Provisionally Approved	Approved	23/02/2024	Private Organisation		Mayo Clinic, Florida, USA	27
2024 FULL 1893 9	Inhaled rifampicin safety and dose finding proof of concept study	Dr Jack Dummer	16/02/2024	20/02/2024	Provisionally Approved	Approved	23/02/2024	Te Whatu Ora locality, Tertiary Education Institution	University of Otago		27
2024 FULL 1860 0	Prophylactic Exclusion of the Left Atrial Appendage for Rheumatic Heart Disease via Epicardial Ligation: Feasibility Study	Dr. Zachary DeBoard	8/04/2024	18/04/2024	Approved NSC	Approved	6/05/2024	Te Whatu Ora locality	Waikato Hospital		27
2024 FULL 1869 7	COG AAML1831: A Phase 3 Randomized Trial for Patients with de novo AML Comparing Standard Therapy Including Gemtuzumab Ozogamicin (GO) to CPX-351 with GO, and the Addition of the FLT3 Inhibitor Gilteritinib for Patients with FLT3 Mutations	Dr Siobhan Cross	13/02/2024	14/02/2024	Provisionally Approved	Approved	19/02/2024	Te Whatu Ora locality	Children's Oncology Group	Children's Oncology Group	28

2023 EXP 18081	Comparing Nail versus Locking Plate in displaced three-part proximal humerus fractures; A pilot randomised controlled trial	Dr Zohreh Jafarian Tangrood	15/09/2023	18/09/2023	Provisionally Approved	Approved	22/09/2023	Te Whatu Ora locality			28
2023 FULL 18562	A PHASE 1, SINGLE CENTER, OPEN-LABEL STUDY TO EVALUATE THE PHARMOKINETICS, BIOAVAILABILITY, DOSE PROPORTIONALITY, SAFETY, AND TOLERABILITY OF SINGLE ASCENDING DOSES OF DIHYDROERGOTAMINE MESYLATE (ZEPHYR) INHALATION POWDER, AND DIHYDROERGOTAMINE MESYLATE INTRAVENOUS, IN HEALTHY ADULT SUBJECTS	Dr Alexandra Cole	13/09/2023	20/09/2023	Approved NSC	Approved	13/10/2023	Private Organisation	Syneos Health New Zealand Ltd.	Ventura, Inc.	28
2023 FULL 18635	A Phase 1b, Single-Centre, Open-Label Dose Ranging Study of an Optimized Formulation of VLS-01 in Healthy Adult Volunteers	Dr Christian Schwabe	12/09/2023	21/09/2023	Approved NSC	Approved	13/10/2023	Private Organisation	Novotech (New Zealand) Limited	Atai Therapeutics Pty Ltd	28
2023 FULL 18134	A Randomized Study of Andexanet Alfa Compared to Usual Care in Patients Receiving a Factor Xa Inhibitor who Require Urgent Surgery or Procedure (ANNEXA-RS)	Dr Laura Young	8/09/2023	20/09/2023	Declined	Declined	13/10/2023	Te Whatu Ora locality	Te Toka Tumai Auckland	Research Monitoring Services Ltd	28
2023 FULL 15375	COG ARST2032: A Prospective Phase 3 Study of Patients with Newly Diagnosed Very Low-risk and Low-risk Fusion Negative Rhabdomyosarcoma	Dr Mandy De Silva	14/09/2023	22/09/2023	Approved NSC	Approved	13/10/2023	Te Whatu Ora locality		Children's Oncology Group	28

2023 EXP 17879	A digital Acceptance and Commitment Therapy and education intervention (ACT for Pēpi) targeting stress for parents and caregivers with preterm babies in the neonatal intensive care unit (NICU): a randomised controlled cluster trial	Dr Jane Alsweiler	2/08/2023	8/08/2023	Provisionally Approved	Approved	16/08/2023	Te Whatu Ora locality	University of Auckland		29
2024 EXP 20266	Exploring Biological Markers for Parkinson's Disease and Associated Neurodegenerative Disorders	Dr Victor Dieriks	27/06/2024	10/07/2024	Provisionally Approved	Approved	19/07/2024	Tertiary Education Institution	The University of Auckland		28
2023 EXP 18411	Patient/consumer perspectives on the use of personal health information for AI and algorithms	Dr Rosie Dobson	30/08/2023	7/09/2023	Provisionally Approved	Approved	13/09/2023	Other, Te Whatu Ora locality, Tertiary Education Institution	Te Whatu Ora Waitematā		28
2024 FULL 17797	Broad-spectrum micronutrients delivered via oral mucosa alongside an online mindfulness programme as a treatment for emotional dysregulation in children aged 6–10 years: a randomised controlled trial	Miss Parris Theobald	11/03/2024	14/03/2024	Provisionally Approved	Approved	15/03/2024	Tertiary Education Institution	University of Canterbury		29
2023 FULL 15536	Development of a non-invasive "liquid biopsy" for <i>Kingella kingae</i> and <i>Staphylococcus aureus</i> infections in children using cell-free DNA.	Dr Amy Scott-Thomas	4/09/2023	7/09/2023	Provisionally Approved	Approved	13/09/2023	Te Whatu Ora locality, Tertiary Education Institution	Director, Research and Enterprise		29
2024 FULL 19267	Morphological awareness in children with/without hearing aids	Miss Caelyn Eades	10/01/2024	17/01/2024	Provisionally Approved	Approved	19/01/2024	Tertiary Education Institution	University of Canterbury		29

2023 FULL 18793	Randomised, double blind, placebo-controlled study to investigate a single administration of BI 765845 on top of standard of care in patients with acute myocardial infarction	Dr Philip Adamson	18/12/2023	20/12/2023	Provisionally Approved	Approved	10/01/2024	Te Whatu Ora locality	Boehringer Ingelheim (N.Z) Limited	Boehringer Ingelheim Pty Ltd	29
2024 FULL 19372	Talk That Heals: Evaluation of a Collaborative Discovery Intervention for Parents with a Mental Illness	Dr Lillian Ng	6/03/2024	8/03/2024	Provisionally Approved	Approved	11/03/2024	Primary Health Care Centre, Te Whatu Ora locality			29
2023 FULL 17949	A Phase 2/3 Randomized, Placebo-Controlled, Double-blind, Clinical Study to Evaluate the Efficacy, Safety, and Pharmacokinetics of Vericiguat in Pediatric Participants with Heart Failure due to Systemic Left Ventricular Systolic Dysfunction (VALOR)	Dr Bryan Mitchelson	21/08/2023	22/08/2023	Provisionally Approved	Approved	31/08/2023	Te Whatu Ora locality	Merck Sharp & Dohme (New Zealand) Limited (MSD), a subsidiary of Merck & Co., Inc., Rahway, NJ, USA	Merck & Co. Inc.	30
2023 FULL 12903	Body Surface Gastric Mapping to Evaluate Patients with Gastrointestinal Symptoms and Controls	Dr Stefan Calder	20/09/2023	22/09/2023	Provisionally Approved	Approved	27/09/2023	Private Organisation			30
2024 FULL 19954	A Multicenter, Randomized Study to Evaluate the Safety and Efficacy of Lutikizumab for Induction and Maintenance Therapy in Subjects with Moderately to Severely Active Ulcerative Colitis	Dr James Brooker	22/04/2024	23/04/2024	Provisionally Approved	Approved	1/05/2024	Te Whatu Ora locality	AbbVie Ltd		31
2024 FULL 18530	A Prospective Phase III Multi-center, Placebo Controlled, Double Blind Study to Evaluate the Efficacy and Safety of "Kamada-AAT for Inhalation" 80 mg per day in Adult Patients with Congenital Alpha-1 Antitrypsin Deficiency with Moderate and Severe Airflow	Dr Michael Epton	21/02/2024	22/02/2024	Provisionally Approved	Approved	1/03/2024	Te Whatu Ora locality	Syneos Health New Zealand Ltd	Kamada Ltd.	31

	Limitation ($40\% \leq FEV1 \leq 80\%$ of predicted; $FEV1/SVC \leq 70\%$)										
2023 FULL 1878 2	A randomized, double-blind, dose-ranging, placebo-controlled study to evaluate the efficacy and safety of PLN-74809 (bexotegrast) for the treatment of idiopathic pulmonary fibrosis (BEACON-IPF)	Dr Catherina Chang	14/11/2023	15/11/2023	Provisionally Approved	Approved	22/11/2023	Private Organisation, Te Whatu Ora locality	PPD Global Limited, part of TMF Group	Pliant Therapeutics Inc	31
2023 FULL 1558 5	A Phase 3 Randomized, Double-blind, Placebo-controlled Study to Evaluate the Efficacy and Safety of Dazodalibep in Participants With Sjögren's Syndrome With Moderate-to-severe Systemic Disease Activity.	Doctor Sunil Kumar	2/11/2023	3/11/2023	Provisionally Approved	Approved	7/11/2023	Private Organisation, Te Whatu Ora locality	PPD Part of Thermo Fisher	Horizons Therapeutics Ireland DAC	32
2023 FULL 1869 8	SWiFT study of whole blood in frontline trauma	Dr Richard Charlewood	13/12/2023	17/12/2023	Provisionally Approved	Declined	20/12/2023	Private Organisation	New Zealand Blood Service	NHS Blood and Transplant	32
2024 FULL 1969 9	A Phase 3 Multicenter Study to Evaluate Efficacy, Safety, and Pharmacokinetics of Upadacitinib with Open-Label Induction, Randomized, Double-Blind Maintenance and Open-Label	Prof. Andrew Day	14/05/2024	16/05/2024	Provisionally Approved	Approved	24/05/2024	Te Whatu Ora locality	Abbvie Ltd	AbbVie Ltd	33
2023 FULL 1811 5	A Phase II/III Multicenter Randomized, Double-Blind, Placebo-Controlled Platform Trial of Potential Disease Modifying Therapies Utilizing Biomarker, Cognitive, and Clinical Endpoints in Dominantly Inherited Alzheimer's Disease	Dr Campbell Le Heron	21/11/2023	22/11/2023	Provisionally Approved	Approved	27/11/2023	Other	IQVIA RDS Pty Limited	Washington University in St. Louis	33

2024 FULL 1970	A RANDOMIZED, PLACEBO-CONTROLLED STUDY TO EVALUATE CLEARANCE OF HIGH-RISK HUMAN PAPILLOMAVIRUS AND SAFETY AFTER ADMINISTRATION OF ABI-2280 VAGINAL INSERTS	Dr Claire Thurlow	10/06/2024	12/06/2024	Provisionally Approved	Approved	21/06/2024	Other, Private Organisation	ICON Clinical Research (New Zealand) Ltd.	Antiva Biosciences, Inc.	33
2024 EXP 20033	A study to differentiate oral lesions based on elasticity parameters using a novel ultrasound device	Prof. Warwick Duncan	18/06/2024	20/06/2024	Provisionally Approved	Approved	5/07/2024	Tertiary Education Institution	University of Otago Otago Innovation Limited		32
2023 FULL 17794	Concentrations of Thioguanine and its metabolite 6TGN in Blood and Rectal Tissue Samples in Patients Administered Thioguanine by Suppository	Professor Murray Barclay	21/12/2023	16/01/2024	Provisionally Approved	Approved	17/01/2024	Private Organisation	Barclay Gastroenterology		33
2023 FULL 17870	A PHASE I/II STUDY TO EVALUATE THE SAFETY, TOLERABILITY, PHARMACOKINETICS, PHARMACODYNAMICS, AND EFFICACY OF NXT007 IN PERSONS WITH SEVERE OR MODERATE HEMOPHILIA A	Dr. Laura Young	11/07/2023	13/07/2023	Provisionally Approved	Approved	20/07/2023	Te Whatu Ora locality		Roche Products (New Zealand) Ltd.	34
2023 FULL 18534	An exploration of the effectiveness, feasibility and acceptability of a DBT in schools (STEPS-A) programme in Aotearoa New Zealand	Dr Liesje Donkin	9/10/2023	10/10/2023	Provisionally Approved	Approved	19/10/2023	Te Whatu Ora locality	Tu Whatu Ora Waitematā		34
2023 FULL 18730	Automated vital sign monitoring devices in acutely unwell general medical inpatients: an exploratory study	Dr Julie Cook	4/12/2023	5/12/2023	Provisionally Approved	Approved	15/12/2023	Te Whatu Ora locality	Fisher and Paykel Healthcare		34

2024 FULL 19740	Screening and managing mild traumatic brain injury in the emergency department.	Professor Alice Theadom	8/05/2024	16/05/2024	Provisionally Approved	Approved	17/05/2024	Te Whatu Ora locality	AUT		34
2024 FULL 19509	SWiFT study of whole blood in frontline trauma	Dr Richard Charlewood	18/04/2024	19/04/2024	Provisionally Approved	Approved	23/05/2024	Private Organisation	New Zealand Blood Service	NHS Blood and Transplant	34
2023 FULL 18148	A multinational, multicenter, prospective, randomized controlled, open label Phase 3 study with best standard of care with and without 177Lu-DOTA-rosopitamab for patients with PSMA expressing metastatic castration-resistant prostate cancer progressing despite prior treatment with a novel androgen axis drug	Dr Remy Lim	6/07/2023	17/07/2023	Provisionally Approved	Approved	24/07/2023	Private Organisation	Telix Pharmaceuticals (NZ) Ltd	Telix International Pty Ltd	35
2024 EXP 19761	New Zealand Arm of the International Spinal Cord Injury (NZ-InSCI) Community Survey	Dr Joanne (Jo) Nunnerley	20/05/2024	4/06/2024	Provisionally Approved	Approved	11/06/2024	Te Whatu Ora locality	Burwood Spinal Service and Brain Injury Rehabilitation Service, OPH & R Te Whatu Ora Waitaha Canterbury	Swiss Paraplegic Research in Nottwil	34
2024 FULL 18513	A proof of concept, three-cohort, open-label study to investigate the safety and preliminary efficacy of TN-001 topical eyedrops (Transforming Growth Factor Beta-3 and dexamethasone sodium phosphate) in male and female adult volunteers with permanent vision loss and in patients with progressive keratoconus.	Dr Rasha Altaie	7/03/2024	10/03/2024	Provisionally Approved	Approved	21/03/2024	Te Whatu Ora locality	TheiaNova Ltd.		35

2024 FULL 1796 1	Pulmonary hypertension in the premature newborn; evaluating the clinical feasibility and utility of a diagnostic guidelines to detect late disease in a high-risk population in the New Zealand setting	Doctor Matthew Buckingham	13/05/2024	16/05/2024	Provisionally Approved	Approved	24/05/2024	Te Whatu Ora locality			35
2024 FULL 1673 3	A multi-centre, Australian and New Zealand, phase II exploratory study of amendments to conditioning regimens in haplo-identical stem cell transplantation – The ANZHIT-2 study	Dr Clinton Lewis	13/06/2024	23/06/2024	Provisionally Approved	Provisionally Approved		Te Whatu Ora locality	Auckland City Hospital		35
2024 FULL 2018 5	A Phase 1/1b Open-Label Dose-Escalation Study of Bcl-2 Inhibitor BGB-21447 in Patients With Mature B-Cell Malignancies	Dr Henry Sze Liang Ngu	5/06/2024	17/06/2024	Provisionally Approved	Provisionally Approved		Te Whatu Ora locality	BeiGene NZ Unlimited		35
2024 FULL 2051 2	A Phase 2 Study to Evaluate the Pharmacokinetics, Efficacy, and Safety of Subcutaneous Pembrolizumab Coformulated With Hyaluronidase (MK-3475A) in Participants with Relapsed or Refractory Classical Hodgkin Lymphoma (rrcHL) or Relapsed or Refractory Primary Mediastinal Large B-cell Lymphoma (rrPMBCL).	Dr Anthony Rahman	11/06/2024	22/06/2024	Approved NSC	Approved	19/07/2024	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	35
2024 FULL 2052 1	A Prospective, Single-arm, Open-label, Interventional, Pilot Study to Evaluate the Efficacy and Safety of the Continuous Glucose Monitoring System 'CareSens Air 2' in Children and Adult Participants with Type 1 and Type 2 Diabetes	Professor Benjamin Wheeler	11/06/2024	21/06/2024	Provisionally Approved	Provisionally Approved		Te Whatu Ora locality, Tertiary Education Institution	Health New Zealand - Southern	i-SENS, Inc.	35

2024 FULL 2054 9	A three-part, multi-centre randomised, double-blind, placebo-controlled study to evaluate the safety, tolerability, pharmacokinetics, and immunogenicity of FB102 after single and multiple ascending dose administrations in healthy participants and multiple dose administration in participants with celiac disease.	Dr Nah Yeon (Tina) Baik	13/06/2024	24/06/2024	Approved NSC	Approved	19/07/2024	Private Organisation	Avance Clinical (Representative, CRO)	Forte Biosciences Australia Pty Ltd	35
2024 FULL 2047 2	Feasibility study of ambulatory Holter monitoring while receiving infusional fluorouracil (5-FU) chemotherapy	Dr Nicola Lawrence	5/06/2024	17/06/2024	Approved NSC	Approved	19/07/2024	Te Whatu Ora locality	University of Auckland		35
2024 EXP 20133	Is increased ionised serum calcium or patterns of change in serum potassium concentration a reliable indicator of hypophosphataemia and refeeding syndrome in extremely low birthweight babies in the first 2 weeks after birth.	Dr Barbara Cormack	6/06/2024	13/06/2024	Declined	Declined	19/07/2024		University of Auckland		35
2023 FULL 1817 6	Ketamine versus Ketamine plus Behavioural Activation Therapy for Adults with Treatment Resistant Depression	Dr Ben Beaglehole	14/09/2023	15/09/2023	Provisionally Approved	Approved	26/09/2023	Te Whatu Ora locality, Tertiary Education Institution	Director, Research and Enterprise		36
2024 FULL 1901 9	Paediatric Patient-Reported Outcomes in Inherited Retinal Diseases	Dr Sarah Hull	4/06/2024	21/06/2024	Declined	Declined	19/07/2024	Te Whatu Ora locality	Auckland University and Greenlane Clinical Centre		36

2024 FULL 20208	The caregiver and parental experience of IFNAR1 deficiency in Aotearoa New Zealand.	Dr Simone Watkins	4/06/2024	13/06/2024	Declined	Declined	19/07/2024	Tertiary Education Institution	University of Auckland		36
2024 EXP 18292	Puku Ora Pilot Study	Dr Stephen Inns	2/02/2024	5/02/2024	Provisionally Approved	Approved	12/02/2024	Private Organisation	University of Otago Wellington		36
2023 EXP 15148	The evaluation of treatment outcomes for methamphetamine dependence in Aotearoa New Zealand	Associate Professor David Newcombe	21/07/2023	24/07/2023	Provisionally Approved	Approved	28/07/2023	Other, Primary Health Care Centre, Private Organisation, Te Whatu Ora locality	University of Auckland		37
2024 FULL 19101	An open-label extension trial of the long-term safety and efficacy of BI 1015550 taken orally in patients with idiopathic pulmonary fibrosis (IPF) and progressive pulmonary fibrosis (PPF) (FIBRONEER™-ON)	Doctor Conor O'Dochartaigh	28/03/2024	4/04/2024	Provisionally Approved	Approved	10/04/2024	Te Whatu Ora locality	Boehringer Ingelheim NZ Limited	Boehringer Ingelheim	37
2024 EXP 19869	Validating the Diagnostic Accuracy of an Artificial Intelligence Tool Intended to Enhance Dermatology Referrals in New Zealand.	Dr Hamish Wu	28/05/2024	10/06/2024	Provisionally Approved	Approved	12/06/2024		Health New Zealand Waikato		37
2024 FULL 19810	1368-0130: Lunsayil LTE: An extension trial assessing long-term spesolimab treatment in patients with Hidradenitis Suppurativa (HS)	Dr Marius Rademaker	8/05/2024	17/05/2024	Provisionally Approved	Approved	24/05/2024	Private Organisation	Boehringer Ingelheim NZ Ltd	Boehringer Ingelheim Pty Ltd	38

2023 FULL 18338	Understanding Measles: Severity and Sequelae - Substudy	Dr Emma Best	30/11/2023	6/12/2023	Provisionally Approved	Approved	15/12/2023	Te Whatu Ora locality, Tertiary Education Institution			38
2024 FULL 19526	A Multicenter, Open-Label, Extension Study Evaluating the Safety and Efficacy of Bomedemstat for the Treatment of Participants Enrolled in a Prior Bomedemstat Clinical Study (MK-3543-017)	Dr James Liang	27/03/2024	27/03/2024	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	39
2024 FULL 19653	Tailored to me: Evaluating the effectiveness and acceptability of behavioural assessments for people living with dementia	Dr Rebecca Sharp	26/03/2024	3/04/2024	Provisionally Approved	Approved	10/04/2024	Private Organisation	University of Auckland		39
2023 FULL 16748	A randomized, double-blind, placebo-controlled Phase 3 study of darolutamide plus androgen deprivation therapy (ADT) compared with placebo plus ADT in patients with high-risk biochemical recurrence (BCR) of prostate cancer	Mr. Kevin Bax	4/07/2023	6/07/2023	Provisionally Approved	Approved	20/07/2023	Private Organisation, Te Whatu Ora locality	Bayer New Zealand Limited	Bayer Consumer Care AG	41
2023 EXP 18567	100 women: Healthcare needs of women referred to community mental health services	Dr Lillian Ng	13/12/2023	14/12/2023	Provisional Approval	Approved	18/12/2023	Te Whatu Ora locality	Te Whatu Ora Counties Manukau		40
2024 FULL 19301	A whole-food diet and obsessive-compulsive disorder: a pilot study	Ms Sophia Dawson	22/05/2024	29/05/2024	Provisionally Approved	Approved	11/06/2024	Tertiary Education Institution	University of Canterbury		42

2024 FULL 20405	Safety and Effectiveness of the Omnipod 5 SmartAdjust 2.0 System in Individuals with Type 1 and Type 2 Diabetes	A/Prof Martin de Bock	14/06/2024	18/06/2024	Provisionally Approved	Approved	4/07/2024	Te Whatu Ora locality, Tertiary Education Institution	University of Otago	Insulet Corporation	42
2024 FULL 18867	A Randomised, Double-Blinded, Placebo-Controlled Trial of Early, Short Course Oral Dexamethasone for the Treatment of Sydenham's Chorea in Children	Dr Hannah Jones	22/01/2024	29/01/2024	Provisionally Approved	Approved	13/02/2024	Te Whatu Ora locality	Starship Child Health		43
2024 FULL 18989	A Randomized, Double-Blind, Multicenter, Active-Controlled, Parallel-Group Study to Evaluate the Efficacy and Safety of Fluticasone Propionate/Albuterol Sulfate Fixed-Dose Combination on Severe Asthma Exacerbations in Patients with Asthma	Dr. Jonathan Huw Noble	4/03/2024	14/03/2024	Provisionally Approved	Approved	28/03/2024	Primary Health Care Centre, Private Organisation	Syneos Health New Zealand Limited	Teva Branded Pharmaceutical	45
2024 FULL 19038	Pilot study of administration of psilocybin in healthy volunteers within a marae setting.	Dr Patrick McHugh	21/02/2024	23/02/2024	Provisionally Approved	Approved	14/03/2024	Other	Mātai Medical Research Institute		46
2024 FULL 18514	A Phase 3 Randomized, Double-blind, Placebo-controlled Study to Evaluate the Efficacy and Safety of Dazodalibep in Participants With Sjögren's Syndrome With Moderate-to-Severe Symptom State	Doctor Sunil Kumar	10/04/2024	16/04/2024	Provisionally Approved	Approved	6/05/2024	Private Organisation, Te Whatu Ora locality	PPD Part of Thermo Fisher	Horizons Therapeutics Ireland DAC	51
2023 EXP 18439	The BeAT-MD Feasibility Trial: Behavioural Activation Therapy for Mood Disorders in Aotearoa	Associate Professor Katie Douglas	8/09/2023	14/09/2023	Provisionally Approved	Approved	6/10/2023	Te Whatu Ora locality, Tertiary Education Institution	University of Otago		51

2023 FULL 1917 5	A phase II, double-blind, randomised, placebo-controlled trial to evaluate the efficacy and tolerability of ZED1227 in celiac disease subjects experiencing symptoms despite gluten-free diet	Dr Nah Yeon (Tina) Baik	21/12/2023	10/01/2024	Provisionally Approved	Approved	9/02/2024	Private Organisation	Novotech (New Zealand) Limited	Dr. Falk Pharma GmbH	53
2023 FULL 1897 1	Paeārahi supported interRAI Check Up Self Report (CU-SR) Assessment Delivery Project	Dr Joanna Hikaka	13/11/2023	14/11/2023	Provisionally Approved	Approved	13/12/2023	Primary Health Care Centre	Te Whatu Ora - interRAI		54
2023 FULL 1271 4	Marine oxygen carrier (M101) for organ preservation in liver transplantation: a randomised exploratory study	Associate Professor Louise Barbier	4/09/2023	12/09/2023	Approved	Approved	16/11/2023	Te Whatu Ora locality	University of Auckland		72
2024 FULL 1992 2	A Phase 3, Randomized, Observer-Blinded, Active-Controlled Study to Evaluate the Safety and Immunogenicity of a SARSCoV-2 rS Nanoparticle and Trivalent Hemagglutinin Nanoparticle Influenza Combination Vaccine with Matrix-M™ Adjuvant and a Standalone Trivalent Hemagglutinin Nanoparticle Influenza Vaccine with Matrix M Adjuvant in Participants ≥ 60 years of Age	Dr Dean Quinn	19/06/2024	2/07/2024	Provisionally Approved	Approved	12/08/2024	Primary Health Care Centre, Private Organisation	PPD, part of ThermoFisher Scientific	Novavax, Inc.	78