Spotlight on Australia Life and Health Sciences

Invest Northern Ireland

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Australia and New Zealand, Invest NI

Invest Northern Ireland

Welcome

- Welcome to Australia everyone – we are open for business!
- Australia is a market that offers transparency in its Life and Health Sciences regulations, commitment to research and clinical trials, and is investing in digital health infrastructure and product, and welcomes international collaboration
- **Today,** the webinar will feature an expert panel of speakers addressing:
  - Market opportunities
  - Logistical and compliance issues
  - Commercial opportunities
- Finally, we will have a Q&A session at the end; where we can answer your immediate questions and hopefully whet your appetite for exporting into Australia

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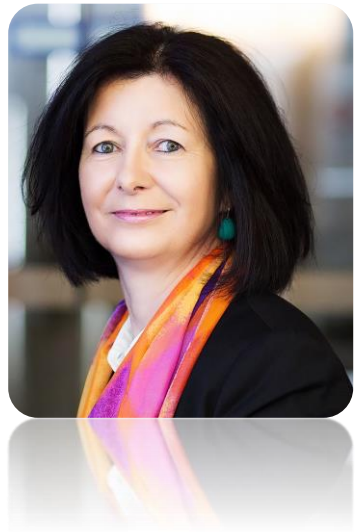
Angela Foley

Founding Director of Foley & Associates Pty Ltd



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SPOTLIGHT ON AUSTRALIA

LIFE AND HEALTH SCIENCES

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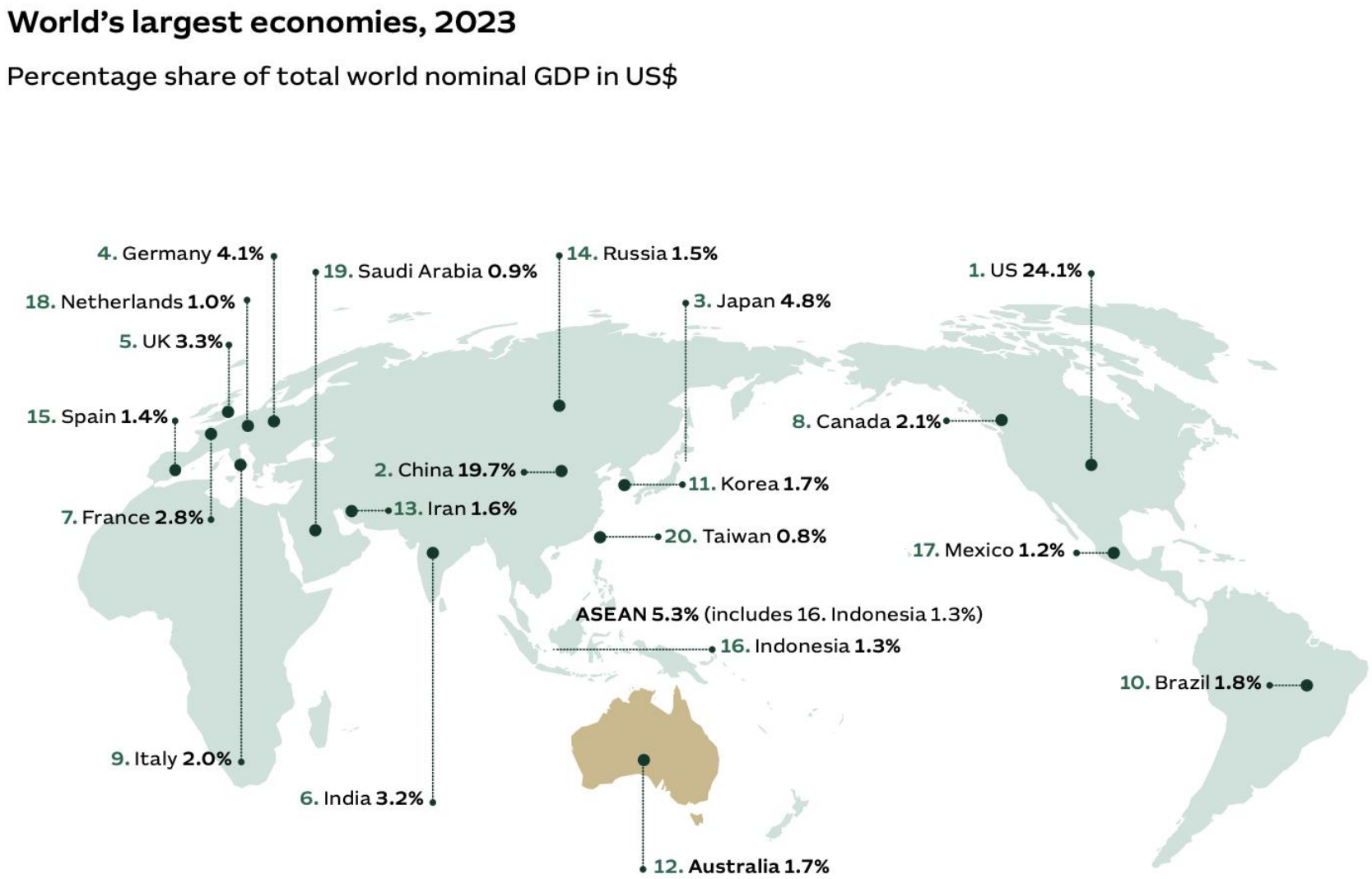
Australia in 2023



Source: Austrade Benchmark Report 2022

Australia set to become the **world's 12th largest economy** in 2023.

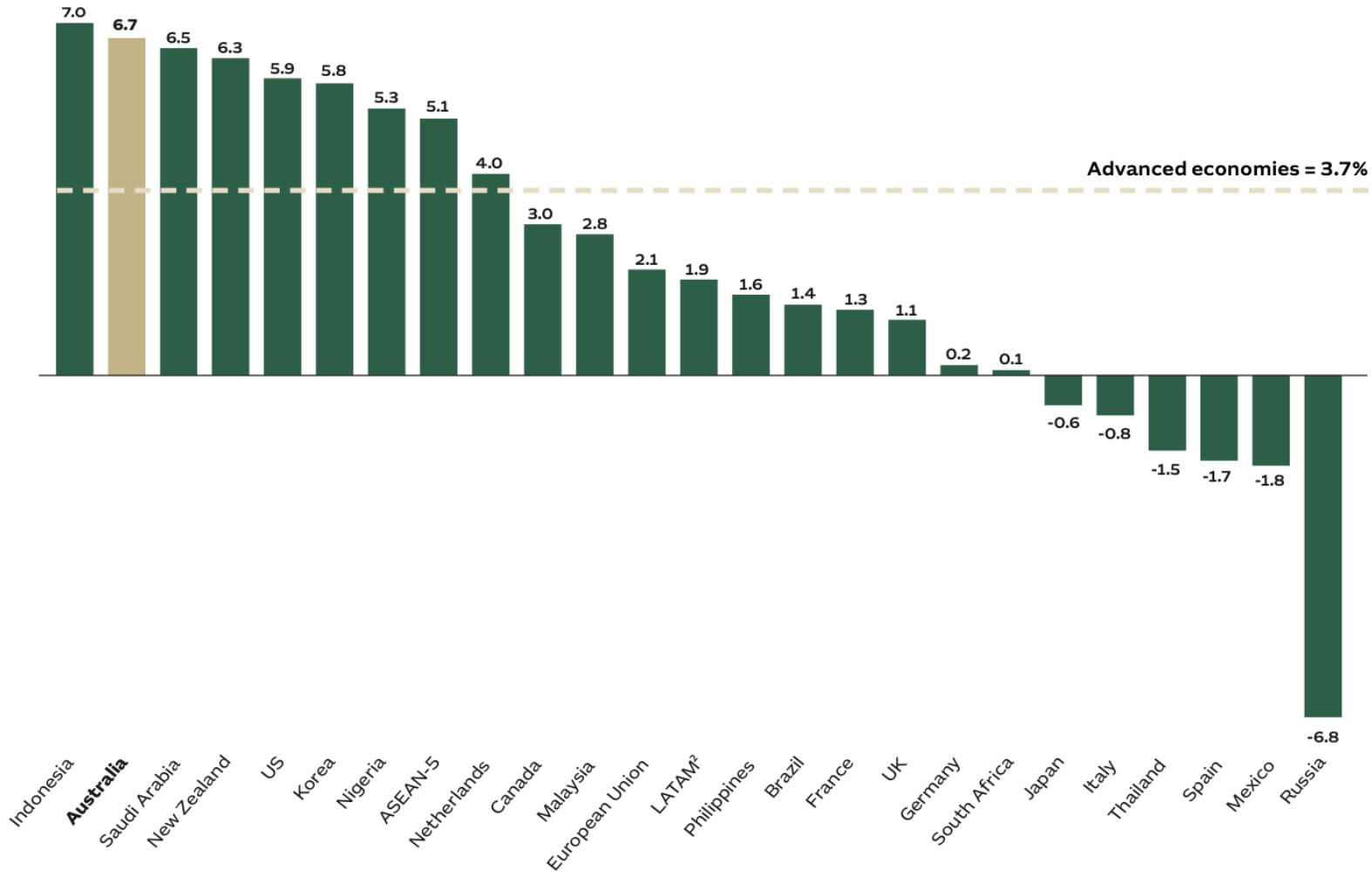
Australia's population accounts for **0.3% of the world's population** but she accounts for **1.7% of the global economy**

Equates to **A$2.5 trillion (~£1.7 trillion) nominal GDP** for 2023.

Australia's Resilience

Expected change in real GDP[1], selected economies

Percentage change from 2019 to 2022



Growth rate expected to remain strong at 4.2% in 2022 (following a solid rebound of 4.7% in 2021).

GDP predicted to be **6.7% larger by the end of 2022 than in pre-pandemic 2019**

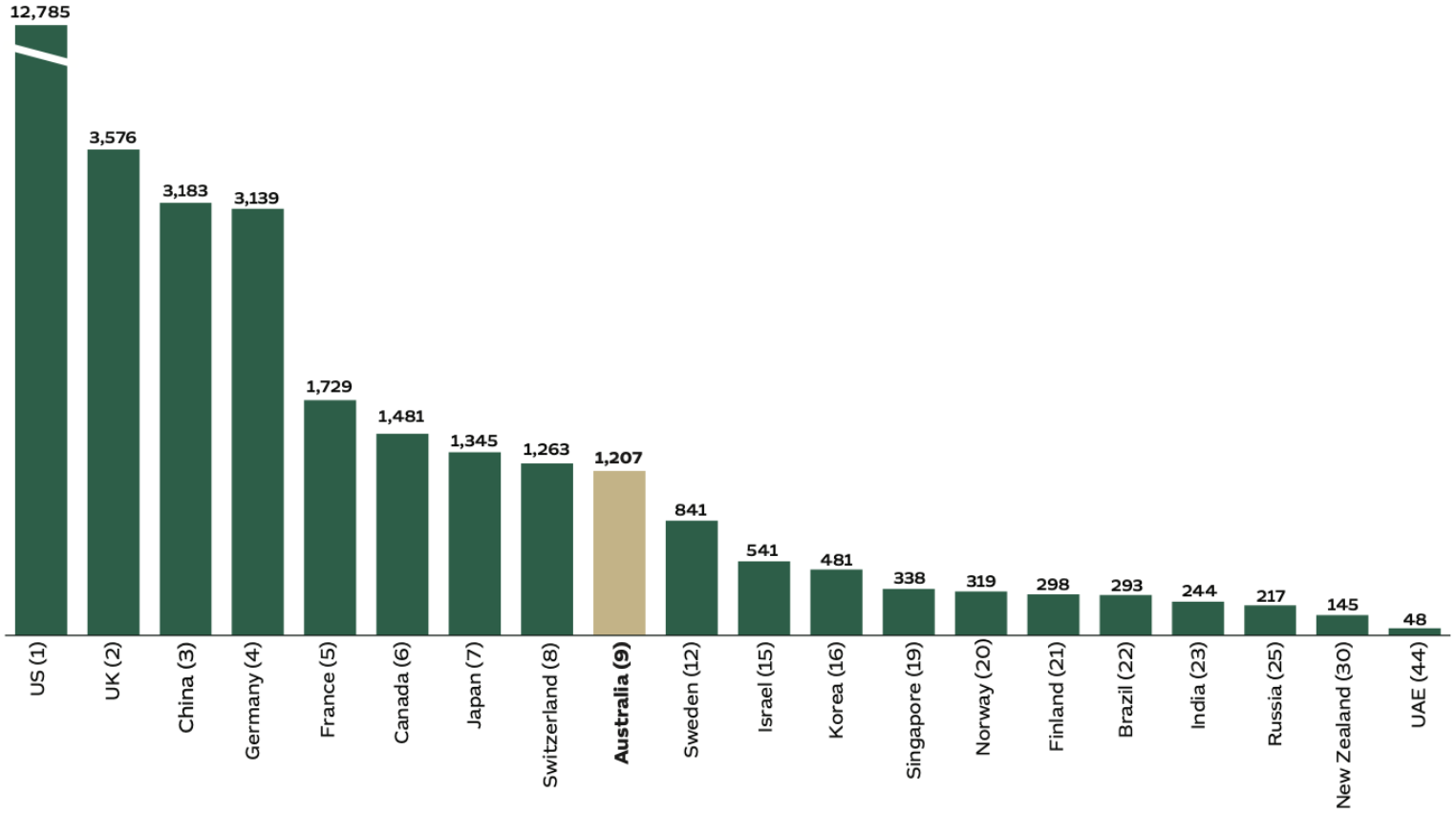
This increase over the pre-COVID-19 level in 2019 is higher than the average for advanced economies (**3.7%).**

Source: Austrade Benchmark Report 2022

Australia is a top 10 contributor to life science research

Health research by country[1]

Life science[2] count index, 1 September 2020 – 31 August 2021



According to an index published by 'Nature':

Australian researchers & institutes published 1,207 academic articles in accredited journals (2020-21).

Note: number in brackets = country's ranking across 162 economies.

Source: Austrade Benchmark Report 2022

Australia – ‘a thriving life sciences hub with a global reach’

Strong Financials

- **Life sciences companies raised A$1.7bn (£1bn)** in Australian equity capital markets in 2020.
- **185+ ASX listed life sciences companies** with **a combined market cap of A$300bn (£170bn).**
- Life sciences and healthcare **exports worth over A$5.6bn (£3.2bn)** in 2021.

Global Large-Caps

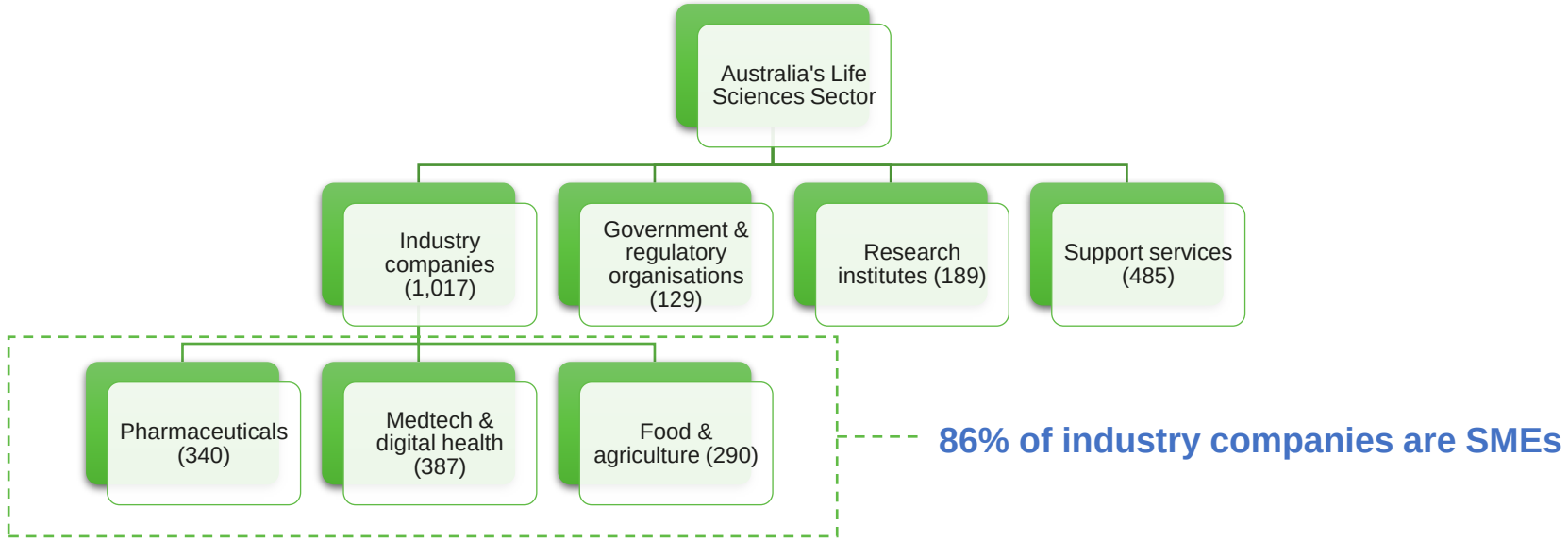
- The ASX is **home to some of the world’s largest and most influential healthcare and life sciences anies**

Cochlear® CSL RAMSAY HEALTH CARE SONIC HEALTHCARE Fisher & Paykel HEALTHCARE

Healthy Banks & Capital Markets

- Australia has **several investment and commercial banks**, as well as investment funds that **actively service the life sciences sector.**

MACQUARIE AustralianSuper Commonwealth Bank J.P.Morgan BARCLAYS HSBC



Source: ASX, AusBiotech, Australian Trade and Investment Commission.

Australia's Digital Health & MedTech Ecosystem

State/Territory Government Health Agencies

Tasmanian Government
Government of South Australia
SA Health
eHealth Queensland
Queensland Government
Government of Western Australia Department of Health
Northern Territory Government
Department of Health
ACT Government Health
NSW Government eHealth
Victoria State Government Health and Human Services

Federal Government Agencies

Australian Government National Health and Medical Research Council
NHMRC
Australian Government Department of Health
TGA
Australian Government Australian Digital Health Agency
Australian Government Australian Institute of Health and Welfare
Australian Government Department of Health Therapeutic Goods Administration

Industry Associations / NGOs

Australasian Telehealth Society
MTAA Medical Technology Association of Australia
aiia australian information industry association
move muscle, bone & joint health
MSIA Medical Software Industry Association
AIDH Australasian Institute of Digital Health
Mental Health Australia
Cystic Fibrosis Australia
Heart Foundation
ACSA Aged & Community Services Australia
Australian Alzheimer's Research Foundation
diabetes australia
ACIITC Aged Care Industry Information Technology Council

Healthcare Providers (Hospitals, Aged Care)

AlfredHealth
Epworth
Healthscope
Bupa
UnitingCare
Opal specialist aged care
Ramsay Health Care
regis aged care
St Vincent's Health Australia
Allity
Estia Health

Private Companies

Pacific Knowledge Systems
Philips Healthcare
GE Healthcare
T Health
Epic
episoft
Device Technologies
medAdvisor
Alcidion
COVIU
Medtronic
curve
Cochlear
medtech
OneView
perx
Baxter
ResMed
Cerner
PainChek Intelligent Pain Assessment
Roche
Vitalic Medical

Private Health Insurance Providers

nib
HCF
Bupa
medibank
Australian Unity
QBE

Growth Centers & Accelerators

cicada INNOVATIONS
MTPConnect MedTech and Pharma Growth Centre
HCF catalyst accelerated by slingshot
AHx Australian Health ACCELERATOR
Planet Innovation
MEDTECH ACTUATOR
ANDHealth Australia's National Digital Health Initiative

Health System

761 Public

1,227 Operating hospitals

466 Private

Complex **matrix of public & private** providers:

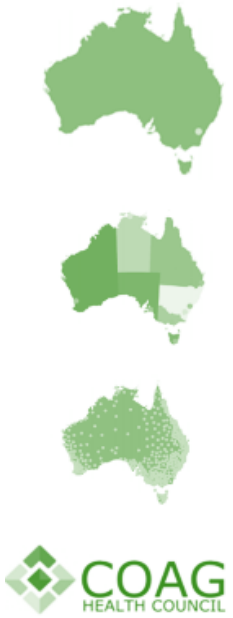
The public health system:

Public hospitals, community-based services and affiliated health organizations predominantly owned and operated by state & territory governments;

The private health system:

Privately owned & managed health service providers e.g., private hospitals, specialist medical and allied health and pharmacies.

Highly **regulated** environment:



- Australian Government
- State & Territory Governments
- Local Governments
- Responsibilities Shared by the Council of Australian Governments (COAG)

End Buyers and Procurement Process

- **Commonwealth Government** is the major source of funding for Australian healthcare, contributing ~**41% of funding**
- State and Territory Governments contribute ~**26% of funding**
- Private individuals contribute ~**A$28.6 billion** (~£15.6 billion) out-of-pocket for purchasing health services
- Public hospitals account for 70% of medical device procurement and private hospitals account for 30%

Government Procurement Process (usually state or territory level)

- Government agencies publicly issue a **Request for Tender** on govt tender websites
- Government procurement **regulated by Commonwealth Procurement Rules**.
- State & Territory governments also have their own procurement policies.

Private Sector Procurement Process

- Private companies rarely publicly advertise
- **Negotiate directly with an established network of suppliers**
- Participation in private sector tenders is often by **invitation only and may not be publicly advertised**
- Could be challenging for NI exporters to participate without in-country partners.

Federal Health Budget 2022-202

Australian Government
Department of Health

Health

- A$2.6bn over 2 years for the **procurement & distribution of RATs & PPE**
- A$1bn over 2 years to support the **Government's emergency response to COVID-19**
- A$892.1m over 2 years to continue the **health response to COVID-19 pandemic**
- A$375.6m over 4 years to contribute to the establishment of **Western Australia Comprehensive Cancer Centre in Perth**

Total A$4.9bn (£2.8bn)

Medical Research

- Medical Research Future Fund (MRFF) A$2.1bn over 10 years from 2022-2023, for **medical translation to support medical discoveries becoming part of medical practice.**
- A$1.4bn over 10 years from 2022-2023, to support patients **by funding innovative treatments, supporting clinical trials, and delivering more advanced health care/medical tech.**

Total A$3.5bn (£2.0bn)

Industry

- A$750m **boost to the Modern Manufacturing Initiative**
- A$53.9m for **Round 3 of the Manufacturing Modernisation Fund**

Total A$804m (£452m)

New South Wales State Budget 2022-2023

Health Services and Infrastructure – Major Spending Activities

Workforce

A$4.5bn (£2.5b) invested in NSW Health workforce to **recruit over 10,000 FTE staff to hospitals and health services across the state**.

Mental Health

A$460m (£258m) for the **Integrated Mental Health Complex at Westmead** (Sydney).

Ambulance

A$1.8bn (£1.0b) to enable **NSW Ambulance to recruit over 2,000 staff and open 30 new ambulance stations** between 2023 and 2026.

Triage and Telehealth

A$94.5m (£53m) to provide in-house **Secondary Triage & Alternative Referral Services within a new Ambulance Virtual Clinical Coordination Centre.**

Resilience

A$776.7m (£437m) for **Health Service resilience programs.**

Children's Hospital Redevelopment

A$185.4m (£104m) in 2022-2023 for **Children's Hospital at Westmead Redevelopment** (Sydney).

Palliative Care

A$743.4m (£417m) over 5 years **to enhance end-of-life palliative care services**.

Health and Academic Precinct

A$126.8m (£71m) in 2022-2023 (as part of a A$740m project) for the **Liverpool Health & Academic Precinct** (Sydney).

New South Wales State Budget 2022-2023

Health Services and Infrastructure – Continued

Biomedical Accelerator

A$154m (£84m) for the **Biomedical Accelerator Complex in Camperdown (Sydney).**

RNA Therapeutics Manufacturing

A$119.1m (£67m) over 10 years in **ribonucleic acid (RNA) therapeutics manufacturing, research and development initiatives.**

Viral Vector Manufacturing Facility

A$49.6m (£28m) to help **develop and test life-saving therapies for rare genetic diseases and cancers.**

Future Economy Fund (investing in science and

Commercializatio n

A$342.4m (£192m) to boost support for the **commercialization of products, services and emerging digital technologies.**

Growth and Investment

A$219m (£123m) to **accelerate growth and investment in priority industry sectors including medtech.**

R&D and Innovation

A$142m (£80m) to **drive R&D and innovation growth in sectors** in which NSW has a **natural competitive advantage**, including life sciences and clinical trials.

Opportunities for NI Exporters - Traditional

- **Healthcare expenditure** (% of GDP) **expected to double** over next 50 years.
- **Aged care is a priority:** Australia's older population expected to double by 2057.
- Total market for medical devices valued at >£3.8 billion *(Medical Technology Association of Australia).*
- > **54% of companies** active in the sector are **SMEs**
- Australia **imports 80%+ of medical devices** **used in the market (~32% from USA)**
- All levels of government are **committing funds** towards: ↑ healthcare resources, new infrastructure, boosting telehealth & mental health support capabilities:

Victoria: A$2.5 billion (~£1.4b) in health, mental health & aged care infrastructure in 2022-23 budget.

New South Wales: A$10.1 billion (~£5.7b) to health infrastructure through 2022-23 including 40+ new / upgraded hospitals.

OPPORTUNITIES FOR NI EXPORTERS:

- SUPPLY OF EQUIPMENT/TECHNOLOGY/SERVICES TO TREAT CORONARY HEART DISEASE, STROKE, DEMENTIA, LUNG CANCER, COPD, BREAST CANCER, PROSTRATE CANCER, DIABETES
- ORTHOPAEDIC & PROSTHETIC MARKET FASTEST GROWING SECTOR (AGING POPULATION)

Future Areas of Demand…

- **Smart medical devices – the new frontier**
  - Integrating digital technologies into traditional devices to improve value proposition
  - ↑ in health technologies & devices using advanced material/robotics/adaptive diagnostic technology platforms etc.

- **Smart monitoring devices & diagnostics and the algorithms that interpret the data**
  - Biosensing wearables such as digital blood pressure monitors, glucose sensors to support telehealth
  - Better wearables for high-risk industries (mining) & ingestible smart devices & biosensors
  - Point-of-care and home diagnostics are also key drivers of market demand

- **Robotic Surgery**
  - Use of a camera arm and mechanical arms to view the surgical site in high-definition, magnified 3D images on a computer

- **Digital Therapeutics**
  - Including emerging technologies such as virtual reality and online therapies to assist people to adopt healthy behaviours and social robots

- **Artificial Intelligence (AI)**
  - AI-enabled chatbots which support patient screen prior to physician assessment
  - Use of computer aided diagnosis to assist with interpreting medical images

Digital Health Overview

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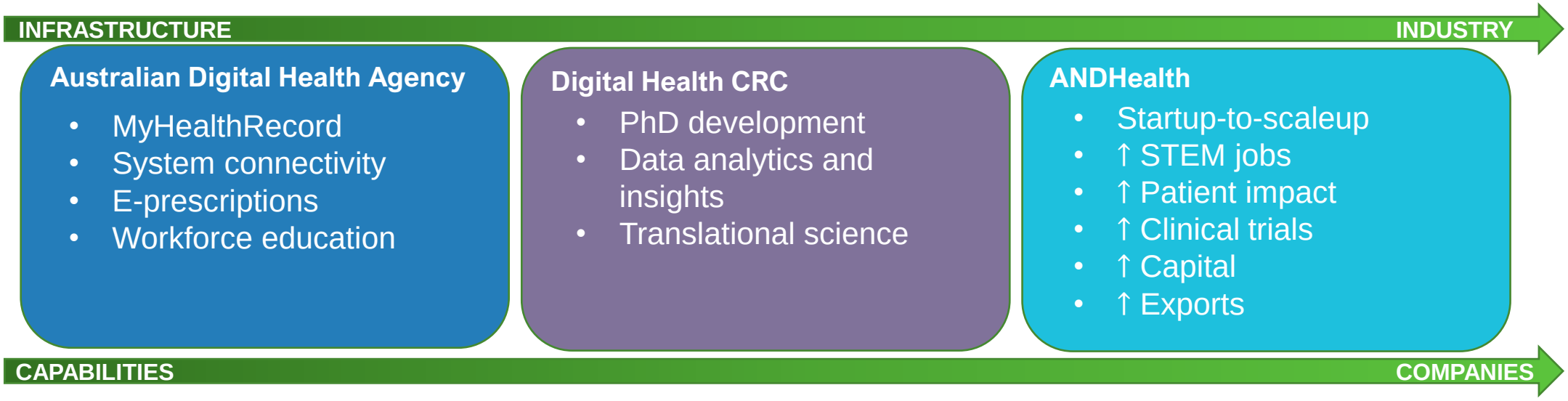
Australia's digital health infrastructure is underpinned by:

Australian Government
Australian Digital Health Agency

medicare

digital health CRC

ANDHealth
Australia's National Digital Health Initiative



Digital Health (digitalthealth.gov.au)

National Digital Health Strategy – Strategic Priority Outcomes (..to

Health information that is available whenever and wherever it is needed	• MyHealth Record
Health information that can be exchanged securely	• Ensures individual and community confidence in digital health systems and infrastructure
High-quality data with a commonly understood meaning that can be used with confidence	• Interoperability of clinical data across health service provision - essential to high quality sustainable healthcare
Better availability and access to prescriptions and medicines information	• Access to views of your prescribed and dispensed medications via MyHealth Record – requesting medications on-line etc.
Digitally-enabled models of care that improve accessibility, quality, safety & efficiency	• Integrating digital solutions across acute & emergency, paediatric, aged & palliative care.
Workforce confidently using digital health technologies to deliver health and care	• Training is critical to ensure effective use of digital health solutions
Thriving digital health industry delivering world-class innovation	• Provide developer tools and services to enable innovation in digital health.

Industry Perspectives

HCF

"Health does not lack innovation, the issue always is in scalability, and execution in a fragmented system"

Pharmaceutical Society of Australia

"Technology on its own…no matter how effective the platform, will not bring about changes in the behaviours of clinicians."

Key Opportunities – Digital Health

IN DEMAND:
Solutions that address Australia's major healthcare challenges

CURRENT CHALLENGE	OPPORTUNITIES FOR NORTHERN IRISH COMPANIES
Over Dependence on In-Patient Care	Telehealth/telemedicine, ambient sensors, home monitoring, wearables (quantified self).
Resource Utilization	Technologies that improve healthcare workflows - demonstrate ROI, e.g., radiology IT, RFID tags
Effective Chronic Disease Management	Predictive solutions for diagnostics & telehealth, cloud platforms for home care, disease management & patient engagement.
Improving Home Care Support	Interoperable systems that provide in-home clinical support without compromising the quality and safety of services & patient data.

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UK TECH IN AUSTRALIA

dna nudge

CovidNudge incl. DNACartridge, a disposable/sealed lab-on-a-chip device & NudgeBox, a standalone instrument that runs RT-PCR tests on the spot (at mine sites etc.). Partnered with Pantonic in Aus.

unmind

App assesses employee wellbeing aiming to optimise wellbeing in the workplace. Offers digital courses, meditation and healthy recipes. Opened a Sydney office.

Considerations for Market Entry

- Find and qualify and in-country partner or consider aligning yourself with key stakeholders in Australia.
- Work with an Australian healthcare provider / medical research institute – in collaboration with a local technology partner - to trial the solution in the local environment.
- Collaboration with private health insurance companies or not-for-profits, aligned with particular diseases, also presents opportunity for market entry.

- Potential for cross-cultural collaboration on trials/pilots
  - conducting trials simultaneously in 2 regions broadens outcomes/prevents study bias.

Dr Duncan Macinnis

Director of Stakeholder Engagement for New South Wales (NSW) and ACT at MTP Connect

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MTPConnect
MedTech and Pharma Growth Centre

Spotlight on Australia | Life and Health Sciences

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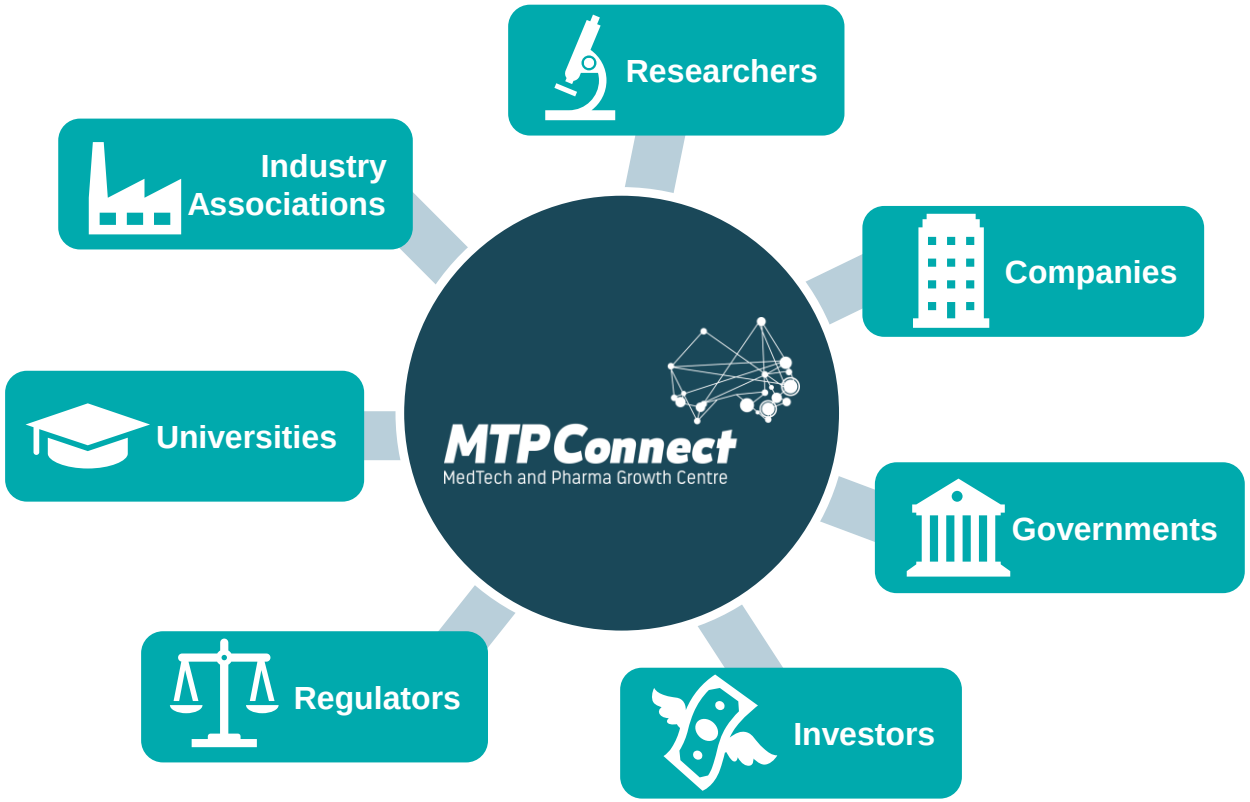
Dr Duncan Macinnis | Director of Stakeholder Engagement (NSW/ACT)

Australian Government
Department of Industry, Science, Energy and Resources

Industry Growth Centres

MTPConnect
Championing a sector-led approach to accelerating the growth of the medical technology, biotechnology and pharmaceutical ecosystem in Australia

MTPConnect's goal is to accelerate the growth of Australia's MTP sector



1. Increasing collaboration and commercialisation across the sector
2. Improved management and workforce skills
3. Optimising the regulatory environment
4. Improved access to global supply chains and international markets

MTPConnect Programs Overview @$182m

Australian Government
Department of Industry, Science, Energy and Resources
Industry Growth Centres

Growth Centre Project Fund

$15.6M grant value

40 projects

$34.8M matched industry contributions (cash and in-kind)

$1.2M State Government contributions

$205.2 external investment

31 projects completed

Australian Government
Department of Health
Medical Research Future Fund

BMTH BioMedTech Horizons PROGRAM
SUPPORTING TRANSLATION OF AUSTRALIAN MEDICAL TECHNOLOGY INNOVATION

$45M grant value
46 projects

bTb PROGRAM Biomedical TRANSLATION BRIDGE PROGRAM

$22.3M grant value
21 projects

RED DEVELOPING AUSTRALIA'S MTP SECTOR WORKFORCE

$32M grant value
13 program partners
31 training programs

TTRA TARGETED TRANSLATION RESEARCH ACCELERATOR
DIABETES · CARDIOVASCULAR DISEASE

$47M grant value
7 research projects

CTCM Clinical Translation & Commercialisation Medtech

$19.75M grant value

WA Life Sciences Innovation Hub

CASE STUDY: East meets West – The Chemistry of a Perfect Match for SpeeDx and SynGenis

MTPConnect
Adelaide Intermediary Program
In partnership with
Adelaide BioMed City
Government of South Australia

Adelaide Intermediary Program

As part of its EXCITE Strategy, the Government of South Australia has invested resources on intermediary functions that drive collaboration and knowledge transfer between researchers and industry in Innovation Districts.

MTPConnect has been appointed by the Government as the External Innovation and Translation Intermediary for Adelaide BioMed City (ABMC). Through targeted activities and services, MTPConnect's Adelaide Intermediary Program is focused on growing South Australia's health and medical industry sector by fostering collaboration, strategically building capacity and attracting new talent and opportunity across the research, innovation and translation value chain.

Growth Centre Catalyst Bodies

Antimicrobial resistance

AAMRNet

Cardiovascular devices

ACvA

Clinical trials

CT:IQ

Genomics

InGeNA

Regenerative medicine

RMCP

Australia's R&D Tax Incentive

Australia's R&D Tax Incentive aims to:

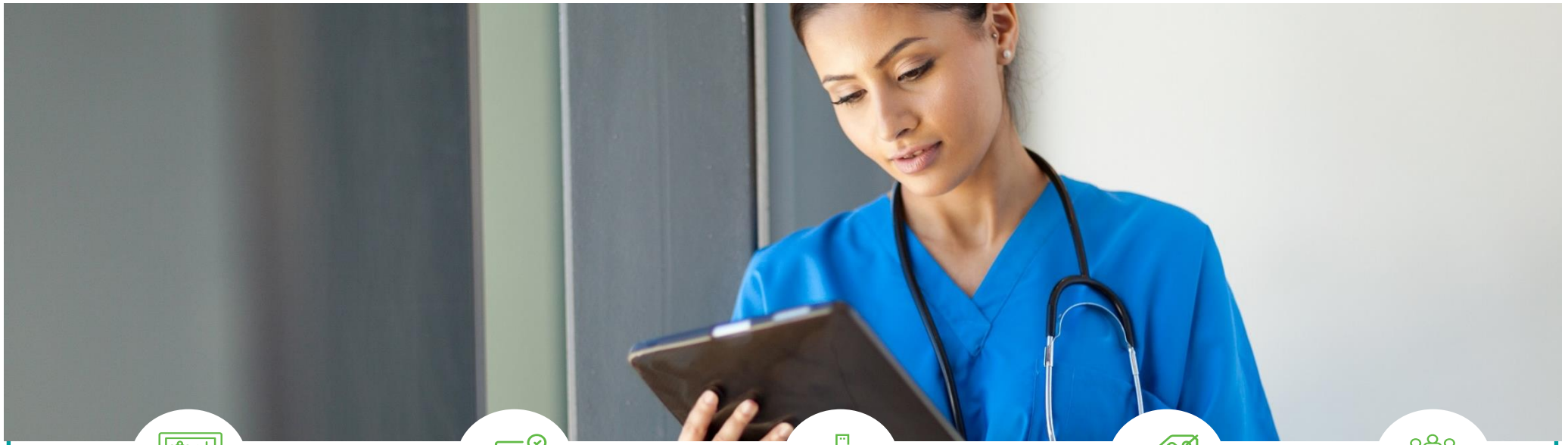
- boost competitiveness and improve productivity across the Australian economy
- encourage industry to conduct R&D
- provide business with more predictable, less complex support
- improve the incentive for smaller firms to engage in R&D

A 43.5% refundable tax offset for eligible entities with an aggregated turnover of less than $20 million per annum.

A 38.5% non-refundable tax offset for all other eligible entities (entities may be able to carry forward unused offset amounts to future income years).

Australia as a Clinical Trials Destination

Australia is an ideal location for clinical trials with many advantages



- Sophisticated medical research environment
- Rapid approvals and robust regulatory framework
- Quality transferable data
- Cost-efficient
- An ethnically diverse patient population

Australia as a Clinical Trials Destination

Proximity to Asian markets backed by Free Trade Agreements

An ethnically diverse population

Seasonal differences

Globally recognised key opinion leaders in major therapeutic areas

Western disease patterns

Multi-lingual population

Australia's Clinical Trials Sector

$1.4 Billion

5% in **EXPENDITURE**
from 2015 to 2019

8,000 Jobs

4% in **EMPLOYMENT**
from 2015 to 2019

95,000

PATIENTS PARTICIPATED
in 2019

Approx.
1,880 Trials

7% in **TRIALS STARTED**
from 2015 to 2019

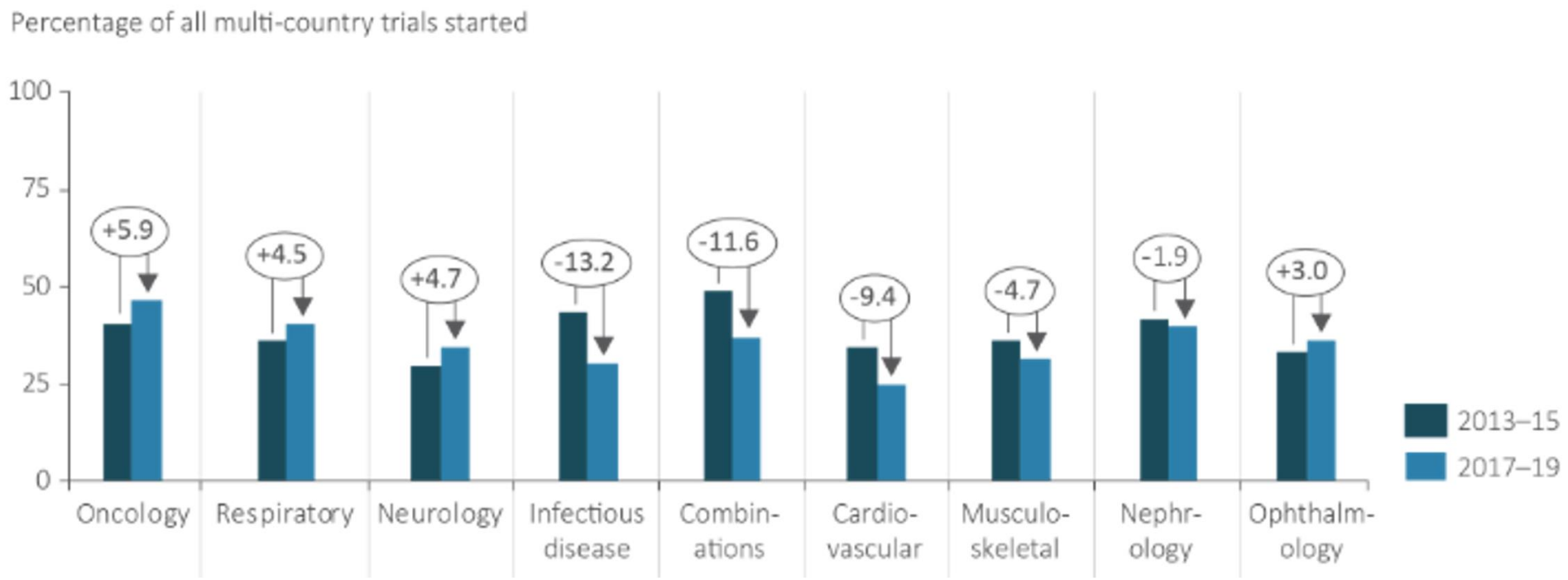
Approx.
5% Share

of **GLOBAL INDUSTRY SPONSORED TRIALS**

Note: * As calculated in *Clinical Trials in Australia* (2017 & 2021) reports

Australia’s Clinical Trials Sector

Australia's share of global industry-sponsored trail – by therapeutic area



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Australian Government
Department of Industry, Science, Energy and Resources

Industry Growth Centres

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Associate Professor Adrian Bootes

MBA, BPharm

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Australian imports vs exports

Australia's Top 20 Imports 2019-20

Rank	Commodity[a][b]	$ million	% share	% change
1	Personal travel (excl education) services	33,288	8.4	-28.1
2	Refined petroleum	21,721	5.5	-13.4
3	Passenger motor vehicles	19,093	4.8	-11.5
4	Telecom equipment & parts	15,230	3.8	4.4
5	Computers	10,398	2.6	6.5
6	Freight services	10,363	2.6	2.5
7	Crude petroleum	9,474	2.4	-29.4
8	Gold	8,812	2.2	59.7
9	Professional services	8,291	2.1	7.4
10	Medicaments (incl veterinary)	8,124	2.0	8.6
11	Goods vehicles	8,075	2.0	-23.6
12	Pharmaceuticals products (excl medicaments)	6,075	1.5	25.5
13	Telecom, computer & information services	5,952	1.5	24.1
14	Technical & other business services	5,792	1.5	4.3
15	Passenger transport services[c]	5,242	1.3	-30.4
16	Charges for intellectual property	4,914	1.2	-2.1
17	Furniture, mattresses & cushions	4,828	1.2	-3.3
18	Civil engineering equipment & parts	4,453	1.1	-12.4
19	Plastic articles	4,099	1.0	6.1
20	Electrical machinery & parts	3,954	1.0	-0.2
	Total imports[d]	**397,905**	**100.0**	**-5.7**

Australia's Top 20 Manufactures Exports 2019-20

Rank	Commodity[a][b]	$ million	% share	% change
1	Aluminium	3,761	7.2	-11.5
2	Pharmaceutical products (excl medicaments)	3,631	6.9	22.9
3	Copper	3,433	6.6	-12.8
4	Medicaments (incl veterinary)	2,912	5.6	10.8
5	Telecom equipment & parts	2,499	4.8	13.8
6	Aircraft, spacecraft & parts	2,354	4.5	-7.6
7	Measuring & analysing instruments	2,043	3.9	35.0
8	Medical instruments (incl veterinary)	1,709	3.3	3.4
9	Zinc	1,302	2.5	-19.0
10	Nickel	1,142	2.2	-31.7
11	Perfumery & cosmetics (excl soap)	1,071	2.0	12.6
12	Pigments, paints & varnishes	987	1.9	0.3
13	Computers	975	1.9	7.0
14	Vehicle parts & accessories	920	1.8	4.4
15	Paper & paperboard	884	1.7	-13.8
16	Civil engineering equipment & parts	813	1.6	11.8
17	Lead	801	1.5	-13.8
18	Specialised machinery & parts	799	1.5	-0.5
19	Jewellery	680	1.3	19.4
20	Starches, inulin & wheat gluten	665	1.3	1.1
	Total manufactures exports(c)	**52,329**	**100.0**	**-3.1**

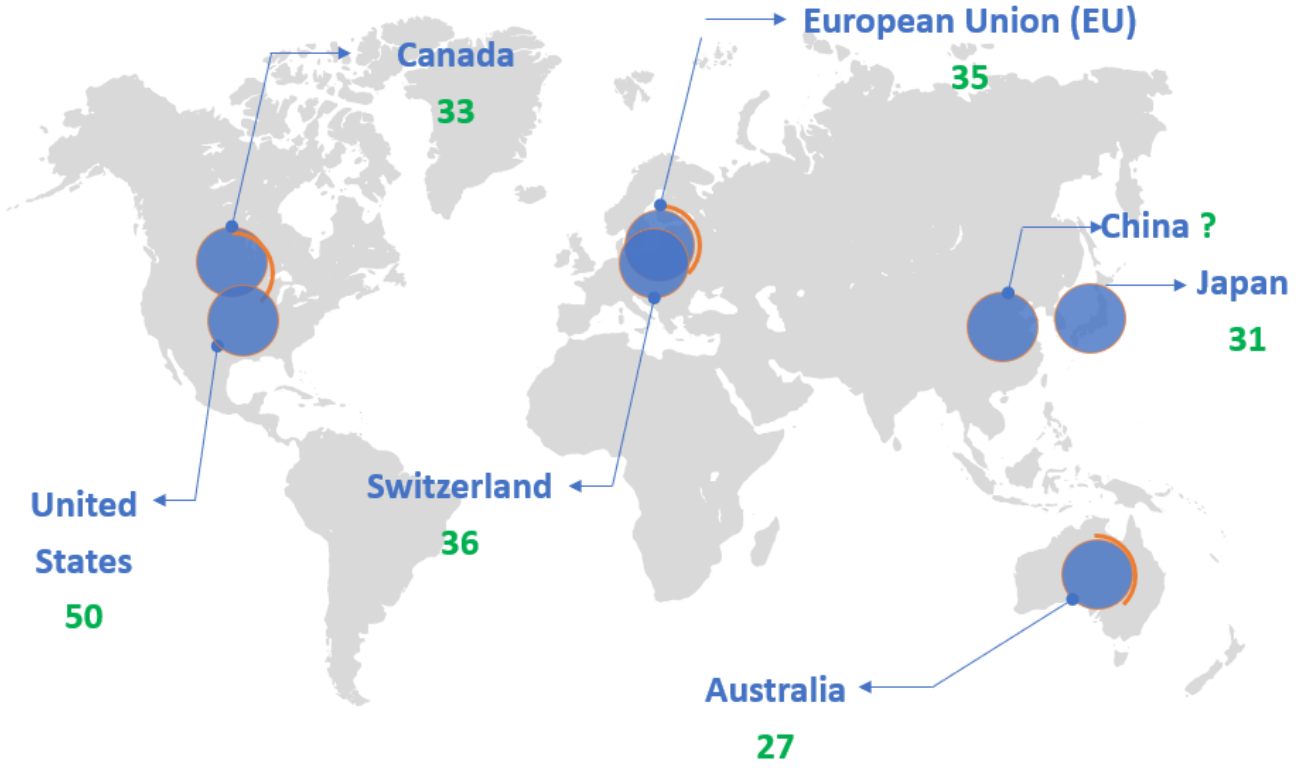
MyMedical DEPARTMENT

Total NAS applications

Similarly, different market needs by country:

NAS = Number of new active substances

Numbers approved in 2020



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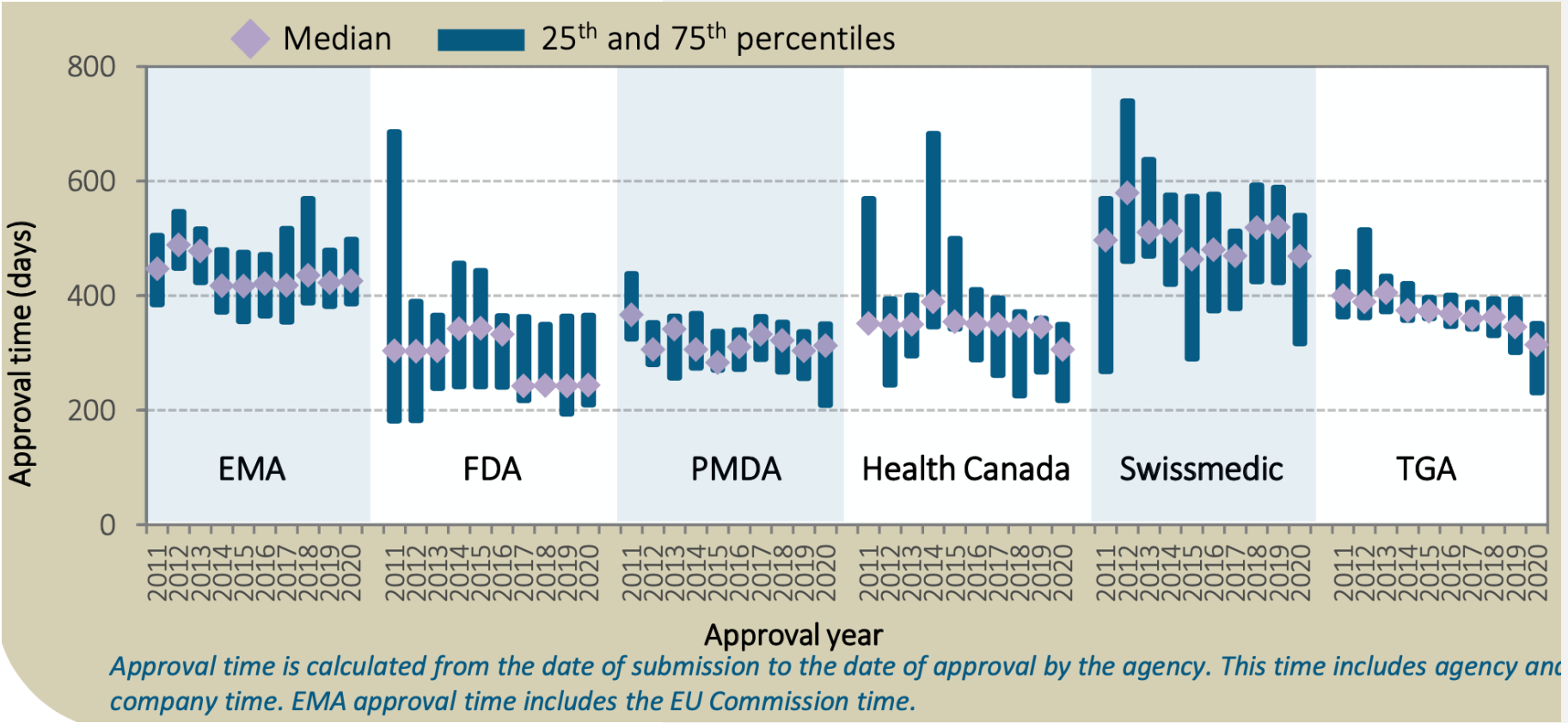
Timeliness & Predictability of NAS Approvals



Approval time is calculated from the date of submission to the date of approval by the agency. This time includes agency and company time. EMA approval time includes the EU Commission time.

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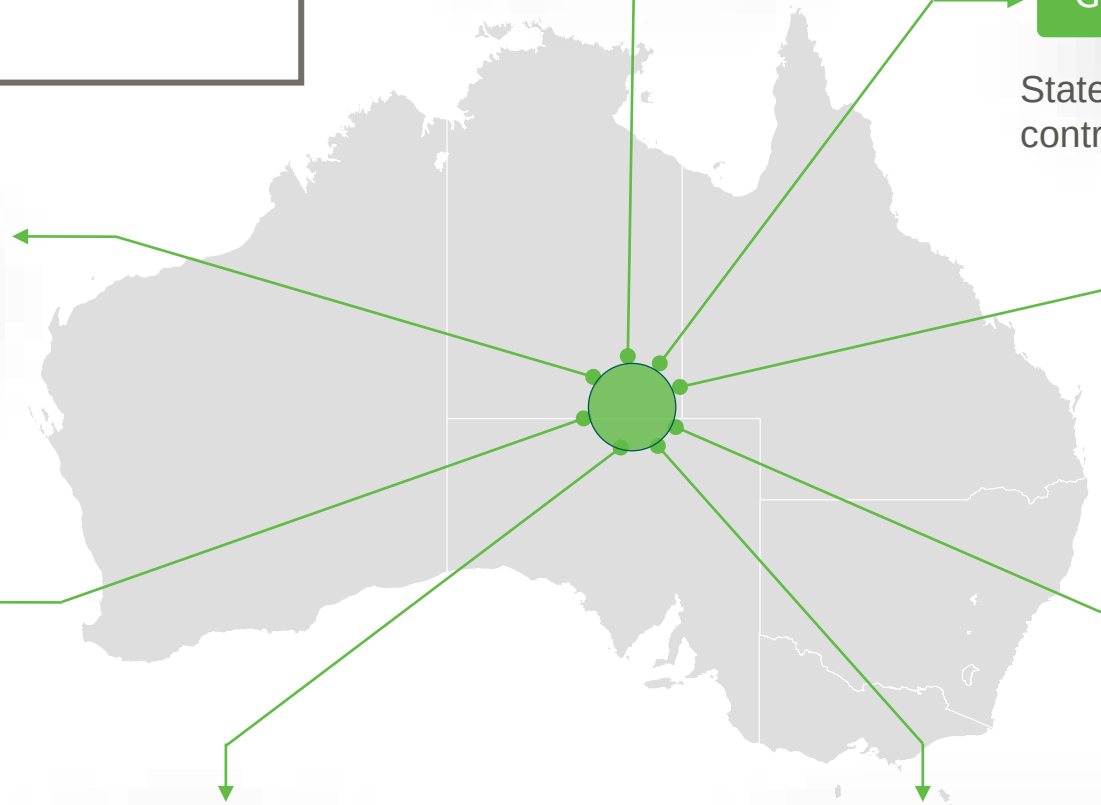
Multiple regulatory and government stakeholders in Australia



State and territories

Poisons and meds scheduling, pharmacists, hospitals

Government Supply Tenders

State government tendering and contracting

Customs and Federal Police

Prohibited imports and exports

TGA Australia

Safe, effective use of medicines and devices

Office of Gene Technologies

Genetically altered products

Pharmaceutical Benefits Schedule

Government-subsidised medicines

FSANZ

Food Standards Australian & NZ

Medicines Benefits Schedule

Government-subsidised devices and procedures, Drs etc.

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The Australian definition of a Therapeutic Good

therapeutic goods, means goods:

a. that are represented in any way to be, or that are, whether because of the way in which the goods are represented or for any other reason, likely to be taken to be:
   i. for therapeutic use; or
   ii. for use as an ingredient or component in the manufacture of therapeutic goods; or
   iii. for use as a container or part of a container for goods of the kind referred to in subparagraph (i) or (ii); or
b. included in a class of goods the sole or principal use of which is, or ordinarily is, a therapeutic use or a use of a kind referred to in subparagraph (a)(ii) or (iii);

and includes biologicals, medical devices and goods declared to be therapeutic goods under an order in force under section 7, but does not include:

Four types of therapeutic goods

Medicine

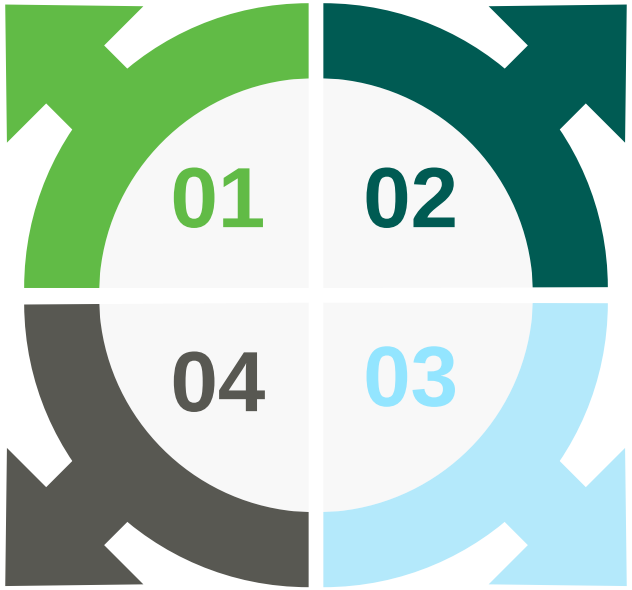
Products that act by pharmacological, chemical, immunological or metabolic means in or on the body of a human.
(includes biological medicines e.g. monoclonal antibodies, vaccines that do not contain human cells, plasma derivatives, recombinant products).

Biological

Product made from, or that contains, human cells or human tissues, or live animal cells, tissues or organs and that is used to:

- Treat or prevent disease, ailment, defect or injury
- Diagnose a condition of a person
- After the physiological processes of a person
- Test the susceptibility of a person to disease
- Replace of modify a person's body parts

(unless excluded or regulated as therapeutic goods, but not as biologicals)



Medical Device

Any instrument, apparatus, appliance, material or other article intended to be used for human beings for the purpose of one or more of the following:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap
- Investigation, replacement or modification of the anatomy or of a physiological process
- Control of conception.

And that that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its function by such means.
Or an accessory to such an instrument, apparatus appliance, material or other article.

Other Therapeutic Goods

Product that is not regulated specifically as a medicine, biological or medical device.
(includes sterilants,
disinfectants and tampons)

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Therapeutic Goods Types of Supply Allowed

- Registered
- Provisionally Registered
- Listed
- Listed (A)

OR

- Clinical Trials – Phase I, II, III and IV
- Special Access Scheme (SAS) – Categories A, B, C
- Authorised Prescriber
- Export Listing
- S19 exemption (personal importation)

Vs *not* TGs

- Animal testing
- Lab testing
- Manufacturing planning

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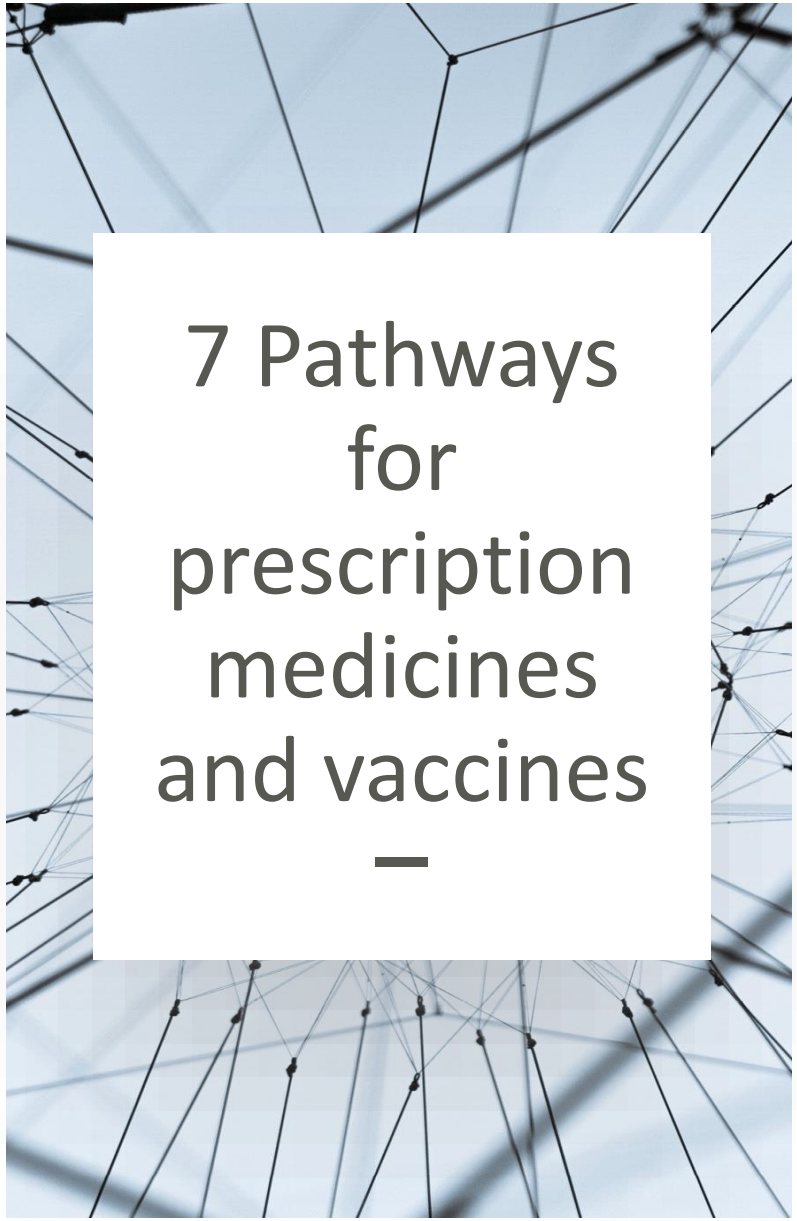
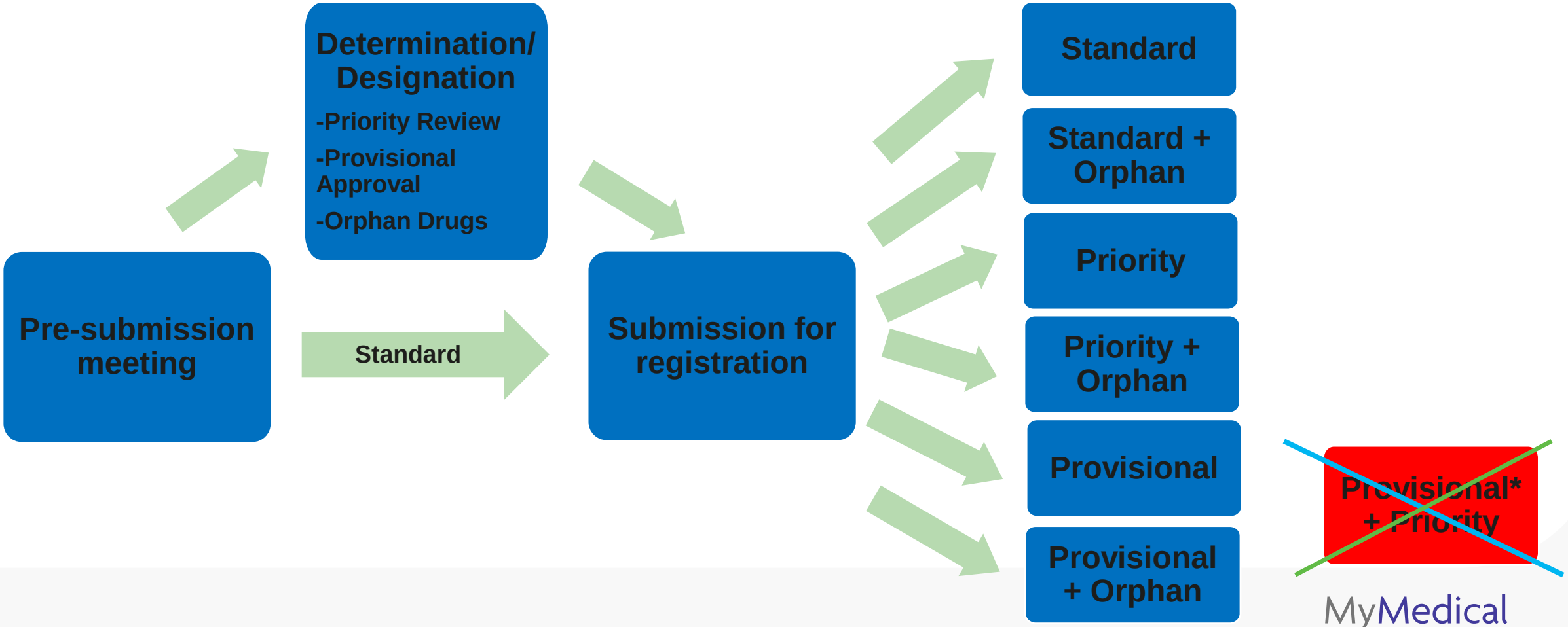


7 Pathways for prescription medicines and vaccines –

1. Standard pathway
2. Priority pathway
3. Provisional pathway
4. ACSS - Australia/Canada/Singapore/ Switzerland evaluations (now extended to the UK and called ACCESS)
5. Project Orbis – US/Canada/Australia (now extended to additional countries) evaluations for oncology medicines
6. Comparable Overseas Regulator – Pathway A
7. Comparable Overseas Regulator – Pathway B

Pre-submission & submission process

(local evaluation pathways)



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The Regulations
–

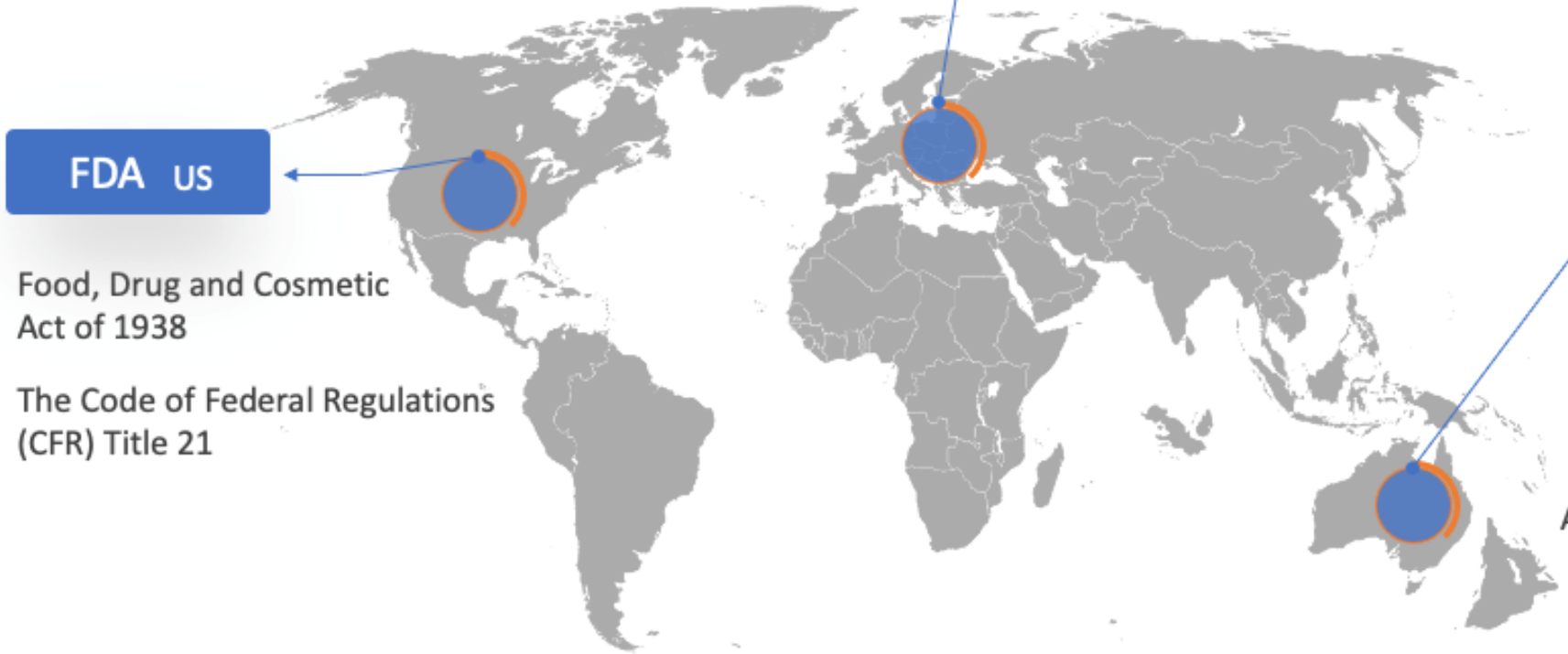
NOTIFIED BODY EU

MDR – Regulation (EU) 2017/745

IVDD Directive 98/79/EC

IVDR – Regulation (EU) 2017/746:

- Applicable from 26 May 2017 with a 5-year transition period.



FDA US

Food, Drug and Cosmetic Act of 1938

The Code of Federal Regulations (CFR) Title 21

TGA Australia

Therapeutic Goods Act 1989

Therapeutic Goods (Medical Devices) Regulations 2002

Australian Regulatory Guidelines for Medical Devices (ARGMD)

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Different types and classes of Medical Devices

–

Benefit vs. risk approach

Medical devices (not including *in vitro* diagnostics)

Class	Risk	Examples
Class I	Low	Tongue depressors, slings
Class I – supplied sterile Class I – incorporating a measuring function Class IIa	Low-medium	Some bandages, wound dressings, catheters Medicine cups with defined units Intravenous tubing, syringes for infusion pumps
Class IIb	Medium	Lung ventilators, medical device disinfectants, some implantable devices (e.g. urethral stents)
Class III	High	Heart valves, devices containing medicines or tissues, cells or substances of animal, biological or microbiological origin
Active implantable medical device (AIMD)	High	Implantable defibrillators

Regulatory Routes

Australia + EU

—

Medical Devices

All Classes

- ✓ Technical File
- ✓ Post market surveillance system
- ✓ Declaration of conformity

Class I (sterile & measuring), IIa, IIb, III

- ✓ Implementation of a QMS:
  - Based on EN ISO 13485
  - Include any additional requirements specified in the Regulations
- ✓ Maintenance of the QMS:
  - Surveillance audits at regular intervals

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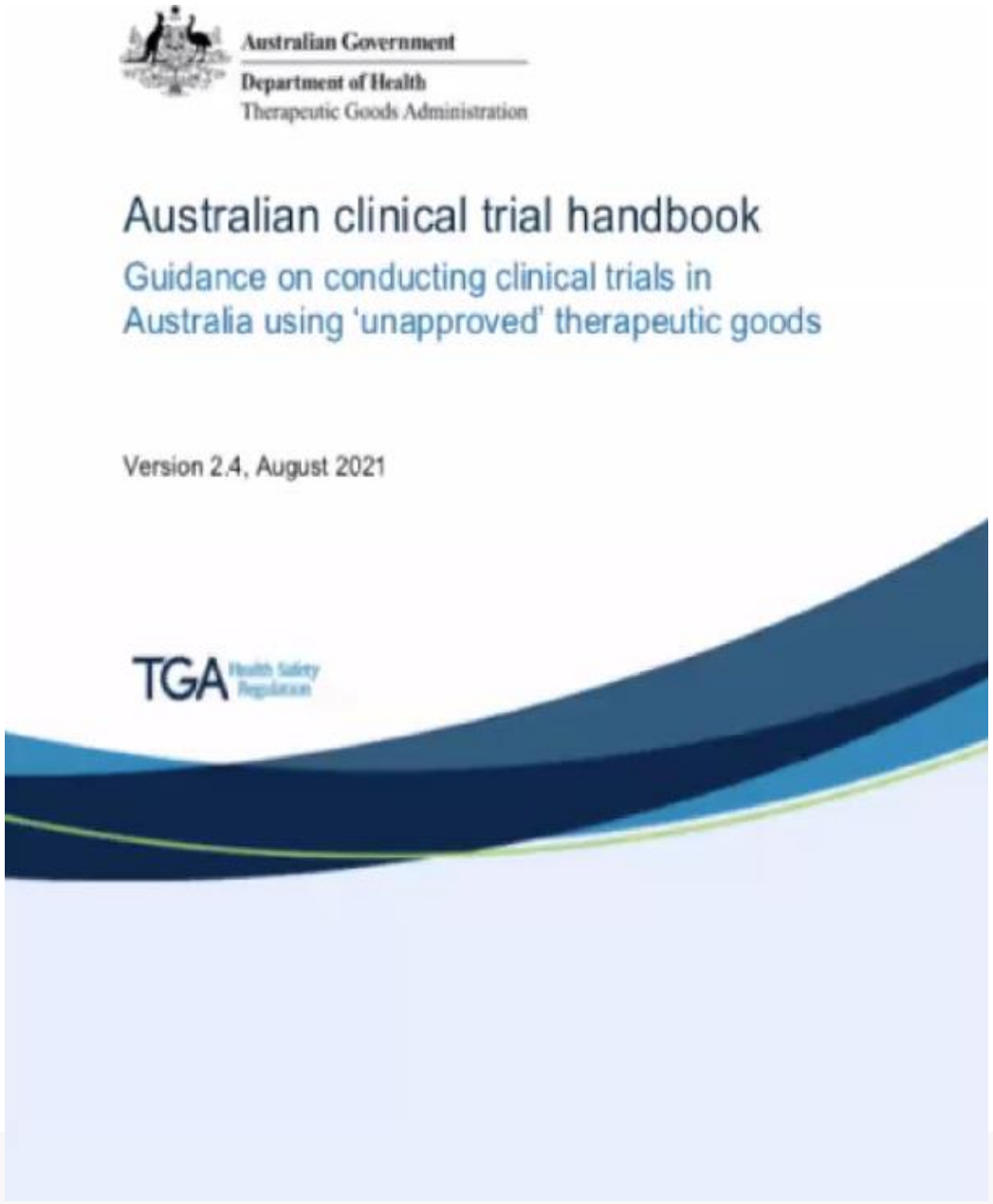

The Best Initial Resource for Australian Clinical Trials

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When to Engage Regulators for Clinical Trials leading up to submission?

For innovative medicines:

FDA – US – pre investigational new drug (IND) filing
EMA – Europe – pre first patient exposure
PMDA – Japan – pre first patient exposure (if Japanese, consider *sakigake*)
TGA – Australia – after phase 2 or 3 studies are positive (NB *suggest engaging with the EMA/FDA first*)

For biosimilars:

Before phase 3 studies against originator

For non-innovative (generic medicines)

Before comparator is finalised for comparative studies (country specific?)

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Key Points

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01

TGA follows a European approach and dossier (ICH, PIC/S, BP/EP/USP are largely accepted, on occasion with Australian additions)

02

Increasing use of international collaboration and reliance pathways for new products and generics

03

Timelines for prescription medicines are reliable and shortening, improvements for OTCs and devices are still being implemented

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Director of Drug Development and Regulatory Affairs

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Life Member and Certified Fellow in Clinical Research,

(retired) Head of The Prescription Medicines Authorisation Branch, TGA

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Q&A

Invest Northern Ireland