



**AusBiotech submission in response to the  
*Draft Industry Research and Development (R&D  
Tax Incentive on clinical trials, Phase 0, I, II, III for  
an unapproved therapeutic good)*  
*Determination 2021***

To: Department of Industry, Science, Energy and Resources  
GPO Box 2013  
Canberra, ACT, 2601  
E-mail: [rdti.engagement@industry.gov.au](mailto:rdti.engagement@industry.gov.au)

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From: AusBiotech Ltd  
ABN 87 006 509 726  
Level 3,15 Queen St  
Melbourne VIC 3000  
Telephone: +61 3 9828 1400  
Website: [www.ausbiotech.org](http://www.ausbiotech.org)

## Introduction

AusBiotech welcomes the opportunity to submit on the draft *Industry Research & Development (Clinical Trials, Phase 0-III for an Unapproved Therapeutic Good) Determination 2021*.

The Research and Development Tax Incentive (RDTI) is the most critical programme in supporting the Government's stated policy objective – to improve Australia's performance when it comes to the commercialisation of medical research; and the Determination will offer certainty to the clinical trial sector, which already contributes around \$1.4 billion to the economy each year, and enhance Australia as a globally-preferred location for clinical trials.

As the Australian representative body for one of Australia's most innovative industries - the biotechnology or life sciences industry - AusBiotech has been a long and strong advocate for the beneficial additionalities that the RDTI offers to Australian life sciences.

AusBiotech is a well-connected network of over 3,000 members in the life sciences industry, which includes bio-therapeutics, medical technology (devices and diagnostics), food technology and agricultural biotechnology sectors. With more than 2,500 organisations and at least 290,000 employees, Australia has a substantial life sciences sector and one which is consistently ranked as one of the top for biotechnology innovation globally.

This response has been developed together with the AusBiotech's Clinical Trial Advisory Group, which provides guidance and advice on clinical trials policy, and AusBiotech members that are tax experts. It is supportive of the Determination, and has offered opportunities and insights into improving clarity and adding greater certainty for the sector through this legislative tool.

Responses have been framed around the Department's feedback questions, as requested in the consultation paper.

### **Question one: Is the draft Determination appropriate for providing more certainty of access to the R&D Tax Incentive for clinical trials in Australia? How effective would the draft Determination be if it were finalised in its current state in providing certainty to your business? Why?**

The RDTI is the most critical policy available to life sciences companies and the draft Determination is a welcome and positive first step in cementing certainty to a programme that has been incentivising investment into the sector for over 10 years.

Clinical trials work in a highly-regulated environment and industry has become familiar with eligibility over the past 10 years; this Determination offers eligibility certainty and consistency and acts as a formal indicator to the national and international life sciences ecosystem that clinical trials are a recognised and eligible core activity under the RDTI.

### **Question two: Should the draft Determination be expanded? Specifically do you agree with the scope of the draft Determination including definitions? Do you consider it should include additional clinical trials? Could it support you more with overseas and advance findings? How?**

#### *Scope*

The Determination seeks to offer certainty to specific core activities within the end-to-end process of a clinical trial.

Definitions are very welcome in order to add certainty and consistency for potential claimants, however, it appears that the current definitions follow the pathway of clinical trials for the development of medicines, and are therefore unsuitable for clinical trials for medical technologies such as devices and diagnostics. Please see diagrams below.

AusBiotech’s commissioned research revealed that the Australian life sciences industry is comprised of at least 1,300 companies, of which approximately one-third were medical technology and digital health companies; the medtech and digital health sector saw a 19 percent growth between 2017 and 2019. Therefore, ensuring this important sector is included within the Determination’s definitions will be critical in offering these companies certainty in their RDTI programme registration.

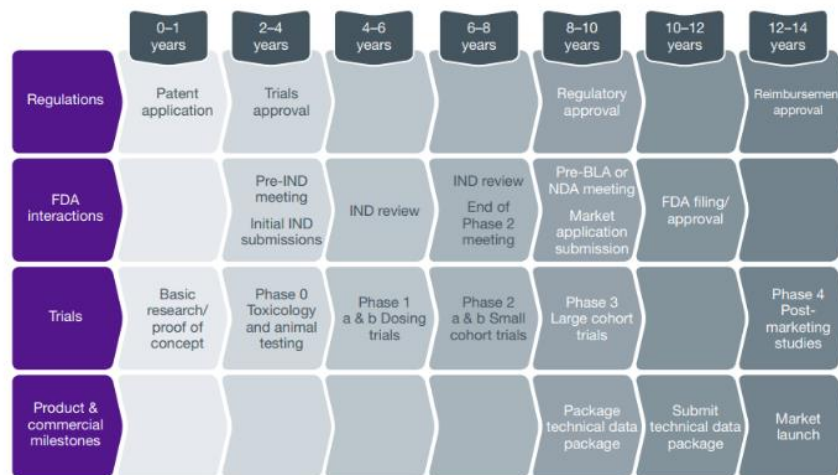
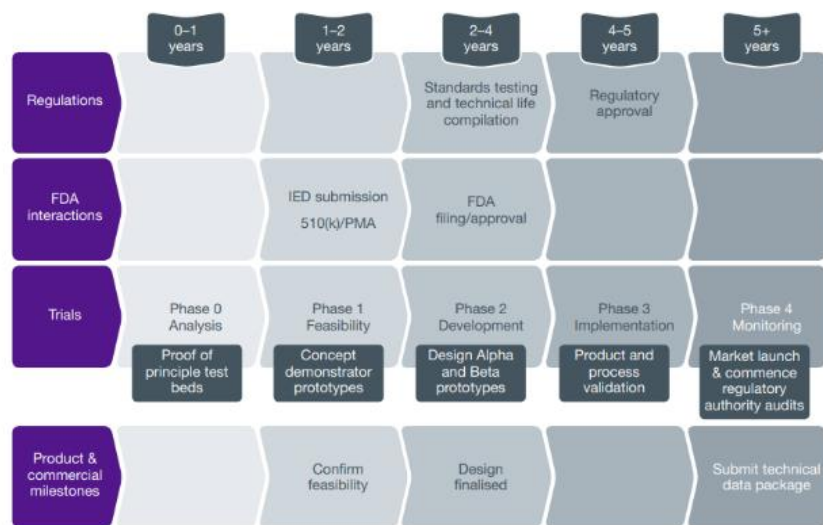


Figure 4. Drug development and approval pathway<sup>44</sup>



Note: This figure outlines the FDA approval route; the CE Mark route in Europe is substantially different.<sup>45</sup>

Figure 5. Product development and approval pathway<sup>47</sup>

This Determination is for “an **unapproved therapeutic good**”; clarity is necessary on whether the instrument will also apply to unapproved therapies that are unapproved for the indication relevant for the clinical trial. This would mean that drugs that have been approved for another use are not excluded from the determination.

Initial **manufacturing** for clinical trials is small scale, bespoke, and expensive, and is core to clinical trial activities. It should also be noted that it is very different from manufacturing for market, which is large scale. Typically, manufacturing products for market utilises different infrastructure, and requires different and further investment. Due to this clear delineation between manufacturing of a

therapeutic to be used in the clinical trial and manufacturing for commercialisation, it is recommended that the scope of the Determination should also expand to include manufacturing *for clinical trials* as a supporting R&D activity.

#### *Definitions*

Development of guidance to be released in conjunction with the Determination would be very welcomed by the industry. Specifically, additional certainty and clarity could be detailed as to what activities are included under each phase, and how decisions are being made. This would help industry to determine how much of their project can be claimed as well as help tax assessors understand and align the nuances of clinical trial practices.

For example, the draft Determination's definition states that "*phase 0 clinical trial means exploratory studies or pilot studies that are used to test how the body responds to an unapproved therapeutic good before phase I clinical trials.*"

Clinical trials may involve non-interventional elements during Phase 0; this is an observational clinical trial that is intended to give clinicians a natural history, and offer real-world data comparisons to the interventional arm of the clinical trial. In addition, Patient Advisory Groups are engaged early to help inform the design of a clinical trial. Both of these activities offer great benefits to the clinical trial process and are being encouraged by the Australian Government as they ultimately reduce the cost of clinical trials and therefore the cost of the technologies; however, they also involve administrative burden to companies and it is unclear if these activities are included in the definition above. Offering support via this instrument will encourage greater uptake of these types of activities.

*Phase IV* is excluded from the Determination, however, definitions and/or guidance needs to clearly state that clinical trials of technologies that are testing a new indication for an already-approved drug (Phase III) are not considered Phase IV. In a world of conditional and expedited approvals, post-approval studies are often still working out safety and efficacy so are akin to Phase III in terms of uncertainty of outcome.

#### *Could it support you more with overseas and advance findings? How?*

It would be a beneficial if, when applying the Determination, a company could include overseas findings by quoting the registered trial number. This would continue to align to TGA regulatory requirements, would be simple for AusIndustry to implement, and would expedite approval times – thereby enhancing Australia as a globally-preferred location for clinical trials. Currently, anecdotal evidence demonstrates that approval of overseas findings can take anywhere between six weeks and up to one year, dependent upon the sector knowledge of the AusIndustry assessor. There is currently no clear determination rulings, algorithms, work flow determination matrixes or case studies available for industry (nor assessors) to refer to. This length of time for these approvals can significantly affect a company's cashflow and the progress of clinical trial activities. Including overseas findings within this Determination would reduce the administrative burden on AusIndustry and offer certainty to this highly-regulated industry.

#### **Question three: Do you see the potential for the draft Determination to be abused, undermining the integrity of the R&D Tax Incentive? Do you consider people may try and apply to register activities that are not core R&D activities? How?**

Once clear definitions and guidance (see above, #2) are incorporated into the Determination, then we see the potential for the Determination to be an overwhelmingly positive improvements to certainty under the program and that it would add integrity rather than undermining to the Program.

**Question four: Do you consider the finalised Determination should identify and require compliance with any specific framework, guideline or standard, such as the Australian Guideline for Good Clinical Practice? Why/why not? If yes, what should be specified?**

*No comment.*

**Question five: Is there anything that confuses you about the draft Determination? Please offer details.**

The life sciences sub-sectors are increasingly converging as technology develops. As noted in #2 above, the medical technology (devices and diagnostics) sector is increasingly growing in Australia, and offers opportunities for the economy, patients, and science. Clinical trials can provide reliable evidence of the effectiveness of the full gamut of health care and these trials have the potential to provide enormous health benefits for Australians. While it is recommended that the scope is expanded to give clarify on the inclusion of medical technologies (such as devices and diagnostics), if they are excluded from the Determination's scope, it would be worthwhile understanding the rationale.

**Question six: Is it clear from the draft Determination that it does not apply to all phases of clinical trials sector but it is limited to specific phases in clinical trials? Is it clear how phases 0, I, II and III are core R&D activities? Why?**

The Determination is clear that phases 0 – III are core R&D activities.

**Question seven: Is the explanatory statement helpful in understanding and applying the draft Determination? Is it clear what evidence you would maintain to apply to the R&D Tax Incentive and that you are still required to maintain evidence of eligible expenditure? Is there anything that confuses you about the explanatory statement? How could it be improved?**

As noted above, it is currently incomplete; to improve it and offer greater confidence, it is recommended that guidelines are developed and definitions are clarified.

**Question eight: Would you know how to apply the draft Determination when applying to the R&D Tax Incentive Program? How? What is clear/unclear?**

*No comment.*