



# **Therapeutic Goods (Clinical Trial Inspections) Amendment Specification 2024**

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I, Marcelle Noja, as delegate of the Minister for Health and Aged Care, make the following specification.

Dated 16 September 2024

Marcelle Noja  
Acting First Assistant Secretary  
Medical Devices and Product Quality Division  
Health Products Regulation Group  
Department of Health and Aged Care

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## 1 Name

This instrument is the *Therapeutic Goods (Clinical Trial Inspections) Amendment Specification 2024*.

## 2 Commencement

- (1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1	Column 2	Column 3
Provisions	Commencement	Date/Details
1. The whole of this instrument	The day after this instrument is registered.	

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

- (2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

## 3 Authority

This instrument is made under subsection 61(5AB) of the *Therapeutic Goods Act 1989*.

## 4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

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## Schedule 1—Amendments

### *Therapeutic Goods (Clinical Trial Inspections) Specification (No. 2) 2020*

#### 1 Section 4

Insert:

*MD Regulations* means the *Therapeutic Goods (Medical Devices) Regulations 2002*.

#### 2 Section 4 (definition of *relevant authorised officer*)

Repeal the definition, substitute:

*relevant authorised officer*, in relation to a clinical trial of therapeutic goods, means:

- (a) the authorised officer who has exercised powers in accordance with regulation 12AC of the Regulations in relation to the clinical trial; or
- (b) the authorised person who has exercised powers in accordance with regulation 7.4 of the MD Regulations in relation to the clinical trial.

#### 3 Schedule 1 (table item 1, column 2)

Omit “, other than medical devices”.