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New Zealand to update clinical trial regulatory guidelines

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To provide further clarity to those involved in conducting clinical trials about their obligations

A plan aiming to streamline clinical trial reporting procedures in some circumstances is now out for consultation in New Zealand.

Medsafe, the New Zealand Medicines and Medical Devices Safety Authority, is seeking public feedback on a series of proposed updates to the regulatory guidelines for people conducting clinical trials for medicines and medical devices.

A key change will be the provision of guidance for conducting first-in-human trials. These trials, where a medicine is administered to humans for the first time, are an important part of medicines development, but they are also the phase of trials associated with the greatest risk for participants.

Medsafe has also been working with the New Zealand Association of Clinical Research (NZACRes) to produce a simple guide to safety reporting requirements for those conducting clinical trials. This guide is also being consulted on.

Other updates aim to keep guidance in line with current best practice. For example, involving consumers and patient advocacy groups in the design and conduct of trials, encouraging the implementation of pharmacovigilance systems and clarifying the responsibilities of those involved in clinical trials.

The last major revision to these guidelines was in 2018, and further updates were put on hold during the Covid-19 pandemic to allow more urgent work to be prioritised. This has also meant that some associated legislation has changed, and the guideline needed to reflect this as well.

A proposed change would also reduce reporting requirements for companies who run their own pharmacovigilance system because they are well set up to respond to any safety issues in a timely manner without needing regulatory input.