Explanatory Statement

Industry Research and Development (Clinical Trials) Determination 2021

Legislative Authority

The *Industry Research and Development Act 1986* (Act) facilitates the administration of the Research and Development Tax Incentive (R&D tax incentive).

Under subsections 27B(1) and 27J(1) of Part III of the Act, Industry Innovation and Science Australia (the Board) may make findings about an R&D entity's registration under section 27A including whether all or part of an activity was a core R&D activity conducted during the relevant income year.

Under subsection 28A(1) of Part III of the Act the Board must, on an application by an R&D entity, make a finding about an activity including whether all or part of the activity is a core R&D activity.

Under subsection 31D(1) of the Act, the Board may, by notifiable instrument, make a determination about the circumstances or way in which the Board will exercise any of its powers, or perform any of its functions or duties, under Part III of the Act.

On **[*insert date*]**, the Board made the *Industry Research and Development (Clinical Trials) Determination 2021* (Determination) which deems phase 0, I, II and III clinical trials meeting certain conditions to be core R&D activities within Part III of the Act on and after the commencement day of **[*insert date*]**.

Purpose and Operation

The Determination identifies the conditions under which clinical trials will be accepted to be core R&D activities when the Board exercises its power to make a finding under section 27B, 27J or 28A of the Act.

When R&D entities submit a registration for the R&D tax incentive under section 27A of the Act or seek a finding under section 28A of the Act, the Board may need to determine if the activity meets the definition of R&D activities. This term is defined in the *Income Tax Assessment Act 1997* and includes "core R&D activities". This term is also defined in the *Income Tax Assessment Act 1997*.

The Determination reduces regulatory burden by providing clarity to R&D entities about the types of clinical trials that will be accepted to be core R&D activities for the purpose of the Board exercising its power to make a finding under sections 27B, 27J and 28A of the Act.

Policy intent

The Board recognises that in Australia, clinical trials are generally conducted within strict regulatory frameworks. This includes complying with any relevant approvals, requirements and standards when conducting these trials. This means many clinical trials meet the definition of "core R&D activities" in the Act if they are conducted in accordance with this regulatory framework.

There is no single accepted industry wide definition of "clinical trial". The World Health Organization (WHO) definition for 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'*.

The National Health and Medical Research Council states that:

'*Clinical trials are research investigations in which people volunteer to test new treatments, interventions or tests as a means to prevent, detect, treat or manage various diseases or medical conditions. Some investigations look at how people respond to a new intervention* and what side effects might occur. This helps to determine if a new intervention works, if it is safe, and if it is better than the interventions that are already available.*

Clinical trials might also compare existing interventions, test new ways to use or combine existing interventions or observe how people respond to other factors that might affect their health (such as dietary changes).'

Compared to these definitions, this Determination applies to a more narrow set of clinical trial activities. This Determination only applies to phase 0, I, II and III clinical trials, which are notified pursuant to item 3 of Schedule 5A of the *Therapeutic Goods Regulations 1990* or item 2.3 of Schedule 4 to the *Therapeutic Goods (Medical Devices) Regulations 2002*, or are approved pursuant to sections 19(1)(b), 32CK(1)(e) or 41HB(1)(e) of the *Therapeutic Goods Act 1989*.

This Determination does not apply to aspects of clinical trials which are not phase 0, I, II and III clinical trials (including phase IV clinical trials), or to clinical trials of generic medicines. The Board accepts that such activities are capable of meeting the definition of core R&D activities in particular circumstances but they are outside the scope of this determination.

This Determination will facilitate registration with the R&D tax incentive program by providing increased certainty on eligibility for the program to those conducting clinical trials in Australia.

Consultation

The Determination has been developed in consultation with the ATO, the Department of Health, and through a public consultation process.

Explanation of provisions

Section 1 – Name
Section 1 provides the name of the instrument.

Section 2 – Commencement
Section 2 sets out the commencement date of the instrument, which is the day after registration.

Section 3 – Authority
Section 3 sets out the legal authority to make the instrument.

Section 4 – Definitions
Section 4 provides definitions for terms used in the instrument.

Section 5 – Determination
Section 5 sets out that phase 0, I, II and III clinical trials which are notified under the *Therapeutic Goods Regulations 1990* or approved under the *Therapeutic Goods Act 1989* will be core R&D activities.

Section 6 – Exceptions
Section 6 sets out exceptions where activities will not be core R&D activities under section 5 of the instrument. It is possible that the described activities are core R&D activities as defined in the *Industry Research and Development Act 1986*, but these activities are outside the scope of the determination.

Section 7 – Part of an activity
Section 7 states that sections 5 and 6 can apply to part of an activity when the Board is making a finding that is covered by the instrument.

Statement of Compatibility of Human Rights

The Determination is not a legislative instrument. Consequently, section 42 (Disallowance of legislative instruments) of the *Legislation Act 2003* does not apply to the Determination and a Statement of Compatibility with Human Rights is not required.