Global female scholars award opens for 2022

September 7, 2021

Nominations are open for the Johnson & Johnson Scholars Award programme that aims to develop female leaders and feed the talent pipeline.

The $150,000 award sponsors women at critical points in their careers, in each of the disciplines: Science, Technology, Engineering Manufacturing, Math and Design (STEM2D).

Johnson & Johnson's goal is to "fuel the research passion of the awarded women and inspire career paths in their respective STEM2D fields. Johnson & Johnson is looking to identify global women leading in both their research fields and leading as mentors, to be a vision for girls and other women in STEM2D."

The global awards will fund one woman per discipline who has completed her advanced degree, is working as an assistant professor (or global equivalent faculty position) and who is not yet tenured at an accredited university, institution or design school.

Australia's leading scientists have been previously well-recognised, with three winners in the past two years.

Dr Shayanti Mukherjee, PhD, Hudson Institute of Medical Research, won the 2021 engineering award for their work on advancing urogynaecological health using nanotechnology and 3D cellular bioprinting, helping to address the unmet medical needs of up to 50 per cent of childbearing women worldwide.

Veronica Garcia-Hansen, PhD, Queensland University of Technology won the 2020 design award for their research in hospital lighting design to help improve health outcomes for patients and overall energy efficiency.

Dr Gayathri Naidu, PhD, University of Technology, Sydney, won the 2020 technology award, for their work researching off-grid solar membrane water treatment, which has the potential to convert seawater to fresh water and contribute to reducing carbon emissions.

The 2022 Johnson & Johnson WiSTEM2D Scholars Award is open for nominations until 27 September 2021.

R&D Tax Incentive administration model review

September 9, 2021

The R&D Tax Incentive's (RDTI) administration model is being reviewed by the Board of Taxation (Board), a non-statutory Government advisory body, to identify opportunities for reducing duplication between the RDTI's two administrators, to simplify administrative processes, and to reduce the compliance costs for applicants.

Changes to the RDTI's broader policy settings, such as eligibility requirements or rates of support, are not being considered.

The RDTI is currently jointly administered by the Australian Taxation Office, which is responsible for the administration and processing of R&D tax offset claims, and Industry Innovation and Science Australia (IISA), which is responsible for registering companies' R&D activities. AusIndustry sits within the Department of Industry, Science, Energy and Resources and delivers the programme on behalf of IISA.

The consultation paper notes, "The Board may make recommendations to modify the [RDTI's] administrative model or to streamline existing administrative functions or processes. If the Board finds that taxpayers experience difficulty in understanding the different roles and responsibilities of the two administrators, the Board should consider whether education programs or communications would assist.

Importantly, the review being co-led by biotech veteran Neville Mitchell, who brings strong industry experience to the table. Mr Mitchell is the former Chief Financial Officer and Company Secretary of ASX-listed Cochlear Limited, and current NED of privately-owned and publicly-listed Australian life sciences companies, including AusBiotech member Q'Biotics Group.

A consultation paper has been developed in order to understand stakeholders' experiences during the registration and claiming processes. The Board is accepting written submissions until 15 September 2021.

The Board will submit its report to the government by 30 November 2021. This review will fulfil a 2020-21 Budget commitment.

Australia's regenerative medicine clinical trials and manufacturing landscapes revealed

September 2, 2021

The opportunity for Australia to be a global regenerative medicine (RM) leader has been revealed as its clinical trials and manufacturing landscapes are benchmarked in two new reports, published by the RM Catalyst, a consortium of seven partners.

Each report provides a new evidence base and model against which to map, build and strengthen our clinical trials and sovereign GMP manufacturing position over time. By leveraging Australia's reputation for delivering high-quality, complex, and safe medical products, as well as our highly-skilled workforce, we can become the clinical trials and manufacturing hub for the region and deliver potentially life-changing treatments to patients, both in Australia and the broader Asia Pacific region.

Despite the COVID-19 pandemic, in 2020 alone the global RM sector attracted USD$19.9 billion in investment. The FDA predicts that by 2025, 10 to 20 products will be approved each year in the USA; global companies are turning their attention to the RM sector and we are seeing more gene and cell therapies being brought to Australia.

Australia's Regenerative Medicine Manufacturing Capacity and Capability (Manufacturing Report)

The inaugural Manufacturing Report highlights how Australia has RM manufacturing sites from East to West, with seven TGA-licenced Good Manufacturing Practice (GMP) sites and five non-TGA licenced sites. Being TGA-licenced means that the manufacturing facility and quality systems have been approved by the local regulatory authority and products manufactured by these facilities meet global regulatory standards such as US (FDA), Europe (EMA), Japan and other jurisdictions. Those sites not yet TGA licenced are aspiring to be, so that they can extend their manufacturing capability to late-stage clinical trials and commercial supply.

RM therapies require highly specialised GMP capabilities and infrastructure, a highly skilled workforce, and complex supply chains. The increasing demand for RM therapy manufacturers is growing and a major bottleneck exists at the GMP manufacturing phase of product development, both in Australia and globally. This progressive direction demonstrates that Australia's capabilities are growing and greater opportunities are available for the sector if further investment is pledged. Investing in and building Australia's sovereign manufacturing capability for complex and advanced RM therapies will ensure faster access to cutting-edge treatments for Australian patients, create new jobs now and for the future, and develop a highly skilled workforce.

There are significant benefits to having manufacturing facilities located onshore in Australia, for patients as well as RM therapy developers: local manufacturing will build resilience for the sector and ensure faster access to cutting-edge therapies for all Australians. Sovereign capability facilitates access not only to early phase trials for Australian patients for locally developed products but also supports access to innovative and cutting-edge international trials.

Download *the* Manufacturing Report here.

Australia's Regenerative Medicine Clinical Trials Database (CT Database)

Australia is an active, globally popular, and internationally competitive destination for clinical trials with a bountiful pipeline of RM therapies seeking to join the six regenerative medicines already approved in Australia.

Delivering clarity of the development landscape, the inaugural CT Database captures the portion of clinical trials in RM and seeks to categorise them into type and phase. This benchmarking is important as the sector prepares to thrive, and enables the ecosystem to develop in a way that capitalises on the opportunities that present now and in the future.

In 2021, there were over 1,220 ongoing clinical trials investigating RM globally; of these, 130 (11 per cent) were ongoing and investigating RM in Australia, and two were in progress and being conducted by Australian companies overseas.

Australia's industry is thriving and companies developing RM therapies include both small biotechs and larger pharma companies. Industry-sponsored trials (~80 percent) outnumbered non-industry sponsored trials in Australia and grew at a compound annual growth rate of 21 percent from 2016-2020, which was seven times higher than non-industry sponsored trials for the same period. Over the study period, the highest number of new trials were recorded in 2019 and 2020 both for industry and non-industry sponsors.

Download CT Database here.

Regenerative Medicine Catalyst Project

The RM Catalyst's seven partners hold extensive insight and experience in the life science and regenerative medicines landscape in Australia. Led by AusBiotech, partners include Medicines Australia, Cell Therapies Pty, Novartis Australia and New Zealand, Biointelect, Research Strategies Australia, and MTPConnect.

The RM Catalyst has received matched funding through MTPConnect's Growth Centre Project Fund Program, an Australian government initiative supported by the Department of Industry, Science, Energy and Resources. It is a competitive matched funding program that aims to invest in ideas to boost the innovation, productivity and competitiveness of Australia's MTP sector.

The project is developing a total of nine reports, to create the foundations for an RM future for Australia.

The comprehensive Regenerative Medicine Value Chain report, released in August, considers the chain of activities involved in RM therapy development, including research capabilities - workforce and infrastructure; supporting Australian research and small and medium-sized enterprises; funding, investment and partnerships; attracting investment in clinical trials; streamlined approvals and incentives; clear pathways to patient delivery; healthcare system preparedness; and, data-driven approaches across the value chain.

Read more about the Regenerative Medicine Catalyst Project here.