Purpose

Guidance for TGA pathway selection for unapproved therapeutic goods and CTN form completion.

Definitions

CTN: Clinical Trial Notification

CTA: Clinical Trial Approval

HREC: Human Research Ethics Committee

TGA: Therapeutic Goods Administration

Guidance

The CTN and CTA schemes are the two avenues provided by the TGA for the importation into and/or supply in Australia of unapproved therapeutic goods for use in a clinical trial. Clinical trials that do not involve unapproved therapeutic goods are not subject to requirements of the CTN or CTA schemes.

It is the responsibility of the Australian sponsor to determine whether a product is considered an unapproved therapeutic good. The choice of which scheme to use lies firstly with the Australian sponsor and then with the HREC that reviews the protocol.

Clinical Trial Notification (CTN)

Prior to use, the Australian sponsor must notify the TGA of the intent to sponsor a clinical trial involving an unapproved therapeutic good via submission of a CTN form. The CTN form must be submitted to the TGA online. CTN submissions must be submitted via the TGA Business Services website.

CTN form Bellberry HREC Contact Officer

(the person who may receive correspondence on behalf of the HREC about the CTN)

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The TGA does not evaluate any data relating to the clinical trial at the time of submission. The TGA delegates to the HREC the authority to review the scientific validity of the trial design, the balance of risk versus harm of the therapeutic good, the ethical acceptability of the trial process, and to approve the trial protocol.

The institution or organisation at which the trial will be conducted, referred to as the 'Approving Authority', gives the final approval for the conduct of the trial at the site, having due regard to advice from the HREC.

It is the responsibility of the sponsor to ensure that all relevant approvals are in place before supplying the unapproved therapeutic goods in the clinical trial.

Clinical Trial Approval (CTA)

The CTA pathway is designed for high-risk or novel treatments where there is no or limited knowledge of safety. In this pathway the research application is reviewed by the TGA first and then by the HREC. Please refer to the TGA website for more information.

References

TGA Access Pathways for Unapproved Therapeutic Goods
Clinical Trial Notification (CTN) Scheme
Clinical Trial Approval Scheme Forms