

TranspariMED

www.TranspariMED.org

Contact: tillbruckner@gmail.com

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Comments on the Therapeutic Products Bill (New Zealand) by TranspariMED

Question C16 Please provide any comments on the change in approach to regulating clinical trials.

[TranspariMED](http://www.TranspariMED.org)¹ is a global campaign that works to end evidence distortion in medicine.

TranspariMED is concerned that the proposed Therapeutic Products Bill falls significantly short of global best practices in clinical trial transparency set out by the World Health Organization (WHO) and endorsed by numerous other stakeholders. Failure to register and fully report clinical trials harms patients, wastes taxpayers' money, and slows down the development of new treatments, vaccines and cures.

The proposed Therapeutic Products Bill fails to ensure that all clinical trials are prospectively registered and rapidly make their summary results publicly available. Therefore, it does not address the problems of publication bias, evidence distortion in clinical trial reporting, and research waste. This runs counter to the interests of trial participants, patients and taxpayers in New Zealand.

[According to Transparency International and Cochrane](#), "decision-makers should bring existing laws, rules and regulations into line with global best practice standards and ensure that they cover all clinical trials, past and present, as defined by the WHO."²

The relevant global best practices as set out by the WHO are as follows:

- All clinical trials should be registered on a WHO-approved [primary] trial registry before the recruitment of the first participant.
- Summary results for all clinical trials should be posted on the registry or registries where they were originally registered within 12 months of study completion.

Please note that the relevant definition of "clinical trial" in this context is that [used by the WHO](#),³ and includes trials of both licensed and unlicensed medicines and trials of medical devices, without making any distinction between them:

"For the purposes of registration, a clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiological procedures, devices, behavioral treatments, process-of-care changes, preventive care, etc."

¹ TranspariMED website. www.TranspariMED.org

² Transparency International et al. 2017. "Clinical Trial Transparency: A Guide for Policy Makers" https://docs.wixstatic.com/ugd/01f35d_def0082121a648529220e1d56df4b50a.pdf

³ WHO. 2019. "Clinical trials" https://www.who.int/topics/clinical_trials/en/

Prospective trial registration is already required in New Zealand in theory, but in practice compliance with this rule has been neither monitored nor enforced, [resulting in widespread violations of medical research ethics](#).⁴

There are currently no rules in New Zealand that mandate the reporting of clinical trial results. This is a remarkable gap that makes New Zealand a negative outlier in clinical trial transparency worldwide, including in terms of [actual trial reporting performance](#).⁵

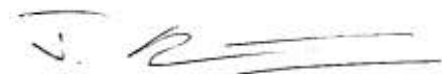
There are precedents for relevant legislation in other countries. For example, the 2007 U.S. Food and Drug Administration Amendments Act (FDAAA) and the 2014 European Union Clinical Trial Regulation both contain trial registration and reporting provisions, with both jurisdictions mandating results reporting on trial registries within the 12 month time horizon recommended by the WHO. The FDAAA sets out a penalty of over US\$ 11,000 for each day a clinical trial is late in posting its summary results onto the American trial registry.

New Zealand must address this legal and regulatory gap by enshrining trial registration and reporting requirements in law, and putting an effective monitoring and sanctions regime in place.

RECOMMENDATION 1. The Therapeutic Products Bill should include provisions that mandate the registration of all clinical trials on a public trial registry before the recruitment of the first participant, establish a mechanism for monitoring compliance, and set out financial penalties for non-compliance.

RECOMMENDATION 2. The Therapeutic Products Bill should include provisions that mandate the posting of the summary results of all clinical trials onto trial registries within 12 months of a trial's primary completion date, establish a mechanism for monitoring compliance, and set out financial penalties for non-compliance.

Yours faithfully,



Till Bruckner
Founder
TranspariMED



⁴ Emma Tumilty and Till Bruckner. 2019. "Clinical trials in New Zealand: Huge transparency gaps"
<https://www.transparimed.org/single-post/2019/03/13/Clinical-trials-in-New-Zealand-Huge-transparency-gaps>

⁵ Emma Tumilty and Till Bruckner. 2019. "Clinical trials in New Zealand: Huge transparency gaps"
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