Regulatory Impact Statement: Clinical Trials

Decision sought	Seeking Cabinet decisions on the regulatory settings for clinical trials of medicines and medical devices under the Medical Products Bill.
Agency responsible	Ministry of Health
Proposing Ministers	Hon Casey Costello, Associate Minister of Health
Date finalised	23 June 2025

Briefly describe the Minister's regulatory proposal
As part of the development of the Medical Products Bill, this proposal sets out a series of changes to improve the regulation of clinical trials in New Zealand. These changes will protect participant safety, align with international approaches, improve approval efficiencies, and promote economic growth for the New Zealand clinical trials industry.

Summary: Problem definition and options

What is the policy problem?
The primary policy challenges facing clinical trial regulation in New Zealand are ensuring the safety of participants and improving the efficiency of trial approval processes. Clinical trials are inherently experimental, which introduces potential risks for participants, many of whom may lack the necessary information or expertise to fully assess these risks of participating in a trial. Trials involving medical devices, are only subject to ethics committee review and no other regulatory involvement, potentially exposing participants to unmitigated risks.

There is no mandatory reporting of serious adverse events during clinical trials, nor is there a mechanism for auditing or inspecting trials or any systematic mechanism to track trial misconduct, adverse events or harm to participants. Current regulation has significant information gaps, with a lack of visibility of harm which increases the risk of undetected harm to participants and undermines public confidence. Despite the information gaps in New Zealand, international best practice for clinical trials has been shaped by learnings from actual harm, including serious adverse events, deaths, ethical breaches and trial misconduct. Effective regulation of trials is essential to safeguard participants while also maintaining the public trust that results in people volunteering for future trials.

An efficient clinical trial approvals system is essential to attract trials and investment in New Zealand research. However, the current regulatory framework in New Zealand is inflexible, inefficient, and is not always aligned international standards. For research funded by the New Zealand Government, inefficient processes waste precious public funds. For commercially funded trials (eg, new medicines), an inefficient trial approval system can be a disincentive. The involvement of multiple agencies and redundant steps compounds these inefficiencies.

Ensuring regulation provides for participant safety, and efficacy is mutually beneficial. The results and data from poorly run trials may not be acceptable to regulators abroad and participants' time is wasted. Risk-proportionate, streamlined regulation that enhances participant safety and aligns with global norms will result in a more favourable clinical research environment. This would support investment in and, economic growth for, New Zealand, improved patient access to new and promising medicines and direct support for high-skilled jobs.

What is the policy objective?

The core objectives for the regulation of clinical trials are:

1. to protect the safety of participants – with secondary benefits of maintaining trust in clinical research and peoples' willingness to participate in trials
2. making New Zealand an attractive place to conduct clinical trials, through efficient approval processes and internationally aligned standards that ensure data generated here is acceptable to medical product regulatory bodies abroad.

The intended outcomes of this change are:

- the safety of clinical trial participants is assured to an appropriate level
- an increase in clinical trial approvals so New Zealanders can have timely access to promising new medical products
- alignment with international standards to encourage New Zealand sites being added to multi-centre (ie, international) trials.

What policy options have been considered, including any alternatives to regulation?

There are three key areas of clinical trial regulation for which options have been considered in this analysis – trial protocol controls, the requirement for ethics approval, and site/activity controls.

We considered the following options for trial protocol controls, which concerns the scientific validity and safety of the trial:

1. the status quo under the Medicines Act 1981 (the Medicines Act) – where all clinical trials of medicines require approval by the regulator, but clinical trials of medical devices do not.
2. all clinical trials (medicines and medical devices) are subject to notification or approval pathways according to risk. This includes a simplified pathway for low-risk trials (the regulator is notified of the trial but no evaluation is undertaken), and an approval pathway for higher-risk trials (the regulator evaluates the trial protocol and decides to approve or not). This option enables the ability to rely on approvals granted by trusted overseas regulators.
3. all clinical trials are subject to approval by the regulator, with the ability to rely on approvals granted by trusted overseas regulators.

We also considered options that could be implemented alongside different approval pathways for trial protocol controls including:

- the requirement for trials to be on listed on a public registry.
- for the regulator to conduct the regulatory assessment of clinical trial.

We considered the following options for the requirement for ethics approval:

- the status quo under the Medicines Act – where there is no legislative requirement for clinical trials to have ethics approval.
- introduce a legislative requirement for ethics approval and investigative powers with more appropriate consequences for the breach of ethics requirement to protect participants.

We considered the following options for clinical trial site/activity authorisation that ensures providers are qualified and sites have appropriate safeguards in place:

- the status quo under the Medicines Act – a voluntary scheme for sites undertaking clinical trials of medicines.
- a required licence for clinical trial procedures.
- site registration and notification pathways to enable risk-proportionate regulation and recognise international accreditation.

What consultation has been undertaken?

This analysis has been informed by significant engagement over the past 30 years. Recent consultation has focused on targeted engagement with key stakeholders in the medical product industry and government. We have incorporated relevant feedback into this analysis. Overall, industry has expressed support for risk-proportionate regulation that utilises reliance and minimises duplication of efforts by regulatory bodies for clinical trials as well as regulation more generally.

Health and Disability Ethics Committees have raised serious concerns about the lack of oversight in clinical trials involving medical devices. Ethics committees are currently the only checkpoint, yet they are meant to assess ethics—not scientific validity or safety—leaving participants at risk. For clinical trials involving both medicines and medical devices, there is no system for tracking adverse events, investigating complaints, auditing studies, or ensuring compensation for injuries, especially in commercial trials not covered by ACC.

When it was considered by Parliament in 2023, the Therapeutic Products Bill received submissions from the clinical trial industry and other key stakeholders. As a result, the views of stakeholders on the Medicines Act and potential replacements are well known and have been taken into consideration for this analysis.

For example, some of these considerations included:

- Industry representatives such as Medicines New Zealand, GSK and Pfizer advocated for harmonisation with global regulatory frameworks.
- Cancer Trials New Zealand stressed the need for a risk-based approach for consideration of applications and that the approval process for starting a clinical trial is efficient to avoid loss of opportunity.
- Auckland Women's Health Council expressed the critical need for the regulator to respond appropriately and promptly to protect participants from harm, they note the significant importance for implantable medical devices.

Is the preferred option in the Cabinet paper the same as preferred option in the RIS?

Yes

Summary: Minister's preferred option in the Cabinet paper

Costs (Core information)

Outline the key monetised and non-monetised costs, where those costs fall (e.g. what people or organisations, or environments), and the nature of those impacts (e.g. direct or indirect)

The monetised and non-monetised costs are expected to be of low impact for this proposal

- **The regulator:** increased workload will be balanced by improved efficiencies and cost-recovery through industry fees.
- **The clinical trial industry**: small increase in one-off costs for regulatory approval of clinical trials of medical devices.

- **Participants**: no cost impact expected.

Benefits (Core information)

Outline the key monetised and non-monetised benefits, where those benefits fall (e.g. what people or organisations, or environments), and the nature of those impacts (e.g. direct or indirect)

- **Participants:** improved access to trial medical products and improved protection. Reduced harm from unsafe or fraudulent trials.
- **The regulator:** improved efficiencies in the approval process through recognising international certification and approval.
- **The Crown**: reduced harm from unsafe or fraudulent trials and economic growth due to an increase in the number clinical trials conducted in New Zealand.
- **The clinical trial industry**: improved alignment with the requirements of the international market, reduced duplication of efforts due to reliance pathways, and decreased cost for applications via the notification or reliance pathways.

Balance of benefits and costs (Core information)

Does the RIS indicate that the benefits of the Minister's preferred option are likely to outweigh the costs?

The preferred options introduce flexible regulation that appropriately regulates trials based on their risk and nature, rather than a 'one-size fits all' approach which can result in overregulation. The inclusion of reliance and notification pathways would reduce cost to industry and relieve resources for the regulator, compared to full assessment pathways.

Instances where costs are increased for industry in this proposal are balanced by better alignment with international standards, improvements in efficiencies and better assurance of safety for participants. Hence, the benefits of the preferred options are likely to outweigh the costs.

Implementation

How will the proposal be implemented, who will implement it, and what are the risks?

Implementing this proposal will require several years to enable a smooth transition period, in addition to the time needed to develop secondary legislation. The Medical Products Bill is anticipated to be introduced in 2026, with a go-live date of late 2030 to allow for transition to the new regime. This includes clinical trial implementation. The Ministry of Health will implement the new regulatory regime. Options on the form of the medical products regulator is yet to be considered by Cabinet. The ethics approval system will be operated by ethics committees.

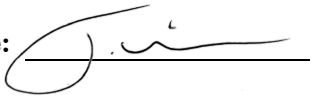
As with all new regulatory systems, there is a risk of time and cost over-runs. To minimise these risks, there are lessons that can be applied from the existing system for clinical trials. In addition, comparable jurisdictions, have already undergone similar regulatory reform, and we can learn from their experiences.

Limitations and Constraints on Analysis

There are no significant limitations or constraints on this analysis.

There has been extensive prior policy development and stakeholder engagement on clinical trial regulation, including through the development of the Therapeutic Products Act 2023 (TPA). While there has been limited time to assess new evidence or test policies which differ significantly from both the status quo and the TPA, proposals considered in this analysis have been circulated to relevant government agencies and Crown Research Institutes.

I have read the Regulatory Impact Statement and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the preferred option.

Responsible Manager(s) signature: 

Tim Vines
Manager, Therapeutics
23 June 2025

Quality Assurance Statement	
Reviewing Agency: Ministry of Health QA panel	**QA rating:** Meets
Panel Comment: The Impact Statement is clear, concise, complete, consulted and convincing. The analysis is balanced in its presentation of the information.	

Section 1: Diagnosing the policy problem

What is the context behind the policy problem and how is the status quo expected to develop?

1. Clinical trial participants do not have the information or the ability to accurately assess risks of trials. Regulation is needed to provide participants assurance that their safety has been assessed and risks have been best managed.
2. Clinical trial regulation should adequately address the safety and risks of clinical trials without adding barriers that could impair access or prevent clinical trials from being run in New Zealand.
3. The current regulatory regime for clinical trials in New Zealand does not achieve this as efficiently as it could. On one hand, trials of medical devices are not regulated, and therefore there is no assurance of the safety or scientific validity of these clinical trials. On the other hand, some lower risk clinical trials of medicines are subject to more rigorous regulatory requirements than necessary, therefore some trials are overregulated by the current regime.
4. In addition, there are inefficiencies in:
    a. the clinical trial approval process
    b. limited repercussions for breach of ethical duties, and
    c. duplication of efforts from regulator bodies due to an inability to rely on approval from overseas regulators.
5. With the development of the Medical Products Bill, there is an opportunity to improve the regulation of clinical trials in New Zealand to align with international standards, benefit industry and better protect participants.

What are clinical trials?

6. Clinical trials are research studies designed to assess the safety and efficacy of medicines and of medical devices. Clinical trials play a critical role in the research, development and evaluation of new medical products, new uses of existing products, and contribute to improved patient safety and public health.
7. Clinical trials involving medicines are not limited to new products. Two existing medicines can be compared to each other through a clinical trial to determine 'comparative effectiveness'. Clinical trials can also include testing existing products for new uses (ie, new 'indications') or in new population groups (eg, infants or young people).
8. Different types of clinical trials impose different levels of risk to participants. For example, a higher-risk trial might test a new medical product in humans for the first time, where the safety of the product needs to be established. Whereas a lower risk trial might test an approved product, with an existing safety profile, for a new condition in the same population group.

Benefits of clinical trials

9. Clinical trials offer a number of social and economic benefits to New Zealand including:
    a. A strong culture of health research helps to attract and retain high quality clinicians, academics, and scientists.
    b. Commercial health research brings investment in research and development and employment opportunities.
    c. New Zealand-generated intellectual property can add significant value to the economy.

d. Clinical trials have been shown to improve the overall standards of health in countries where they are carried out.
e. Healthcare professionals can gain early experience and expertise in the selection and use of new therapeutic interventions.
f. Relevant and timely access to evidence from clinical trials can support healthcare professionals and policy makers to implement public health interventions.
g. Clinical trials can provide valuable insights into how a trialled product works within the New Zealand population, particularly Māori and Pacific people. This allows treatments to better address the specific needs and genetic factors of New Zealanders.

10. New Zealand has some features that make it an attractive place for researchers to conduct clinical trials. These include diverse participant groups, ethnic sub-population groups, and an English-speaking health sector with an established ethics system, a highly trained and regulated workforce of clinicians, and trusted academic research infrastructure.
11. The development of the Medical Products Bill is an opportunity to review and update clinical trial regulation to best protect participant safety, improve efficiencies, fully realise New Zealand's potential as a clinical trial destination, and support knowledge-based innovation.

Status quo: regulation of clinical trials under the Medicines Act 1981

12. Approval of clinical trials in New Zealand involves two separate but parallel processes; ethics approval and regulatory approval:
    a. Ethics approval is concerned with ensuring research is conducted according to ethical standards, particularly to protect the rights and safety of participants, and
    b. Regulatory approval is concerned with ensuring research is conducted safely, in compliance with quality standards such as Good Clinical Practice and Good Laboratory Practice, and in a way that produces scientifically valid results.
13. Currently, ethics approval by a Health Research Council of New Zealand (HRC) ethics committee is required for clinical trials of medicines and most medical devices, while regulatory approval is required for only clinical trials of medicines.

Regulatory approval for clinical trials of medicines

14. Section 30 of the Medicines Act requires that approval from the Director-General of Health, based on recommendations from the HRC be obtained before a new (unapproved) medicine can be used in a clinical trial.
15. Regulatory approval is administered by Medsafe (the medicines and medical devices regulatory authority for New Zealand) but the HRC conducts the assessment. Medsafe is responsible for processing clinical trial applications and approvals under delegation from the Director-General of Health. This requirement applies to all types of clinical trials of new medicines.
16. The regulatory approval process can be summarised as follows:
    a. An application is received by Medsafe and forwarded to the HRC.
    b. A committee of the HRC considers the scientific and clinical components of the application.
    c. The HRC makes a recommendation to the Director-General on the application.
    d. The applicant is issued an approval, provisional approval or a decline letter by Medsafe based on the HRC recommendation, under authority delegated from the Director-General.

17. Under the Medicines Act, clinical trial applications outcomes must be issued within 45 working days of receipt of an application (or five working days for an abbreviated approval). The statutory approval timeframes help industry plan timelines for their trials.
18. Assessment by the HRC involves a fee, paid by the Ministry of Health. Medsafe is unable to cost-recover activities in relation to clinical trials.
19. The HRC's role in clinical trial approval raises a conflict of interest with another HRC responsibility - to manage the government's investment in research in New Zealand. This does not align with clinical trial approval processes in comparable jurisdictions.
20. With Medsafe managing applications and the HRC performing the assessment, there are unnecessary steps to the approval process for clinical trials of medicines. The time spent liaising and sharing information between the organisations is time consuming, inefficient and not cost-effective.

Regulation of clinical trials of medical devices

21. There is no explicit regulation of clinical trials of medical devices in the Medicines Act 1981 or elsewhere.
22. Medsafe have a voluntary notification system where sponsors of clinical trials of medical devices notify Medsafe of their trial. However, this is not required and there is no incentive for the sponsor to do so.
23. Medsafe are unable to assess the scientific validity and safety information of a medical device clinical trial nor intervene when things go wrong.
24. There is no requirement for reporting to Medsafe of adverse events that arise in clinical trials of medical devices. As a result, there is no safeguard to stop or monitor clinical trials of medical devices that have serious safety issues or adverse events.
25. A case in the New Zealand Medical Journal highlights a situation where a patient with a chronic condition participated in a clinical trial conducted primarily for the benefit of a medical device manufacturer. The patient developed a severe complication shortly after entering the trial and could not be compensated.
26. In New Zealand, participants in clinical trials that are deemed as being conducted for the benefit of the manufacturer are not eligible for Accident Compensation Corporation (ACC) coverage if they suffer an injury from participating in the trial.[1]

Ethics approval of clinical trials

27. Ethics approval is required for most clinical trials (medicines and medical devices) by ethics committees and by journals for publication. Ethics approval is administered by HRC ethics committees established under the Health Research Council Act 1990.
28. Unlike comparable jurisdictions, the requirement for ethics approval for research is not outlined in legislation; therefore the process relies on 'good actors' in the sector.
29. The ethics committee considers the application against ethical standards, which are set out in the National Ethics Advisory Committee guidelines. Approval must be granted or denied within 35 calendar days for full reviews or 15 calendar days for expedited reviews.
30. Certain types of trials are exempt from needing ethics approval, such as studies on low-risk medical device trials (eg, sterile dressings, reusable surgical instruments).
31. Ethics committees require annual progress reports from the sponsor for all trials, and an annual safety report attached to the progress report for studies involving new (unapproved) medicines. There is no general requirement for sponsors to submit reports

[1] participant-injury-in-clinical-trials-conducted-in-new-zealand-for-the-benefit-of-manufacturers-an-unfair-system.pdf

of suspected unexpected serious adverse events to the ethics committees, as the committees do not have the resource or expertise to review.

32. Ethics approval may be suspended or cancelled due to serious concerns about:
    a. the health and safety of participants
    b. competence of investigators or sponsors
    c. the feasibility of the study
    d. suspension or cancellation of regulatory approval (by Medsafe) for the study.
33. Once the trial has commenced, it is the responsibility of the researchers – not ethics committees – to ensure the research always meets the ethics standards throughout the trial.
34. Ethics committees have no investigative or enforcement powers, so while they can make conditional requirements of reporting in their ethics approval, they have no follow up ability to ensure trial protocols are carried out to uphold ethics standards.

Clinical trial registries

35. A condition for ethics approval is that the trial must be registered in a clinical trials registry approved by the World Health Organization (WHO). This must be done before trial commencement in New Zealand.
36. The Australian New Zealand Clinical Trials Registry (ANZCTR) is an online public register of clinical trials being undertaken in Australia, New Zealand and internationally. It is one of the registries recognised by the WHO International Clinical Trials Registry Platform. Trials registered with ANZCTR contribute data to the international platform. Registration is free of charge to the sponsor.
37. The registry records trial information including objectives, main design features, sample size and recruitment status, treatments under investigation, outcomes being assessed, principal investigator and contact person.
38. The ethics committee requirement doesn't specify which registry New Zealand clinical trials should register with. Registration of trials aligns with international standards and is often a requirement of publication.

Further context on the need for reform

39. The Medicines Act has been considered not fit-for-purpose since the 1990s. This view has been shared by successive governments, practitioners, industry and the public. The Therapeutic Products Act 2023 (TPA) was intended to replace the Medicines Act with modern legislation which could appropriately regulate medical products.
40. There were concerns from industry and other stakeholders that the TPA would have made clinical trial approvals too difficult, expensive and time-consuming to obtain.
41. The TPA was repealed in December 2024, meaning status quo regulation under the Medicines Act will continue. In developing a new regulatory regime, feedback from the TPA is being taken into consideration.
42. On 30 September 2024, Cabinet agreed to repeal and replace the Medicines Act with a new Medical Products Bill [SOU-24-MIN-0115]. Cabinet invited Associated Minister of Health, Hon Casey Costello to report back by the end of the first quarter of 2025 on further policy proposals, including on clinical trials.
43. There is a high degree of ministerial interest in ensuring the Medical Products Bill appropriately regulates innovative medical products and activities that support innovation, such as clinical trials.

44. In New Zealand, partially attributed to the funding structure, people with rare diseases and/or cancers often access new innovative treatments through clinical trials. Supporting access to innovative medical products through clinical trials helps to address inequities in access [Government Policy Statement on Health 2024–2027, Priorities 1 and 6] and timely access in general.

What is the policy problem or opportunity?

45. Clinical trial participants do not have the information or ability to adequately assess the risk of a trial, hence regulation is needed for safety and assurance. There are key areas of clinical trial regulation in New Zealand that achieve the following outcomes:
    a. assure participants that trial risks are best managed according to the nature of the trial, prioritising their safety
    b. align with international standards, supporting economic growth
    c. prevent duplication of efforts by regulatory bodies and increase efficiency of clinical trial approval to support industry and access.

46. Key limitations of the current regime that are preventing the outcomes mentioned above include the:
    a. current legislation is not fit for purpose and inefficient
    b. lack of regulation for clinical trials of medical devices
    c. lack of audit and monitoring powers of the regulator
    d. regulatory requirements for clinical trials of medicines are not risk-proportionate
    e. lack of harmonisation with overseas jurisdictions.

Current legislation is not fit-for-purpose

47. Clinical trials are a crucial step in the development of safe and effective medical products. However, clinical trials present risks to participants, as they are by their nature, experimental.
48. Safeguards are required to ensure that trials are ethical and scientifically sound, the people undertaking trials are appropriately qualified, and that systems and procedures are in place to respond to adverse events.
49. The current legislation relating to clinical trials in New Zealand is inadequate for modern practice and is out of step with international standards.
50. The Medicines Act does not allow for reliance on decisions by other regulators in respect to clinical trial authorisation, which can lead to duplication of efforts by different regulatory bodies.
51. There is an expectation, but no explicit requirement under the legislation, for investigational medicines to be manufactured to Good Manufacturing Practice standards. Additionally, there is no requirement for trials to be undertaken by suitably qualified people or to adhere to Good Clinical Practice and Good Laboratory Practice. Hence, the current regime is reliant on good actors and the Ministry has no auditing abilities so there is no mechanism to monitor if there are in fact 'good actors'.
52. The Australian Therapeutic Goods Administration Good Clinical Practice inspection program[2] 2023-2024 reported deficiencies in 'protection of participants', which were identified in 10 out of 12 routine inspections.

Lack of regulation for clinical trials of medical devices

53. Whilst most clinical trials of medical devices must meet ethical standards as required by the Health and Disability Commissioner Code of Rights, there is currently no requirement in the Medicines Act to obtain regulatory approval from Medsafe.
54. The Medicines Act does not require approval of medical device trials, even those involving high-risk implantable medical devices. This means there is minimal assurance that a

[2] Good Clinical Practice (GCP) Inspection Program 2023 – 2024, Australian Therapeutic Goods Association.

medical device trial is being conducted according to Good Clinical Practice and may enable substandard trials to be conducted in New Zealand.

55. No comparable jurisdictions exclude medium and high-risk trials of medical devices from their regulatory approval regime due to the level of risk to the safety of participants, making New Zealand an outlier due to outdated legislation.
56. There is minimal traceability of the conduct of medical device trials without involvement of the regulator. The enforcement of regulatory requirements (such as following conditions of ethics approval) is weak and lacks an appropriate enforcement regime.

Lack of audit and monitoring powers

57. Audit and monitoring powers are essential to protect participant safety and ensure trials are being run lawfully and according to best practice.
58. The legislation does not require regulatory controls for clinical trial sites, such as having emergency procedures in place, or to have procedures documented. Nor does Medsafe have statutory powers to audit or monitor clinical trials of medicines and medical devices and has no enforcement powers to suspend or revoke trial approval due to non-compliance or misconduct.
59. One example of misconduct in clinical trials in New Zealand occurred in 2022 where a person used fake medical credentials to secure a job as a clinical researcher in Middlemore hospital in Auckland[3]. It was six months before the person was stood down due to a doctor that grew suspicious of the validity of the persons registration.
60. This incident put patient safety at risk, threatened the validity of the results from the study and impacted New Zealand's clinical research reputation. Auditing and monitoring powers would improve the likelihood of earlier detection and further prevention. Both auditing and monitoring powers, alongside good practice guidelines, are necessary steps to improve the appropriateness of clinical trial practice.

Regulatory requirements for clinical trials of medicines are not risk-proportionate

61. As mentioned earlier, different types of clinical trials have differing levels of complexity which impose different levels of risk to participants. Despite this, the current regulation of clinical trials does not adopt a risk-proportionate approach. This results in lower risk medicine trials being subject to more rigorous regulatory requirements than necessary, while some high-risk trials may be underregulated which increases inefficiencies in the clinical trial approvals process and regulatory regime.

Lack of harmonisation with overseas jurisdictions leading to less economic growth and a barrier to global market access

62. Harmonisation is a necessary factor to support New Zealand's reputation as a credible, regulator of medical products, for example through the WHO global benchmarking process for evaluation of national regulatory schemes.
63. Aligning with international standards allows for clinical data generated in New Zealand trials to be more likely to be accepted by international regulators, thereby facilitating the process of bringing a medical product to the international market, supporting economic growth and market access.
64. The current regulatory regime in New Zealand is out of step with comparable overseas regulators and with international standards, such as those set out by the International

[3] https://www.stuff.co.nz/national/crime/300660771/yuvaraj-krishnan-what-we-know-about-alleged-fake-middlemore-doctor

Council for Harmonisation (ICH). Impacting the ability for New Zealand to compete internationally and restricting the opportunity for economic growth for the New Zealand clinical trial sector.

65. ICH guidelines are used worldwide to inform local regulatory requirements for medicines, including Good Clinical Practice for clinical trials. Overseas jurisdictions such as the United States of America and the European Union publish guidelines that are harmonised with ICH guidelines.
66. International standards, such as those set out by the International Medical Device Regulators Forum (IMDRF) and the International Organization for Standards (ISO) inform requirements for clinical trials of medical devices.
67. The development of the Medical Products Bill is an opportunity for New Zealand to harmonise with other jurisdictions through adopting ICH and IMDRF guidelines and ISO standards to inform a new regulatory regime that aligns with international best practice guidelines.
68. Harmonisation with international standards, guidelines and reliance on overseas regulators increases efficiencies for internal and external applicants for clinical trials in New Zealand. Reliance allows faster trial approvals increases efficiency and makes New Zealand a more attractive location for international clinical trials ultimately supporting economic growth.

Stakeholder engagement

69. This RIS has been informed by significant engagement over the past 30 years. Most recently, this included engagement in 2023 in relation to the Therapeutic Products Bill, which received over 16,000 submissions. As a result, the views of key stakeholders on the Medicines Act and potential replacements are well-known.
70. Consultation in developing the Medical Products Bill will focus on targeted engagement with key stakeholders. Development of the Medical Products Bill will also draw strongly on submissions on the Therapeutic Products Bill. In combination with targeted engagement, these submissions will be used to ensure that concerns about the now repealed TPA are appropriately addressed in the Medical Products Bill.

Stakeholder views: Consumers (as trial participants)

71. Trial participants need assurance that medical products being trialled, and the trial protocol meet regulatory standards. It is key that participant safety is a priority for clinical trial regulation.
72. Certain groups are more likely to participate in clinical trials than others and are therefore more subject to the risks involved.
73. **Disabled people and people with long-term or rare health conditions** are more likely to participate in a clinical trial in their lifetime due to trials being a pathway to access medical products for rare or long-term conditions. Often, without trial participation, they would experience significant decline in quality of life. For this group, it is essential that participant rights and safety are protected.
74. **Māori** tend to have higher rates of ill-health and are therefore more reliant on medical products and more affected if products are unsafe or inaccessible. The lack of clinical trial data involving Māori participants means that any adverse effects disproportionately involving Māori are less likely to be detected.
75. **Women** have been traditionally excluded from clinical trials, which has meant that side effects and other issues are less likely to be discovered if they affect women. Compared to other patient advocacy groups, the women's health groups that submitted on the TPA

tended to take a more cautious approach to products, and to prioritise safety over access. In terms of medical device trials specifically, women have heightened concerns regarding medical device harm compared to other groups of consumers. One study found that women experienced around two-thirds of reported harms from medical devices in the United States.[4] Women's health advocates are more involved in medical device issues because of the harms experienced with medical devices, particularly implantable medical devices such as contraceptive devices and surgical mesh.

Stakeholder views: Clinical trial industry

76. The clinical trial industry includes, but is not limited to, clinical researchers, pharmaceutical companies, the medical device sector and academic institutes.
77. Industry have expressed support for a stratified, risk-based approach to clinical trial protocol requirements and site controls. It has been widely emphasised that any change to the regulatory regime should avoid duplication of efforts across organisations or creating unnecessary barriers for researchers that could impact the availability of medical products or New Zealand's desirability as a clinical trial destination.
78. Industry and research groups support the current regulatory regime, in particular the statutory approval timeframes. Research groups have explicitly expressed support for the future regulatory regime to include statutory approval timeframes to allow for timeline planning and to ensure trials can start promptly.
79. To support efficiency and timeline planning, industry have suggested that if a future regime includes site licencing as well as trial protocol approval and ethics approval, that these processes could run in parallel.
80. Industry feedback has emphasised that regulation of clinical trials should be **internationally harmonised and enable regulatory reliance and recognition pathways** for the following reasons:
    a. harmonisation enables better translation of domestic trials into global markets and enhances the commercial viability of new products for New Zealand innovators, enhancing efficiencies, supporting economic growth and job creation within the clinical trial sector
    b. reliance and recognition pathways for trial protocol approval can encourage and facilitate timely approval of New Zealand arms or large international trials, minimise compliance costs and prevent duplication of regulatory processes for the researchers
    c. reliance and recognition pathways reduce the time and cost for clinical researchers to set up branches of international trials in New Zealand, thereby ensuring participant access to trial medical products
    d. regulatory reliance does not impact sovereignty and pursuing a harmonised regulatory reliance model does not prevent New Zealand from making unique decisions to benefit its public.
81. Industry is supportive of **risk-proportionate** regulation that enables:
    a. lower-risk clinical trials to be subject to simplified regulatory procedures commensurate with risk that promote innovation and reduce unnecessary burdens on researchers.

[4] https://www.icij.org/investigations/implant-files/we-used-ai-to-identify-the-sex-of-340000-people-harmed-by-medical-devices/

b. the level of regulatory oversight, the evidence requirements and the elements of trial assessment to be more robust for higher risk trials.

82. The Healthy and Disability Ethics Committee (HDEC) has raised concerns about the lack of regulatory oversight for medical devices. In addition, they raised that there is no system-wide oversight of adverse events, compensation, or repeat offenders. HDEC lacks the tools to track or respond to systemic issues, leaving participants vulnerable and the system blind to recurring risks.
83. Their main issues include:
    a. Insufficient scientific oversight: Ethics committees review ethical aspects but not the scientific validity or safety of device trials. This gap rises risks, with HDECs fearing liability if harm occurs.
        i. Examples of harm include a participant death, injury from a lung device, and unsafe use of non-removable stents.
        ii. Safety issues have only been identified due to individual expertise, not systemic checks.
    b. Complaint handling: HDECs have limited powers to investigate complaints, relying solely on researchers or referrals to the HDEC. They cannot follow up with other participants or gather broader evidence.
    c. Adverse events: reporting is not mandatory, and there's no clear responsibility between HDECs and Medsafe. The link between research and adverse events is lacking.
    d. Insurance Coverage: Injury from commercial trials isn't covered by ACC due to the risk level of these trials. These companies are required to have insurance, but compensation for injured participants is variable. As mentioned previously (para 26) there are cases where we know serious injury has or even death occurred without compensation.
    e. Continuation of therapy: Trial sponsors sometimes fail to continue beneficial treatments post-study. Legal action is rare due to cost barriers.
    f. Lack of audit function: Unlike Australia, ethics committees cannot audit studies to ensure compliance with approved protocols.

84. The concerns raised by HDEC directly reinforce the core policy problems: the need to ensure participant safety and improve the efficiency of clinical trial regulation in New Zealand.
85. Their concerns highlight that current oversight is fragmented and inadequate, particularly for medical device trials, where there is little to no scientific scrutiny or mandatory reporting of adverse events. Ethics committees are being relied upon to fill regulatory gaps they are not equipped to manage, increasing the risk of harm to participants and undermining public trust. At the same time, the lack of coordination, data sharing, and audit mechanisms creates inefficiencies and blind spots in the system—making it difficult to identify risks, enforce accountability, or learn from past incidents.
86. This supports the case for a risk-proportionate, streamlined regulatory model that both protects participants and enables high-quality, efficient research aligned with international standards. For example, proper regulation will ensure appropriate commercial insurance arrangements are in place for trials where ACC will not cover injury.

Addressing other regulatory requirements

87. There are many intersecting legislations that are important for the reform of clinical trial regulation, such as the Privacy Act 2020 or the Health Information Privacy Code 2020. These legislations will need to be considered in future through the design of clinical trial regulation. However, this analysis will focus on streamlining regulatory process.

What objectives are sought in relation to the policy problem?

88. The main objectives are that regulation of clinical trials will maintain and improve the safety of participants and make New Zealand an attractive place to conduct clinical trials. A quality measure for this activity is that clinical trials are conducted in accordance with international best practice.
89. Additional objectives are to ensure there is visibility over the clinical trial system in New Zealand involving medical devices. This includes improving the ability to monitor adverse events and ensure trials are conducted appropriately by qualified individuals.

What consultation has been undertaken?

90. In the development of this analysis, we have undertaken targeted engagement with several key industry stakeholders including the Medical Technology Association of New Zealand, the New Zealand Association of Clinical Research, and Fisher and Paykel Healthcare.
91. Agency consultation took place from 29 January to 11 February 2025. PHARMAC expressed overall support for the proposals in this analysis and the Office of the Privacy Commissioner expressed support for greater regulatory oversight of clinical trials. The Ministry for Business, Innovation and Employment supported the reliance pathways for its alignment with international standards and improvement of efficiency. We have incorporated relevant feedback into this analysis.

Section 2: Assessing options to address the policy problem

What criteria will be used to compare options to the status quo?

92. The criteria are:
    a. **Protection**: extent to which the option will provide assurance to participants that the clinical trial meets appropriate standards of safety, quality and scientific validity. A high-scoring option would assure that the risks are suitably managed and the trial is appropriately run to produce valid data.
    b. **Efficient**: will the option achieve the objective without unnecessary time and resource cost for the Crown or industry? A high-scoring option will minimise time to decision making and the minimise unnecessary duplication (eg, between ethics, scientific and regulatory review bodies)

93. We consider that the following criteria are a subset of **efficient**:

    a. **Proportionate**: will the option enable appropriate regulation of all clinical trials in a way which makes sense for their nature and risk profile? A high-scoring option would be sufficiently flexible to accommodate trials of differing risk profiles.
    b. **Harmonised**: the extent to which the option is aligns with international approaches.

94. A policy option that meets the efficient criteria will contribute to economic growth for New Zealand.

What scope will options be considered within?

The type of trials in scope

95. The scope of products proposed to be regulated in the clinical trial regulatory regime includes medicines and medical devices. For medical devices, this includes general medical devices, in vitro diagnostic medical devices and software that is used for a therapeutic purpose (Software-as-a-Medical Device – SaMD).
96. The scope of clinical trials proposed to be regulated in the clinical trial regulatory regime includes international trials with a New Zealand arm. This is where a study that is led in another jurisdiction and includes a New Zealand site that trials the investigational product with New Zealand participants.

Options in scope

97. Options that support compliance to guidelines such as Good Clinical Practice, and from the ICH, IMDRF and the WHO are in scope of this analysis.
98. Options that align with approaches of comparable, trusted jurisdictions are in scope of this analysis.
99. Options that align with, and support, other work programmes to improve clinical trials in New Zealand are in scope of this analysis. Some examples of other work programmes for clinical trials in New Zealand include the development of decentralised clinical trial methodology[5], the National Clinical Trial Centre and the clinical trial site maturation framework.
100. A well-designed clinical trial framework will also support investment pathways for new medical products by ensuring good quality clinical data is produced to support procurement processes used by Pharmac and Health New Zealand such as the Health Technology Assessments.

What is out of scope?

101. The Government's goal to reduce regulation has limited the scope to not include any options that would significantly increase regulatory requirements.
102. Engagement with industry has signalled that changes to regulation that would increase or introduce uncertainty of time to approval would disincentivise undertaking trials to New Zealand, hence such options are out of scope of this analysis.
103. Whilst the requirement to get ethics approval is discussed in this analysis, the criteria and standards that ethics committees use in the assessment for ethics approval sit outside the Medicines Act. These standards sit under the Pae Ora (Healthy Futures) Act 2022, and therefore are outside the scope of this review.
104. Advertising of trial medicines and medical devices are out of scope of this analysis as this falls under the responsibility of the ethics committees. Ethics committees review clinical trial material relating to seeking participation including advertisement. Any information on advertising that is cleared by an ethics committee would not be subject to the offences and penalties outlined by the Medical Products Bill.
105. Statutory timeframes for the assessment of clinical trials are outside of the scope of this analysis. Options will be provided as part of a separate analysis on statutory timeframes.

What options are being considered?

106. This options analysis consists of three components:
    a. trial controls
    b. requirement for ethics approval

[5] Process of development of decentralised clinical trial methodology for cancer clinical trials in Aotearoa New Zealand, Lawrence et al 2024, New Zealand Medical Journal

c. site/activity controls.

107. It should be noted that the process of a medical product transitioning from a clinical trial to product approval is a key part of clinical trial regulation and facilitating access to medical products. This RIS only covers regulation of clinical trials and not the transition to product approval.
108. It should be noted that throughout this analysis 'the regulator' is used because while Medsafe is currently the relevant regulator, this may be subject to change with the passage of the Medical Products Bill.

Question 1: What are the controls for clinical trials of medicines?

What options are being considered?

109. This section looks at how best it can deliver the objective of supporting regulation of clinical trials that will foster innovation, enable access to advanced and innovative medical products while also protecting the safety of participants and ensuring research is conducted in accordance with international best practice.
110. The options are:
    - **Option 1.1 Status quo under the Medicines Act**: All medicine clinical trials require approval by the regulator and HRC assessment prior to commencement. Clinical trials of medical devices do not require approval by the regulator.
    - **Option 1.2 Notification and approval pathways:** All clinical trials (medicines and medical devices) are subject to one of two pathways: notification or approval.
    - **Option 1.3 Approval for all clinical trials:** All clinical trials (medicines and medical devices) need approval by the regulator.

Option 1.1 – Status Quo - approval of clinical trials for medicines, no regulation of clinical trials for medical devices

111. The status quo is described in detail in section 1.
112. Without an approval process for medical device clinical trials, the status quo provides no assurance that trials are carried out according to standards of clinical safety. For clinical trials of medicines, the status quo provides assurance of safety to participants and assurance of scientific and clinical validity to overseas markets and research journals.
113. With the HRC completing the assessment and Medsafe administering the approval process, the status quo adds unnecessary administrative processes.
114. The current system charges a fee at the time of application but doesn't enable additional fees for subsequent changes to the trial (during the trial) that requires review by the regulator, therefore the fee charged does not always completely recover costs.
115. Additionally, the fee is not adjusted based on the risk or complexity of a trial, therefore low risk trials are potentially overcharged, and more complicated trials are potentially undercharged.
116. The status quo doesn't have flexibility to adapt the regulatory requirements to the risks of a trial. For example, a novel medicine being used in a first-in-human trial is treated the same as an existing, approved medicine being trialled for a new purpose in the same population.
117. Under the status quo, the regulator has no legislative powers to carry out basic safety monitoring of clinical trials. For example, if an adverse event or emergency from a trial is flagged to the regulator, they don't have the ability to inspect the trial premises or audit the researchers. This limits the assurance that trials are being conducted according to the protocol and according to Good Clinical Practice for the entire duration of the trial.

118. The status quo does not enable reliance pathways. Currently an application for a New Zealand arm of an international trial, that has been approved overseas, must go through the full approval process with the regulator and the HRC.
119. Under the status quo, it is optional for clinical trials conducted in New Zealand to register with the Australian New Zealand Clinical Trials Registry (ANZCTR). This has led to New Zealand clinical trials being registered across many different registries, making it difficult for clinicians and the public to search trials being conducted in New Zealand. This limits the transparency and traceability of trials being conducted in New Zealand.

Option 1.2 – Risk-proportionate notification and approval model

120. This option is divided into three components - the role of the regulator, application pathways and trial registry.

Role of the regulator

121. Under this option the regulator would conduct the clinical and safety assessment, rather than the HRC. This relieves the conflict of interest discussed in section 1.
122. This option creates a more streamlined and efficient process for the regulator and industry. This option contributes to a 'whole of life' approach to the regulation of medical products with the regulator having oversight spanning from clinical trials to product approval and to post-market monitoring.
123. This option best uses the scientific and clinical expertise for application assessment that already exists within the regulator, however, would require additional resourcing to manage the increased workload. Using the regulators expertise will ensure all trials are scientifically sound, meaning that they will produce robust results, reducing any inefficiencies that may arise from poor trial design (particularly for medical devices).
124. Unlike the status quo, this option will expand the regulators legislative powers to carry out basic safety monitoring of clinical trials such as:
    - inspecting the premises and auditing clinical trial sites
    - setting and changing conditions of approval, including requiring further information
    - implementing safeguards and protocols for safety breaches
    - requiring reporting of adverse events
    - suspending or revoking approvals.
125. This would provide assurance that trials are being conducted according to the protocol, as submitted in the application, and according to best practice for the entire duration of the trial. In the case of adverse events or emergencies that arise during a clinical trial, the regulator will have better access to investigate issues and a better ability to respond.

Application pathways – notification and approval

126. Under this option, all clinical trials (medicines and medical devices) would be subject to one of two pathways: notification or approval. The appropriate pathway would be determined by the risk of the trial and the type of medical product being trialled. Low-risk medical devices (class I) do not usually require clinical evidence for regulatory approval, so clinical trials for this class of medical device generally do not need to be undertaken.
127. The notification pathway is currently only appropriate for lower-risk medical device trials, but as medical products and clinical trials develop, this pathway could be used for other types of lower-risk trials in future. These pathways will also enable exemptions, where appropriate. This option contributes to flexible, risk-proportionate, and future-oriented regulation.

Table 1: Summary of the proposed notification and approval pathways

	Notification pathway	Approval pathway
Type of trial	Lower-risk trials (eg, trials involving moderate-risk medical devices).	Higher-risk trials (eg, medicines trials and trials of high-risk implantable medical devices).
Regulatory requirements	Sponsor to notify the regulator with details of the trial prior to commencement (no assessment conducted). Regulator will undertake some auditing activities of notified trials to ensure it is the appropriate pathway and prevent attempts to game the system.	Regulator assesses the safety, and the clinical and scientific validity of the trial before deciding whether to grant approval. Reliance is enabled– expedited approval of trials that have been granted approval by trusted overseas authorities. Trials eligible for reliance must have the same trial protocol as approved overseas, except for any New Zealand-specific elements, such as population groups.
International alignment	A notification system (mostly for lower-risk medical device trials) is adopted by comparable jurisdictions including the in Australia and the US.	The reliance option aligns with ICH recommendations and international best practice. Reliance also simplifies the process of introducing a NZ arm of an international trial.
Fee	Small fee to industry to cover administrative processing	Fee to industry to cover regulatory assessment and administrative processing.

128. Considering the rapid rate that medical technology is evolving, this option would give the regulator an ability, if needed, to conduct more rigorous assessment for innovative devices and trial designs that have unestablished or higher-risk safety profiles. This option would provide flexibility and adaptability therefore future-proofing for advancements in the medical device industry and changes to best practice.
129. Under this option, there will be an ability to cost-recover work undertaken by the regulator through industry fees for changes to a trial that requires substantive review. Overall, compared to the status quo, the costs to industry may be the same on balance, if not slightly higher to better account for activities that currently aren't fully cost recovered. Conversely, a risk-proportionate model would reduce costs to industry for low-risk medicine trials.
130. However, any added cost is offset with more assurance of safety and quality of clinical trials and would be consistent with comparable jurisdictions.

Trial registry

131. Under this option, all clinical trials conducted in New Zealand will be required to register with a specified clinical trial registry (such as the ANZCTR) prior to the recruitment of the first participant. Some clinical trials will be exempt from this requirement such as lower-risk medical device trials. The exemption criteria would be elaborated on in secondary legislation.
132. Registering clinical trials with a specified registry has a wide range of benefits including supporting access, minimising bias, enhancing transparency and aligning with comparable jurisdictions and international best practice.

133. A single registry for all trials means that the public and clinicians have to search only one database to identify all trials in New Zealand that they could potentially participate in.

Option 1.3 – approval for all clinical trials

134. This option proposes the same changes from option 1.2:
    a. approval to be undertaken by the regulator (not the HRC)
    b. give safety monitoring powers to the regulator
    c. enable reliance pathways in the approval process
    d. require all trials to be registered with a specified clinical trial registry.
135. Unlike option 1.2, under this option, all clinical trials (medicines and medical devices) would require approval by the regulator prior to commencement. This option does not have a notification pathway like option 1.2.
136. Like option 1.2, this option:
    a. enables early identification of emerging risks and encourage changes to trials to mitigate such risks before commencement of the trial
    b. would require a fee to account for the time and resources of the regulator for assessment of the application.
137. Compared to the status quo and option 1.2, this option will add the most regulatory requirements, which would significantly increase workload for the regulator. It should be noted that it would be essential for the regulator to have the resourcing and capacity to cope with the increased workload from this option. Without improved resourcing of the regulator, this option would lead to delays in approval timeframes.
138. With many medical device trials considered as lower-risk, rigorous oversight would not be appropriate. This option would over-regulate many of the medical device trials and place unnecessary costs and timing delays on industry. It would also significantly increase the workload for the regulator compared to option 1.2 and 1.1.

How do the options compare to the status quo?

	Option 1.1 – Status Quo	Option 1.2 – Notification and approval pathways	Option 1.3 - Approval for all clinical trials
Protection	0	+ High protection for trials through the approval pathway. Relatively less assurance of safety, quality and efficacy through the notification pathway but is appropriate according to risk. This option provides the regulator with transparency of clinical trials in New Zealand.	++ Highest assurance of safety, quality and efficacy for all trials due to all trials being assessed by the regulator. This option provides the regulator with transparency of all clinical trials in New Zealand.
Efficient	0	++ Reliance reduces unnecessary regulatory requirements and the time taken to grant approval. Notification pathway minimises regulatory requirements for lower-risk trials and prevents delays. Shorter evaluation processes reduce the work undertaken by the regulator and therefore costs recovered from industry through fees.	+ Reliance would reduce unnecessary regulatory requirements and the time taken to grant approval. Less efficient than option 1.2 due to all trials needing approval, which takes more time and resources than notification.
Proportionate	0	++ The regulatory requirements of the notification and approval pathways are flexible and consider the nature and risk profile of the trial.	0 The regulatory requirements don't consider the nature and risk of the trial.
Harmonised	0	++ Regulating clinical trials of medical devices and offering a notification pathway for lower risk trials aligns with comparable jurisdictions. Reliance and registration align with international best practice and is endorsed by WHO.	+ Regulating clinical trials of medical devices aligns with international approaches, but most other jurisdictions offer a notification pathway for the lower risk trials. Reliance and registration align with international best practice and is endorsed by WHO.
Overall assessment	0	+ 7	+4

What option is likely to best address the problem, meet the policy objectives, and deliver the highest net benefits?

139. Option 1.2 is the best option to address the problem when considering the four criteria together. The risk-proportionate approach of option 1.2 allows for more effective, proportionate and harmonised regulation of clinical trials, relative to the status quo and option 1.

Question 2: What are the powers of ethics committees in the regulation of clinical trials?

What options are being considered?

140. The options are:
    - **Option 2.1 Status quo**: no legislative requirement for clinical trials to have ethics approval.
    - **Option 2.2 Ethics approval with elevated powers:** legislative requirement for ethics approval and stronger implications if ethics approval is revoked.

Option 2.1 – Ethics approval Status Quo

141. Under status quo, there is no legislative requirement for clinical trials in New Zealand to be granted ethics approval. This makes New Zealand an outlier to comparable overseas jurisdictions.
142. While there are some incentives for gaining ethics approval (eg, to publish in international journals) the incentives are not robust enough to guarantee that a trial will be conducted in an ethical manner and are therefore are not sufficiently protective.
143. Once the trial has commenced, it is the responsibility of the researchers themselves – not the ethics committees (HDECs) – for ensuring that the research always meets the ethics standards throughout the duration of the trial. HDECs have no investigative or enforcement powers, so while they can make conditional requirements of reporting in their ethics approval, they have no follow up ability to ensure trial protocols are be carried out in a way that upholds ethics standards. This visibility of cases of non-compliance of ethics conditions that may warrant cancellation of ethics approval.
144. Ethics approval is publicly funded in New Zealand, so there are no fees for the sponsor. The pace of processing applications depends on the amount of public funding available, which can at times be a constraining factor in turnaround time for approvals.
145. Whilst affordable for industry, ethics approval is at the expense of time and resources for the ethics committees. Changes to fees for ethics approval, whether justified or not, is out of scope of the Bill.
146. This option provides assurance that the initial protocol for a clinical trial, as submitted to the ethics committee for approval, meets ethical standards. However, there is limited assurance that clinical trials maintain the ethical good practice throughout the entire duration of the trial.
147. Without any legislative requirement or any true impact of revoking ethics approval the status quo lacks incentive for industry to get ethics approval, which impairs the effectiveness of this option.

Option 2.2 – Ethics approval with elevated powers

148. Under this option, ethics approval would be a legislative requirement for clinical trials in New Zealand, and the HDEC would have elevated investigative powers.
149. This option would increase the number of applications to the HDEC. To account for increased applications, this option would require either an increase in public funding to the HDECs or for sponsors to be charged for ethics review. Charging for ethics review is an approach adopted by comparable jurisdictions, such as Australia.
150. Like the status quo, this option would allow for exemptions from the requirement for ethics approval, for example lower-risk medical device trials. The exemption criteria would be established in secondary legislation.

151. Under this option, the ethics assessment, and the scientific/clinical assessment by the regulator (outlined in question 1) could occur in parallel. However, ethics approval must be granted before approval by the regulator.
152. The approval timeframes and expedited review pathway, as set out in the status quo, would be maintained in this option. This would support timely approval of clinical trials and contribute to efficiencies for industry.
153. This option would give HDEC investigative and enforcement powers, so they have:
    a. the visibility to ensure trial protocols are be carried out in a way that upholds ethics standards
    b. the ability to cancel ethics approval when an investigation discovers a breach of ethics standards.
154. Like the status quo, ethics approval may be suspended or cancelled due to serious concerns. In this option, cancelling ethics approval would have more implications than under the status quo. Cancelling ethics approval would revoke the permission for the sponsor to complete the clinical trial in New Zealand. This would better incentivise sponsors to adhere to ethical standards more than the status quo.
155. This option provides more assurance that ethical standards are met from the initial protocol for a clinical trial and throughout the entire duration of the trial than the status quo.

How do the options compare to the status quo?

	Option 2.1 – Status Quo	Option 2.2 – Ethics approval with elevated powers
Protection	0	+ The legislative requirement for ethics and investigative powers to ethics committees ensures trials meet ethics standards throughout its duration
Efficient	0	+ Ethics committees better resourced (either from funding or charging fees) will improve ability to process applications quicker. Slightly increases cost for industry, but outweighed by the increased efficiency of processing applications
Proportionate	0	0 Enables the same exemptions for lower risk medical device trials as option 2.1
Harmonised	0	+ Better aligned with international approaches than option 2.1 by giving ethics committees investigative powers and more appropriate consequences for breaches of ethical requirements
Overall assessment	0	+3

What option is likely to best address the problem, meet the policy objectives, and deliver the highest net benefits?

156. Option 2.2 is the best option to address the problem as it scores better than the status quo in all criteria apart from the proportionate criterion which scores equal to status quo.

Question 3: Procedure controls of clinical trial sites

What options are being considered?

157. This section looks at the regulatory controls on general procedures at clinical trial sites.
158. Regulatory approval of clinical trials, discussed in question 1, relates to the scientific validity and safety of the trial protocol. This section isn't concerned with protocol details of a certain clinical trial but looks at regulatory controls related to general health and safety protocols that are conducted at trial sites. For clarity, these health and safety procedures will be referred to as 'general procedures' for this analysis.
159. The options are:
    - **Option 3.1 status quo**: Voluntary scheme for clinical trials of medicines.
    - **Option 3.2 licencing system**: a licence requirement for clinical trial procedures
    - **Option 3.3 registration and notification system**: requirement to register or notify clinical trial procedures with the regulator.

Option 3.1 – Status Quo

160. Under the current regime there is a lack of clarity on what general procedures are in place and if they are appropriate to the risks of trials that the site hosts.
161. Without modern regulation and audit powers of the regulator, it can be difficult to know that trials are being undertaken appropriately to protect participants.

Lack of clarity of general procedures at clinical trial sites

162. Under the status quo, section 30(3)(g) of the Medicines Act specifies that when applying for Medsafe approval, applications for clinical trials of medicines must include information about the site(s) of the trial and the facilities available at those sites.
163. The Medicines Act does not set out any requirements for general procedures of sites that host clinical trials of medical devices, like it does for trials of medicines.
164. As such, Medsafe administers a voluntary Clinical Trial Site Notification (CTSN) scheme to facilitate the collection and processing of this information. CTSN is only for clinical trial sites where participants are required to stay overnight for monitoring purposes.
165. The CTSN form is a tick-box form that declares the site has:
    a. round-the-clock emergency qualified and trained staff on duty
    b. critical incident procedures in place to ensure the safe care of participants
    c. critical incident training and refresher courses for staff.
166. The notification scheme doesn't require evidence to support the above declarations. Hence, there Medsafe cannot check the information, such as that the investigators and staff involved at the trial site are appropriate for the trials they conduct.
167. The safety procedures differ greatly based on the type of trial. For example, low-risk medicine trials compared to first-in-human trials of gene therapies require different protocols and personnel with different levels of experience and qualifications. However, under the status quo, these sites are subject to the same tick-box declarations.

Lack of audit powers for the regulator

168. Under status quo, Medsafe has no legal ability to visit and audit the sites, and therefore no ability to confirm that the site meets the conditions declared on the CTSN form.

Option 3.2 – Site licensing

169. This option would require site managers to apply to the regulator for a licence that would permit them to undertake general procedures relating to the site. This licence would be held by the site, rather than assigned to specific trials.
170. The licence application would require evidence of the general activities which would be assessed by the regulator. This could include the type of trial (eg, first-in-human) and the qualification and experience of investigators, particularly in respect to the type of trial. The licence requirements would be in accordance with Good Clinical Practice.

171. Under this option, the regulator would have a legal ability to visit and audit the sites. Audits would be done as appropriate for additional assurance, rather than a condition of authorisation. Here, the regulator can assess whether procedures are being undertaken appropriately and would have the ability revoke authorisation if standards are not being upheld.
172. There is scope to expand the requirements of granting a licence over time to require compliance with internationally recognised standards, however, this would be introduced in a phased way, and in consultation with industry.
173. Exemptions could be utilised to remove the requirement for a licence where appropriate. Requiring a licence for these activities, without exemptions, would be inflexible.
174. If implemented, this option would require additional resource for the regulator to conduct the assessment and audit.

Option 3.3 – Site registration and notification system

175. This option would require site managers to either notify the regulator or register the general procedures of the clinical trial site with the regulator. Under this option, the requirement to register or notify can be administered flexibly by the regulator in a risk-proportionate manner and adapt over time.
176. The notification pathway would be similar to the status quo but would not be voluntary. This pathway would be appropriate for lower-risk clinical trials.
177. Registration would not be an approval per se but would allow the regulator to confirm the information submitted is appropriate. This review would be minimal so as to not cause significant delays or uncertainty for trial sites and sponsors. Over time, specific requirements could be introduced for registration applications to include an accredited certificate of compliance with an internationally recognised system. The regulator would verify the certificate. Registration would be appropriate for clinical trials of medicines and high-risk medical devices.
178. Where industry holds accreditation or certification under internationally recognised standards for certain activities, such as Global Standard Certification for Clinical Research Sites, these could be recognised by the regulator.
179. Under this option, the regulator would have the ability to decline an application and suspend or cancel a registration in justified situations, such as improper conduct by investigators or serious unexplained adverse events. Such concerns could be raised after monitoring and auditing activities by the regulator.
180. This option would enable the regulator to have visibility of the general activities at clinical trial sites. Through this visibility, this option would facilitate faster response in the event of an emergency or adverse event in a trial.
181. The regulatory burden for trial sites to register with the regulator and submit basic identifying information is relatively low. The likely compliance costs associated with this option will also be relatively low, and associated fees related to cost-recovery for administering the registration will be minimal.
182. There is scope to expand the requirements of registration over time to require the compliance with internationally recognised standards under a risk-proportionate approach. This would be introduced in a phased way and in consultation with industry.
183. This option enables the regulator to adapt to evolving needs over time to ensure clinical trial site activities are appropriately controlled.

How do the options compare to the status quo?

	Option 3.1 – Status Quo	Option 3.2 – Site licencing system	Option 3.3 – Site registration and notification system
Protection	0	++ All sites subject to assessment of general activities to get a licence. Audit ability protects participants from unsafe sites and protects validity of results.	+ Less protection than 3.2 for lower risk trial sites via notification pathway. For other trials, the regulator has visibility of general activities to protect participants but doesn't conduct assessment. Audit ability protects participants from unsafe sites and protects validity of results.
Efficient	0	- Time to assess and grant licences would impact timelines and increase work for the regulator. Industry would be subject to fees to account for the increase in workload for the regulator. Creates uncertainty for when/if a license will be granted.	0 The notification and registration options would not significantly impact timelines.
Proportionate	0	+ Offering exemptions for lower risk trial sites enables a degree of flexibility. Ability to change requirements overtime enables future-proofing and flexibility.	++ Offering notification and registration provides flexibility and considers the nature and risk profile of the trial sites. Ability to change requirements overtime enables future-proofing and flexibility.
Harmonised	0	0 No comparable jurisdiction adopts a site licencing system.	+ Recognising international accreditation/certification aligns with international best practice.
Overall assessment	0	+2	+4

What option is likely to best address the problem, meet the policy objectives, and deliver the highest net benefits?

184. Option 3.3 is the best option to address the problem when considering the four criteria together. Option 3.3 ranks better than the status quo in the protection, proportionate and harmonised criteria and has equal efficiency to the status quo.

Is the Minister's preferred option in the Cabinet paper the same as the agency's preferred option in the RIS?

185. Yes.

What are the marginal costs and benefits of the preferred options (1.2, 2.2, 3.3) in the Cabinet paper?

Affected groups *(identify)*	**Comment** *nature of cost or benefit (eg, ongoing, one-off), evidence and assumption (eg, compliance rates), risks.*	**Impact** *$m present value where appropriate, for monetised impacts; high, medium or low for non-monetised impacts.*	**Evidence Certainty** *High, medium, or low, and explain reasoning in comment.*
Additional costs of the preferred option compared to taking no action			
Clinical trial industry	Increased one-off costs for regulatory approval for clinical trials of medical devices. Ongoing efficiency gains from better approval processes	Low-medium costs for approval (noting fee waivers may be available for non-commercial trials) Unable to quantify cost-benefit from efficiency gains	High Low
Crown	Crown agencies may be the applicant for clinical trials and would incur costs associated with cost-recovering assessment, as is the status quo. Costs would be the same as for clinical trial industry, unless alternate arrangements put in place.	See above	See above.
Regulator	Increased workload balanced by improved efficiencies. This would likely result in net neutral costs of undertaking assessments which will be recovered through industry fees.		
Clinical trial participants	No cost impact expected.		
Total monetised costs		Low	
Non-monetised costs		Low	
Additional benefits of the preferred option compared to taking no action			
Clinical trial industry	Improved alignment with requirements of the international market, reduced duplication of efforts due to reliance pathways.	Unable to quantify cost benefit Direct financial cost (benefit) to applicants of moving to notification	Low

	Decreased cost for applications via the notification or reliance pathways.	system difficult to quantify. Notification under the Australian regime is AUD 429 per application vs AUD 2,046 - 26,426 under the approval pathway[6].	High
Crown	Reduced harm from unsafe or fraudulent clinical trials. Increase in clinical trials conducted in New Zealand.	Rate of harm from clinical trials has not been modelled and varies according to trial phase and product. Injuries from commercial clinical trials not eligible for ACC funding. The increase in direct investment in clinical trials in New Zealand has not been modelled.	Low Low
Participants	Improved access to trial medical products and improved protection. Reduced harm from unsafe or fraudulent clinical trials.	Unquantified benefit. Rate of harm from clinical trials has not been modelled. Injuries from commercial clinical trials not eligible for ACC funding.	Medium Low
Regulator	This would be a new activity for the regulator, leading to increased costs which will be recovered through industry fees. The increase in activity will be minimised through more efficient approval processes, and through recognising international certification/approval.	Neutral cost/benefit as efficiencies expected to result in lower costs and charges for applicants.	Medium
Total monetised benefits			
Non-monetised benefits			

Section 3: Delivering an option

How will the proposal be implemented?

186. Decisions on who would implement the new regulation will be subject to future government decisions. Implementation will include development of secondary legislation which will set out details of the system, particularly elements which are likely to need to change over time.
187. The approval/notification system will be operated and enforced by the Crown. Options on the form of any regulator is has been considered by Cabinet separately.
188. The ethics approval system will be operated by the ethics committees.

[6] https://www.tga.gov.au/sites/default/files/2024-12/fees_and_charges_summary_1_january_2025.pdf.

189. The regulation of clinical trials, particularly for medical devices, will change significantly. This will require several years to enable a smooth transition period, in addition to the time needed to develop secondary legislation.
190. Education campaigns are likely needed for industry, where there are significant changes from the status quo.
191. Consistent with the Pae Ora (Healthy Futures) Act 2021, the Ministry of Health will retain a stewardship and oversight role.
192. As with all new systems, there is significant risk of time and cost over-runs. The proposed medical products regulatory regime is a broad programme of work, which will take place over several years. Due to the complexity of the programme, it is likely there will be areas that are more challenging to implement and it is difficult to predict or quantify the specific risks regarding implementing the clinical trial provisions. There are lessons New Zealand can learn from its existing system for clinical trials. In addition, comparable jurisdictions, such as Australia, have already undergone similar regulatory reform, and we can learn from their experiences. Costs can be minimised in the design of the different pathways for clinical trial approval, in particular those involving reliance and notification.

How will the proposal be monitored, evaluated, and reviewed?

193. The regulator will have reporting requirements, to be determined as part of policy work on the form and responsibilities of the regulator. The metrics are likely to include:
    a. time taken to approve clinical trials via the various pathways
    b. time taken to process applications for site controls
    c. compliance and enforcement action taken.
194. There is open communication between the health sector, the Ministry of Health and Ministers of Health. We expect them to be proactive in raising any problems or concerns with the new system.
195. Work will be needed to ensure that any participant problems with a new system are heard and responded to.