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# Research and Development Tax Incentive

A BioTech and MedTech Guide



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## Advances in technology and changing regulatory environments are creating new opportunities for BioTech and MedTech companies to design and develop exciting new products and processes.

From innovations in food and fuels through to health and hospital care, the Research and Development (R&D) Tax Incentive is available to a range of Australian businesses as a valuable way to access Australian Government funding.

Whether you're tackling big innovation challenges or taking on niche markets or products, research and development is fundamental for industry leaders to effectively disrupt or enhance the status quo within their sector.

An understanding of the R&D Tax Incentive and a proactive approach to your R&D program will help to maximise the Australian Government funding available to your business. Too often we see mistakes made by businesses and their advisors, leading to money left on the table or excessive claiming with the risk of having to pay back thousands to the ATO.

**This guide provides insight into the key R&D eligibility criteria for companies in the BioTech and MedTech industries specifically, including common errors to look out for.**

### Is my company structure correct?

Before you've designed your first logo, as an innovator you should set up a company in the best way to make the most of the R&D Tax Incentive.

This should also take into account the protection of the company's IP, its longer-term goals and your personal affairs.

An eligible R&D entity is a corporation that is incorporated under an Australian law. There are a few exceptions, including, in some circumstances, a foreign corporation. A trust is not an eligible R&D entity.

Too often we see companies conducting their R&D in the wrong company structure and accidentally blocking their access to hundreds of thousands of dollars in funding. Company structures can be changed, but only a time machine would help you claim those old costs.

The right company structure can't be prescribed using a one-size-fits-all approach. It's best to check in with an advisor who can help you get set up correctly to claim the R&D Tax Incentive.

### Am I conducting an eligible R&D activity?

Eligible R&D activities must fall under one of two categories: Core R&D Activities and Supporting R&D Activities.

## Core R&D Activities

Core R&D Activities apply a systematic and experimental approach, proceeding from hypothesis through to observations and logical conclusions.

The outcome is not known to an expert in the field without undertaking the experiment. The activities aim to generate new knowledge in the form of new or improved materials, products, devices, processes or services.

Examples in the MedTech and BioTech fields include:



Drug formulation development, such as reformulating existing products to reduce side effects



Designing and developing devices or materials that are safer, more efficient or biodegradable



Designing and developing new medical equipment for enhanced performance or new applications



Clinical trials of new therapeutics or treatments

## Supporting R&D Activities

Supporting R&D Activities are activities directly related to Core R&D Activities.

Although they are experimental, they directly support the experiment and, in most cases, would not have been undertaken without the Core R&D Activity occurring.

Supporting R&D Activities can include things such as:



Background research/knowledge reviews into existing products and processes available in the market



Design of initial product concepts



Manufacture of prototypes to be tested in the core activity



Training of staff to assemble new products or to use new equipment/processes that needed to be completed before the core activity could be tested for performance



Project management activities

## What costs can I include in my R&D claim?

The general rule is that expenditure on R&D activities is claimable in the income year it is incurred. Such costs may include:

-  wages, super and taxes for employees and Directors
-  contractor fees
-  clinical trials
-  depreciation on assets used for conducting R&D activities
-  materials
-  payments made under the CRC program
-  a relevant portion of the business overhead, including rent and utilities

## What common claim errors do we see?

-  Businesses don't conduct R&D in the right company structure to be eligible
-  Incorrect self-assessment leads to the inclusion of ineligible activities (or the exclusion of eligible activities)
-  Poorly worded project descriptions sent to AusIndustry that raise the risk of a time-consuming review or a project being denied
-  Companies don't take a wide enough view of their expenses that could be eligible, limiting the size of their claim
-  Poor documentation does not support the activities/ expenditure
-  The method used to apportion overhead expenses is not reasonable
-  Inclusion of costs where the activities are not being conducted by the company on its own behalf
-  Inclusion of commercial, legal and administrative aspects of patenting, licensing or other activities
-  Inclusion of R&D activities conducted for a third party
-  Inclusion of costs incurred to associates that are not paid within the financial year
-  Incorrect accounting for the sale or use of the product of the eligible R&D activities in the company's income tax return

# Future Bionics

## Case Study

Future Bionics Pty Ltd (Future Bionics) is an Australian company that specialises in the manufacture of state-of-the-art bionic prosthetic limbs for amputees. The company operates a facility with 15 employees, including an R&D team who continually improve on many facets of the prosthetics.

More recently, Future Bionics has undertaken research into neural interfacing technologies to be incorporated into their existing line of bionic hands as an added capability and a more lifelike movability for the user. As the synthetic neural network must have connectivity with the user's neural network,

experimentation is required to test the ability of the two separate neural networks (synthetic and natural) to connect, as well as the resulting functionality of the bionic hand.

Future Bionics identified that the next stage of its R&D program was to establish the viability of the neural interfacing bionic hand on test patients to determine the useability via a number of different neural connections (electrodes on the brain versus amputated limb endings) or amputee situations (success on recent amputees compared to older amputees).

### Core R&D Activity 1

## Testing of the new bionic hand on a sample set of patients

Future Bionics installed the new bionic hand on the four test subjects and ran a series of tests over a six-month period to establish the viability of the prototype across the four scenarios. The testing activity differed from business as usual in that the addition of neural interfacing technologies had not previously been attempted in bionic limbs, and nor were such designs publicly available.

The outcome of the activity could not be determined in advance without undertaking the experiment.

At the end of the tests, Future Bionics had collected data on the effectiveness of the arm and identified a number of areas for improvement. It concluded that the neural interfaces of the bionic hand worked effectively in each scenario and worked best on recent amputees where the electrodes were added directly to the newly exposed nerves in the arm.

### Supporting R&D Activity 1

## Developing the experimental process

The company undertook literature reviews, internet searches and competitor reviews to identify potential methods to include neural interface capabilities in bionic limbs. This research was directly related to the Core R&D Activity because it informed the design and methodology of the experimental activities.

### Supporting R&D Activity 2

## Manufacturing the prototype bionic hand with neural interfacing capability

Future Bionics used its manufacturing line to produce the four prototype bionic hands to test the performance of the neural interfacing capability when attached to the test patients.

This activity was not a Core R&D Activity as the process of manufacturing bionic hands was well known and the company believed the inclusion of neural circuitry didn't present any additional complexity or uncertainty. Consequently, there was no need to design and undertake experiments to produce the prototypes.

The manufacture of the prototypes progressed as Future Bionics expected and the company did not encounter any problems that couldn't be resolved by its staff using currently available expert knowledge, information and experience.

As the activity produced goods in the form of the bionic hands, Future Bionics assessed that the dominant purpose was to support the Core R&D Activity because the

prototype bionic hands were manufactured solely for use in the experiments and were not made available for sale or otherwise used by the company.

## What documentation did Future Bionics keep?

Future Bionics kept detailed records and reports throughout the development of the new bionic hand, including the very first literature and internet searches when first looking into neural interfacing technologies, to first design concepts and prototype development, meeting minutes discussing the experimental approach and all reports maintained during the patent trial.

This information is valuable for tracking R&D progress, as well as for supporting the work undertaken and costs associated with the development.

## How can BlueRock help?

As R&D Tax Incentive experts, we demystify the complex regulation and guidance to ensure you get the most out of your R&D Tax Incentive claim.

That means we work with your team to clearly identify the project's eligible activities and costs, then communicate these to AusIndustry in the most effective way to ensure your R&D application is accepted.

The process of applying for the R&D Tax Incentive with assistance from BlueRock involves:

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Speak to our R&D Tax Incentive experts to unlock thousands of dollars in Australian Government funding for your R&D activities.

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GET STARTED



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