



Consultation on proposed regulatory changes for clinical trials of medical devices

The Therapeutic Goods Administration (TGA) is the government authority responsible for evaluating, assessing, and monitoring products that are defined as therapeutic goods. They regulate medicines, medical devices, and biologicals to help Australians stay healthy and safe.

As part of the TGA's Action Plan on Medical Devices, a commitment was made to review the arrangements for medical devices that are used in clinical trials to ensure the use of these devices meet community expectations. Between 17th August and 28th September 2022, through the consultation on the [proposed regulatory changes for clinical trials of medical devices](#), the TGA sought feedback on two approaches that would strengthen safety oversight of clinical trials for medical devices.

1. To increase the degree of regulatory oversight of clinical trials of certain unapproved, high-risk medical devices by requiring that they obtain TGA approval through the Clinical Trial Approval pathway.
2. To include clinical trials of all medical devices in Australia's Good Clinical Practice Inspection Program which will enable selected trials and documentation supporting these trials to be inspected.

Cancer Council supported the proposed changes to reduce future, potential significant safety risk to people, while highlighting that such changes should seek to avoid resulting in unnecessary delays to patient access or be a deterrent for sponsors conducting clinical trials in Australia.