Australian Government

National Health and Medical Research Council

# *Guide to Evaluating Industry-Relevant Experience*

## Principles

NHMRC is committed to ensuring that knowledge from health and medical research is translated through commercialisation (e.g. by pharmaceutical or medical devices companies), improvements to policy, health service delivery and clinical practice.

Therefore, as a complement to other measures of research excellence (e.g. publication and citation rates), NHMRC considers industry-relevant skills, experience and achievements in its assessment of applicants' track records.

These measures recognise that applicants who have invested their research time on technology transfer, commercialisation or collaborating with industry, may have gained highly valuable expertise or outputs relevant to research translation. However, NHMRC acknowledges that these researchers will necessarily have had fewer opportunities to produce traditional academic research outputs (e.g. peer reviewed publications).

Therefore, peer reviewers should:

- Appropriately recognise applicants' industry-relevant experiences and results
- Allow for the time applicants have spent in commercialisation/industry for *"Relative to Opportunity"* considerations (refer to Section 6 of the NHMRC Funding Rules)

## Who might have industry experience or be preparing for industry experience?

Many applicants to NHMRC may have had industry experiences of various kinds. Examples include, but are not limited to:

1. Researchers who have left academia to pursue a full time career in industry (e.g. in pharmaceutical, biotechnology or start-up companies). In such instances, outputs must be assessed 'relative to opportunity', as there may have been restrictions in producing traditional research outputs (such as peer reviewed publications), but highly valuable expertise gained or outputs produced relevant to research translation (such as patents or new clinical guidelines). Refer to Section 6.1 of the *NHMRC Funding Rules*.

2. Academic researchers whose work has a possible commercial focus. These researchers might not have yet entered into commercial agreements with industry and have chosen to forego or delay publication in order to protect or extend their intellectual property (IP).

3. Academic researchers who have translated their discovery into a collaborative agreement with industry. The researcher may be collaborating with the company in further research and development; may have a licensing agreement; or may have licensed or assigned their IP to the company. A researcher may ultimately leave the academic institution and become Chief Executive Officer, Chief Scientific Officer, Chief Technology Officer, Scientific Advisory Board Member or consultant for a start-up or other company, based on their experience.

4. Academic researchers who are actively collaborating with companies, for example by providing expert research services for fees. Publications of such work might be precluded or delayed according to contract arrangements. The specialised nature of this research might also restrict publication to specialised journals only, as opposed to generalist journals.

## Relevant industry outputs

| Level of experience/ output | IP | Collaboration with an industry partner | Established a start-up company | Product to market | Clinical trials or regulatory activities | Industry participation |
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| Advanced | • Patent granted: consider the type of patent and where it is granted. It can be more difficult to be granted a patent in, for example, the US or Europe than in Australia, depending on the patent prosecution and regulatory regime of the intended market<br>• National phase entry and prosecution or specified country application | • Executed a licensing agreement with an established company<br>• Significant research contract with an industry partner<br>• Long term consultancy with an industry partner | • Achieved successful exit (public market flotation, merger or acquisition)<br>• Raised significant (>$10m) funding from venture capital or other commercial sources (not grant funding bodies)<br>• Chief Scientific Officer, Executive or non-executive role on company boards | • Produce sales<br>• Successful regulator submission to US Food and Drug Administration (FDA), European Medicines Agency, TGA etc.<br>• Medical device premarket submission e.g. FDA 510(k) approved | • Phase II or Phase III underway or completed | • Major advisory or consultancy roles with international companies |
| Intermediate | • Patent Cooperation Treaty (PCT) or 'international application'<br>• Provisional patent | • Established a formal arrangement such as a consultancy or research contract and actively collaborating | • Incorporated an entity and established a board<br>• Has raised moderate (>$1m) funding from commercial sources or government schemes that required industry co-participation (e.g. ARC Linkage, NHMRC Development Grant) | • Generated regulatory standard data set<br>• Successful regulatory submission to Therapeutic Goods Administration or European Conformity (CE) marking<br>• Medical device: applications for pre-market approval | • Phase I underway or completed<br>• Protocol development<br>• Patient recruitment | • Advisory or consultancy role with a national company |
| Preliminary | • IP generated<br>• Patent application lodged<br>• Invention lodged with Disclosure/s with Technology Transfer/Commercialisation Office | • Approached and in discussion with an industry partner under a non-disclosure agreement. No other formal contractual arrangements. | • Negotiated licence to IP from the academic institution | • Developed pre-good manufacturing practice (GMP) prototype and strong supporting data<br>• Established quality systems | • Drug candidate selected or Investigative New Drug application filed<br>• Preclinical testing | |