Australian Government
Department of Defence
Science and Technology

CERTARA®

Medical Countermeasures Initiative:
National Capability Audit 2017 Summary

Contents

Medical countermeasures in Australia

Defence Science and Technology (DST) has established a national initiative to develop Australia's medical countermeasures (MCM) capabilities.

Medical countermeasures refer to medical interventions such as vaccines, and therapeutic and diagnostic technologies which can protect people against emerging infectious diseases, pandemics, as well as chemical, biological, and radiological threats.

A national audit of Australia's medical countermeasures was conducted in 2012 by d3 Medicine in collaboration with DST.

In 2017, DST sought to recalibrate its understanding of Australia's medical countermeasures capabilities to better inform a national MCM Initiative.

Partnering again with d3 Medicine (now a Certara company), DST surveyed universities, research institutes, government departments, and biotech and pharmaceutical businesses around the country.

Data from more than 130 respondents was received. Businesses and universities comprised three quarters of respondents, with half of all respondents being from Victoria.

Then and now

The 2017 audit revealed a number of findings that were consistent with the 2012 audit. In particular:

- Australia's medical countermeasure capabilities are spread geographically, with the highest concentration found in Victoria followed by Queensland, New South Wales, and South Australia. Key capabilities are found primarily in industry followed by academic/research institutions.
- Albeit modest, Australia has representation in all key capability areas allowing it to significantly contribute to global MCM product development activities.
- A key challenge will be harnessing existing national capabilities and establishing a collaborative network to develop products for MCM.

There have been some promising developments since 2012:

- Overall, the amount of time spent on product development activities appears to be increasing.
- There has been some level of aggregation, consolidation, and improvement in coordination of capabilities and infrastructure at the state and national levels.
- Early medical countermeasures R&D and translational science continues to grow from a strong base.
- Translational medicine strategies to accelerate product development such as human infection challenge models have been established onshore.
- The clinical trials network for emerging infectious diseases is in the establishment phase.

Key findings

Research

- There is robust research capability in several different areas, but drug discovery research is particularly strong, a finding which is consistent with Australia's established reputation for excellence in drug discovery.
- R&D capabilities were fairly evenly distributed across the three product areas: diagnostics, vaccines, and therapeutics.
- Particular areas of strength include: biology, molecular biology, biochemistry, immunology, microbiology including virology and bacteriology, and clinical medicine.
- There is a healthy capability in bioinformatics, the science of collecting and analysing complex biological data to support development decisions.

Manufacturing

- The bulk of manufacturing activity is therapeutics-oriented.
- Manufacturing capabilities exist for diagnostics and vaccines, however overall capacity is low.
- Areas of particular weakness include formulation and packaging, and appropriate storage.
- Although most manufacturing services are available, capacity to upscale production is a major weakness of onshore MCM capability.

Clinical studies

- The clinical study ecosystem in Australia appears capable of supporting the development of MCM products.

Strategic regulatory affairs

- There is a small but competent group with expertise in regulatory affairs.

Collaboration

- Collaboration exists between Australian and international governmental agencies, but there is room for improvement.
- The scope of current collaborations cover the full MCM product development pipeline, ranging from *in vitro* assays to clinical studies and regulatory support.

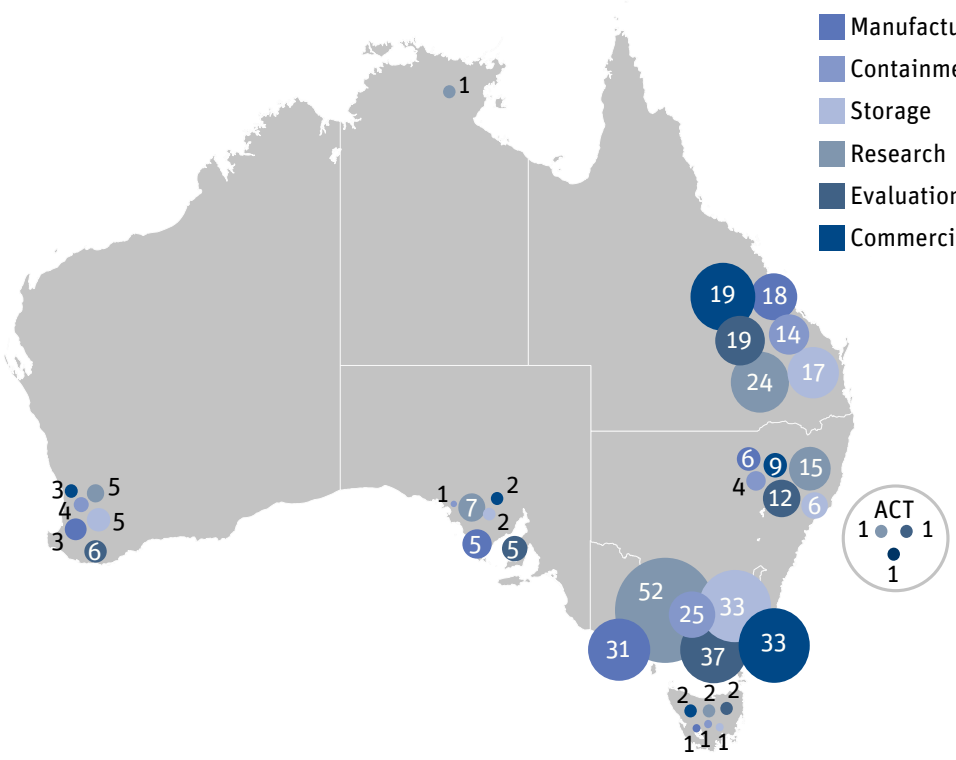
Product developers

- One-quarter of respondents spend more than 75% of their time on product development activities.
- There may be a small trend for increasing time spent on product development. Those spending 0% to 25% of their time decreased from 55% to 43% in 2017.

Commercial activity

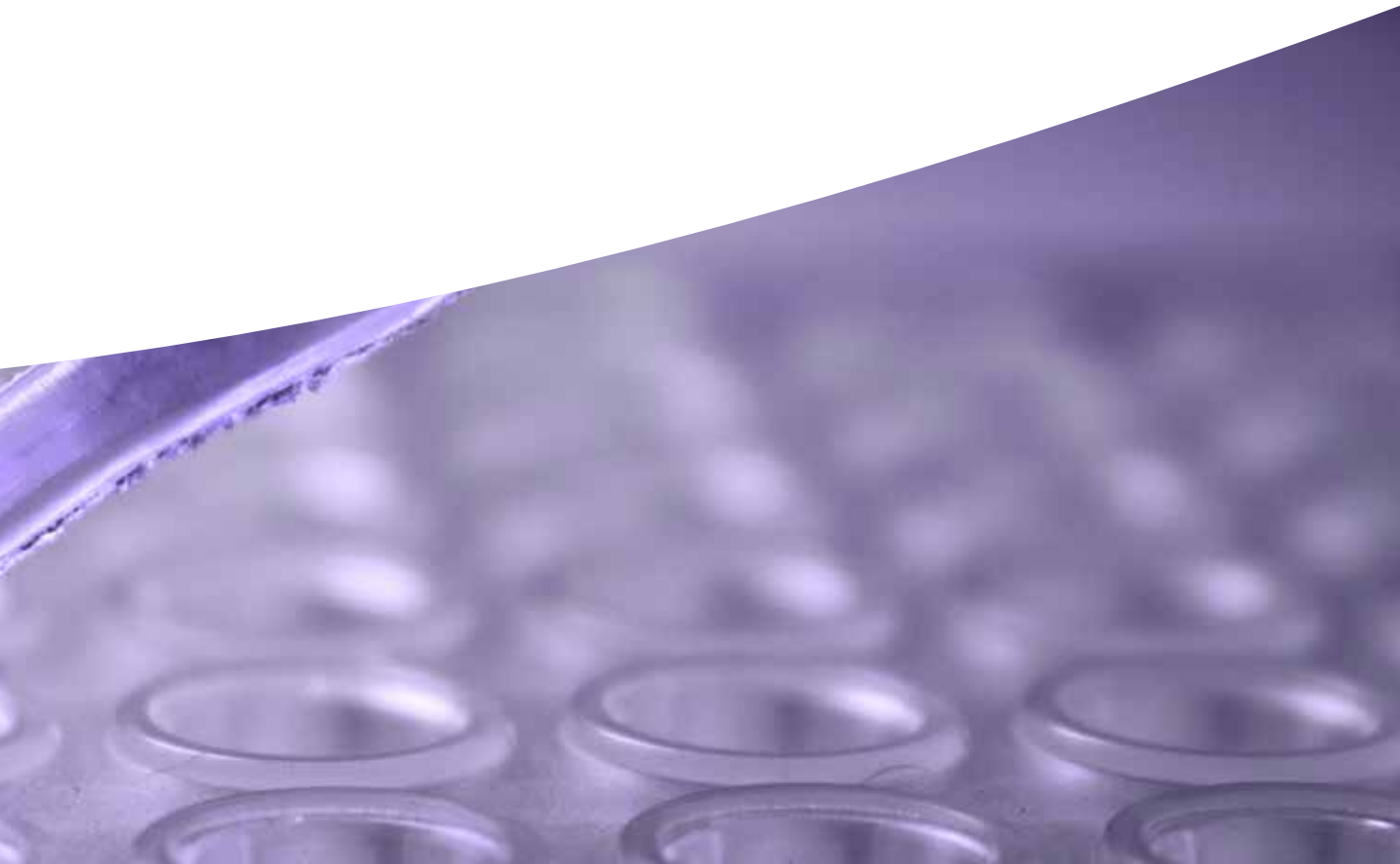
- More than half of the respondents have made deals worth more than AUD $1M since 2014.
- Nearly 70% of deals originate from outside Australia.
- 72% of respondents have a dedicated department that supports business development, licensing, and acquisition activity.
- Types of deals: co-development (43%); public-private (20%); product acquisition (9%); company acquisition (7%); and various others such as license acquisition, trade sale, and divisional divestment (21%).

Geographic distribution of MCM capabilities



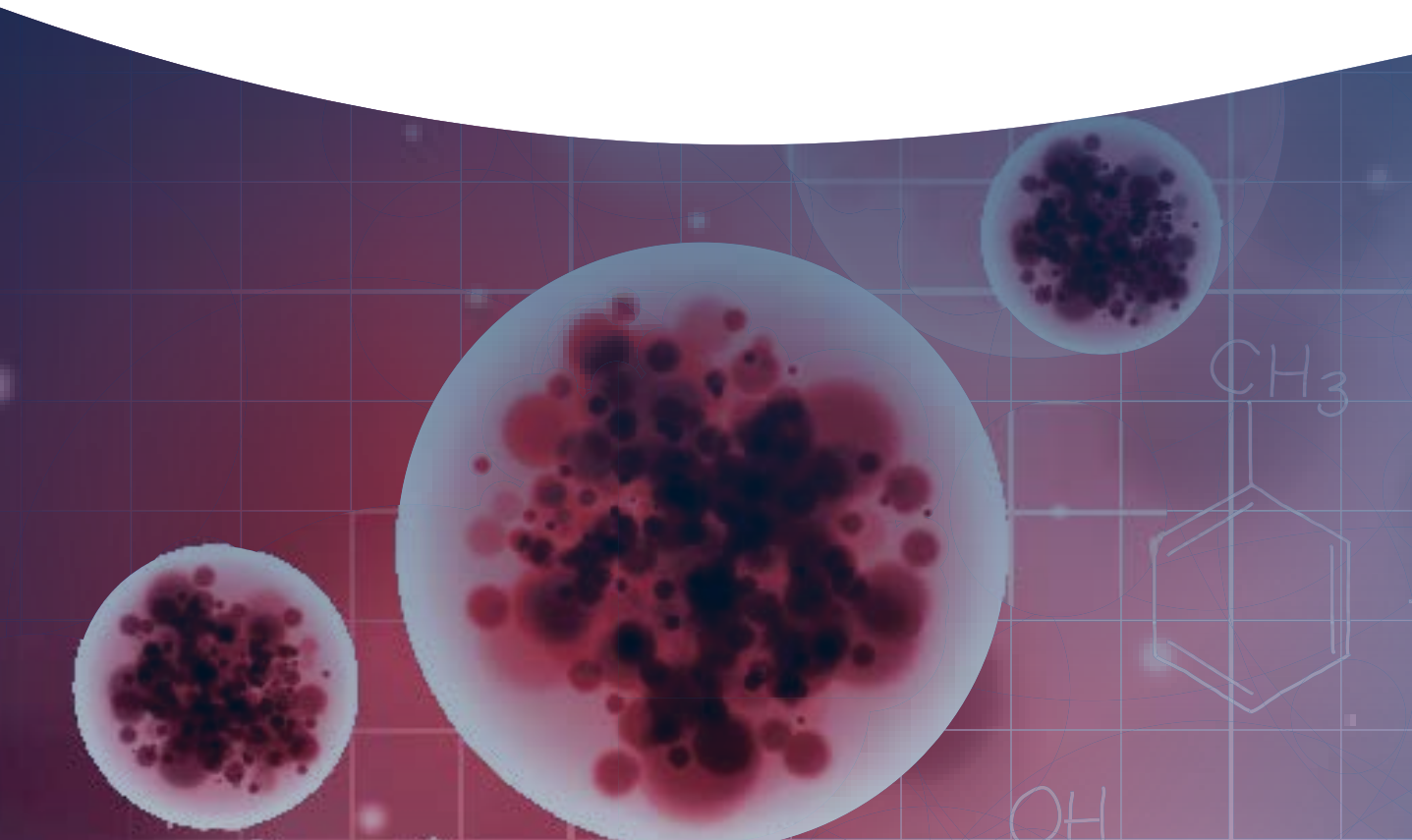
National strengths

- Australia has a dispersed, relatively small but experienced discovery and development community with expertise relevant to product development including vaccines, therapeutics, diagnostics, and devices.
- In general, Australia has extensive breadth and depth in early discovery and R&D capabilities resulting in an expansive repertoire of available assays and technologies to support the development of medical countermeasures.
- Australian researchers have good access to R&D facilities.
- Australia has an internationally competitive clinical trials ecosystem that is well suited to investigational medical countermeasures products.
- Australia has globally-recognised investigators in infectious diseases in addition to a well-established public health laboratory network supporting national and regional surveillance and response.
- Australia has a small but highly experienced pool of medical countermeasure product developers.
- Australian medical countermeasures researchers have a strong international network of collaborators across government, industry, regulatory, not-for-profit, academic, and life science investment sectors.



National challenges

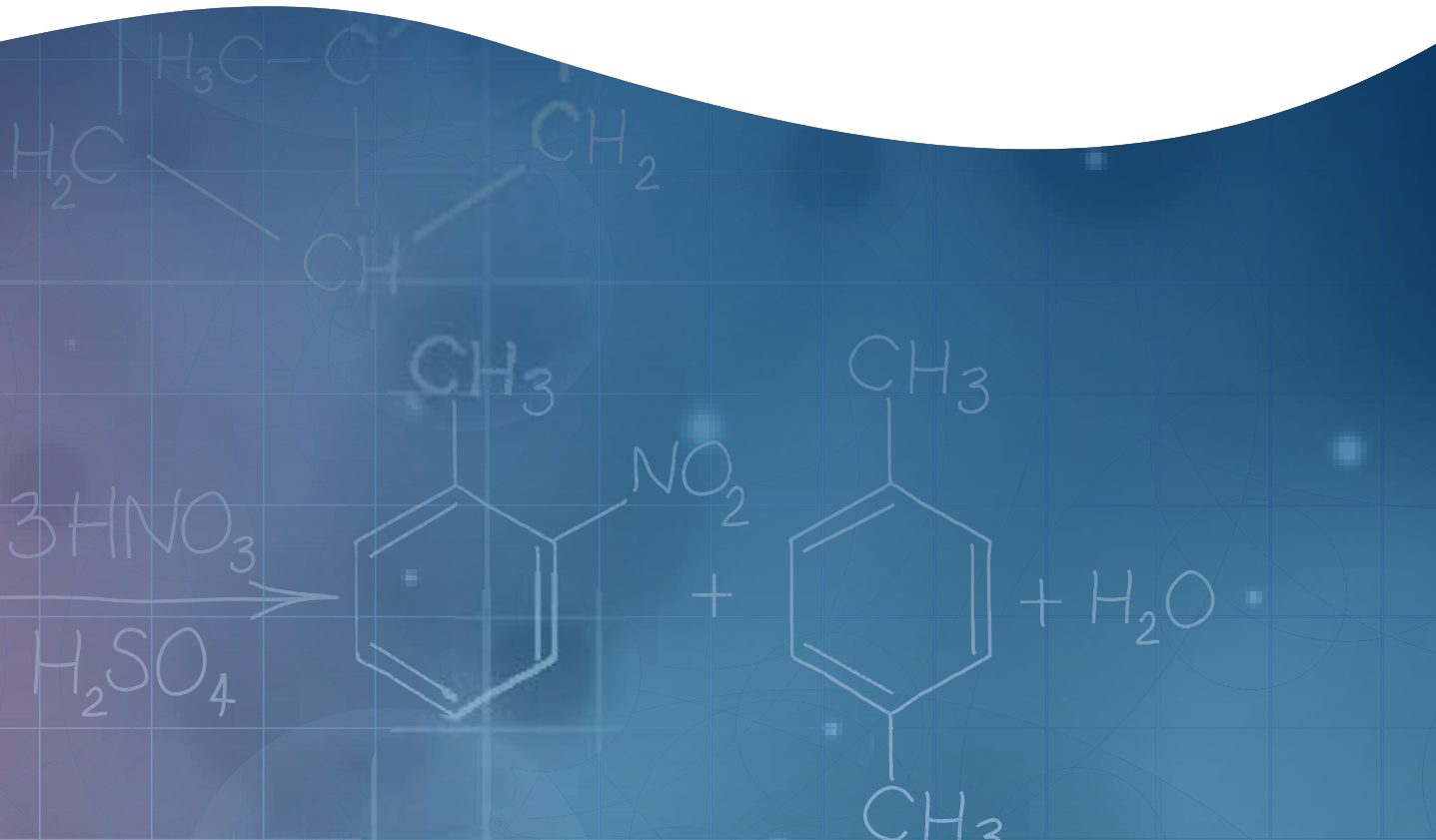
- Although a medical countermeasures product development capability exists, in many instances it lacks critical mass and is not readily accessible or functionally connected to enable end-to-end product development onshore.
- Due to limited expertise and a lack of appropriate training programs, industry often has to acquire talent from overseas or move offshore. In particular, there is a critical shortage of expertise and experience in product development, manufacturing, regulatory science, translational medicine, clinical pharmacology, project management and pharmacology/toxicology.
- The availability of suitable manufacturing facilities is limited.
- The availability of appropriate non-clinical services such as pharmacology, toxicology, bioanalysis is limited.
- Despite a strong capability in clinical trials for infectious diseases, the coordination of clinical trials targeting emerging infectious diseases is not yet established.
- Minimal onshore capability exists for the development of products to counter chemical or radiological threats.



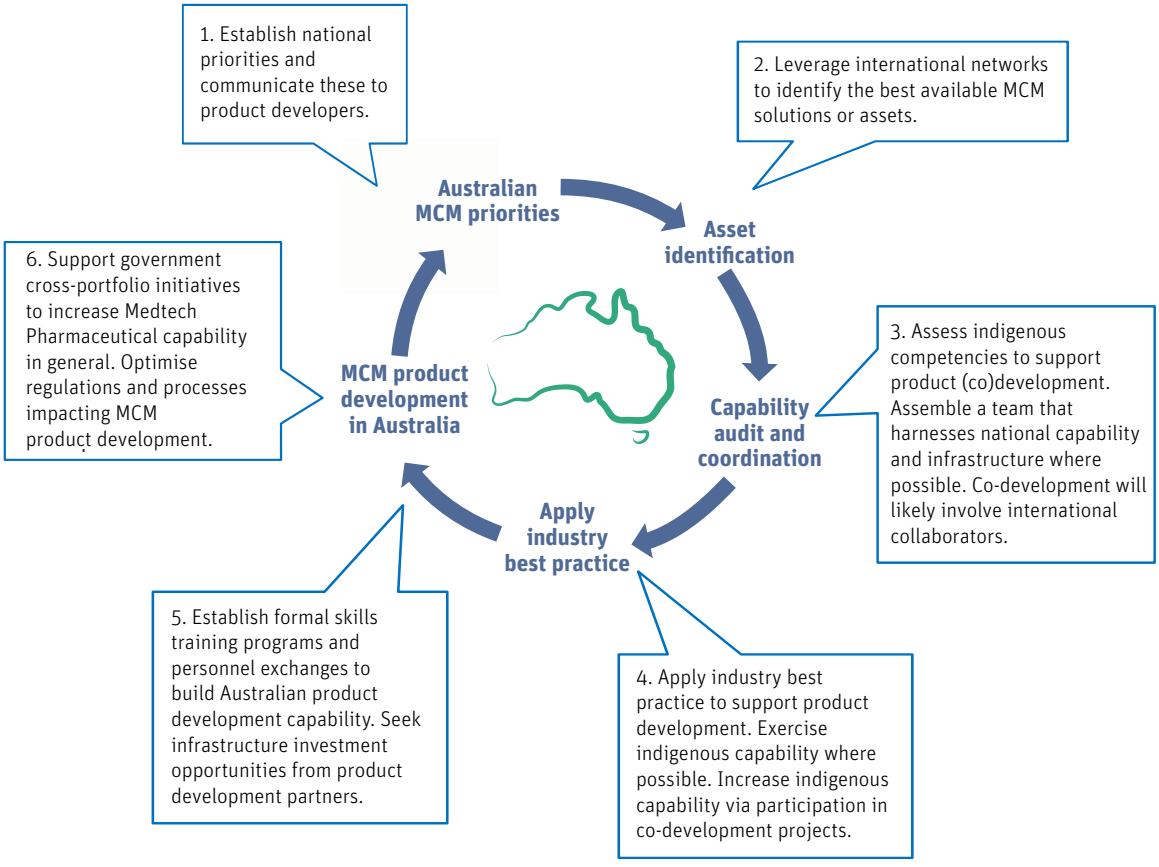
Recommendations

The recommendations of the 2012 audit remain relevant. These recommendations included:

- Formally recognise the urgent need to establish a national medical countermeasures initiative.
- Establish the initiative as a public-private partnership where industry leads the management and execution of product development activities.
- Develop incentives, including R&D tax incentives and innovation grants that would support and encourage industry engagement in product development.
- Align existing Australian state and federal research grants to encourage national and international cross-sector engagement in achieving a national medical countermeasures capability.
- Prioritise and provide resources to enable the use of available Australian government infrastructure.
- Encourage engagement of state and local governments to support a national MCM product development initiative.
- Integrate the Australian MCM product-based initiative into the existing national emergency response network.
- Provide support to the Therapeutic Goods Administration to establish a cross-sector task force to improve and harmonise regulatory processes for MCM-related products.
- Stimulate the creation of advanced manufacturing platforms of therapeutics and diagnostics through specialised funding mechanisms.
- Encourage collaboration across the region. The government should foster relationships with our regional neighbours in this respect.



To build an indigenous MCM capability, the following is recommended:



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