

CELEBRATING **20** YEARS OF EXCELLENCE

Bb Bellberry Limited
supporting research and ethics

Clinical Trial Activity Report

2023

January — December

CELEBRATING **20** YEARS OF EXCELLENCE

Australia's largest reviewer

Human Research Ethics Committees

Working across all phases of clinical and device trials, and social and behavioural studies, our teams support researchers in private, public, academic and government settings Australia-wide.

Since 2004 we
have supported...

43%

of CTN
clinical
trials in
Australia



1,450+ research
organisations

6,180+ investigators
and site staff

10,600+ research
applications

Foreword

Bellberry is a national, independent, Not-For-Profit organisation that returns surplus funds to the medical research sector, supporting the advancement of research knowledge through philanthropy and education.

As the largest reviewer of clinical trials in Australia, Bellberry provides high quality, time-efficient, independent assessment and oversight for more than 40% of Australia's Therapeutic Goods Administration (TGA) registered clinical trials.



Bellberry is the first Australian organisation to achieve accreditation by the global Association for the Accreditation of Human Research Protection Programs (AAHRPP).

The Bellberry Human Research Ethics Committees (HRECs) review a broad range of research activity, from clinical trials to social and behavioural science studies, and support researchers in private, public, academic and government settings Australia-wide. This report seeks to share insights from the clinical trials sector in Australia and the contribution Australia makes to global clinical trial activity. The 2023 Clinical Trial Activity Report is the fourth in a series of reports.



Bellberry Dataset

- Research approved by Bellberry HRECs (2023 calendar year).
- NSW Early Phase Clinical Trial (EPCT) Framework (2023 calendar year).

Includes both clinical trials and other human research.

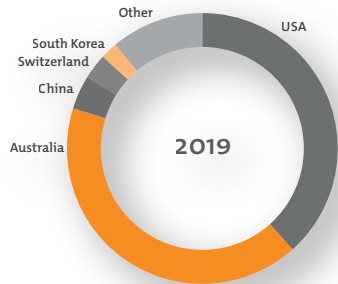
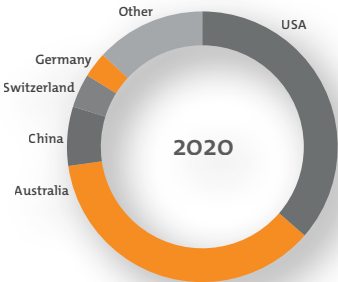
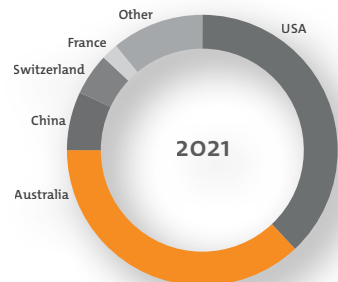
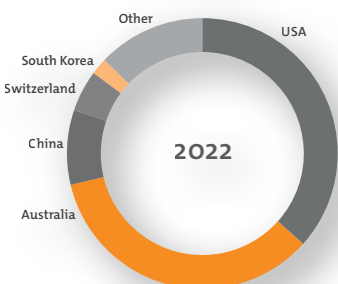
More than 40% of TGA Clinical Trial Notifications (CTNs).
Includes reanalysis of dataset from 2019-2022.

Diverse and broad user base:

- Public Sector research.
- Private hospitals and clinical providers.
- Independent clinicians and researchers.
- Government departments (at Commonwealth and State/Territory level).
- Primary care.

Public-based research includes studies from
NSW EPCT and SA Health.

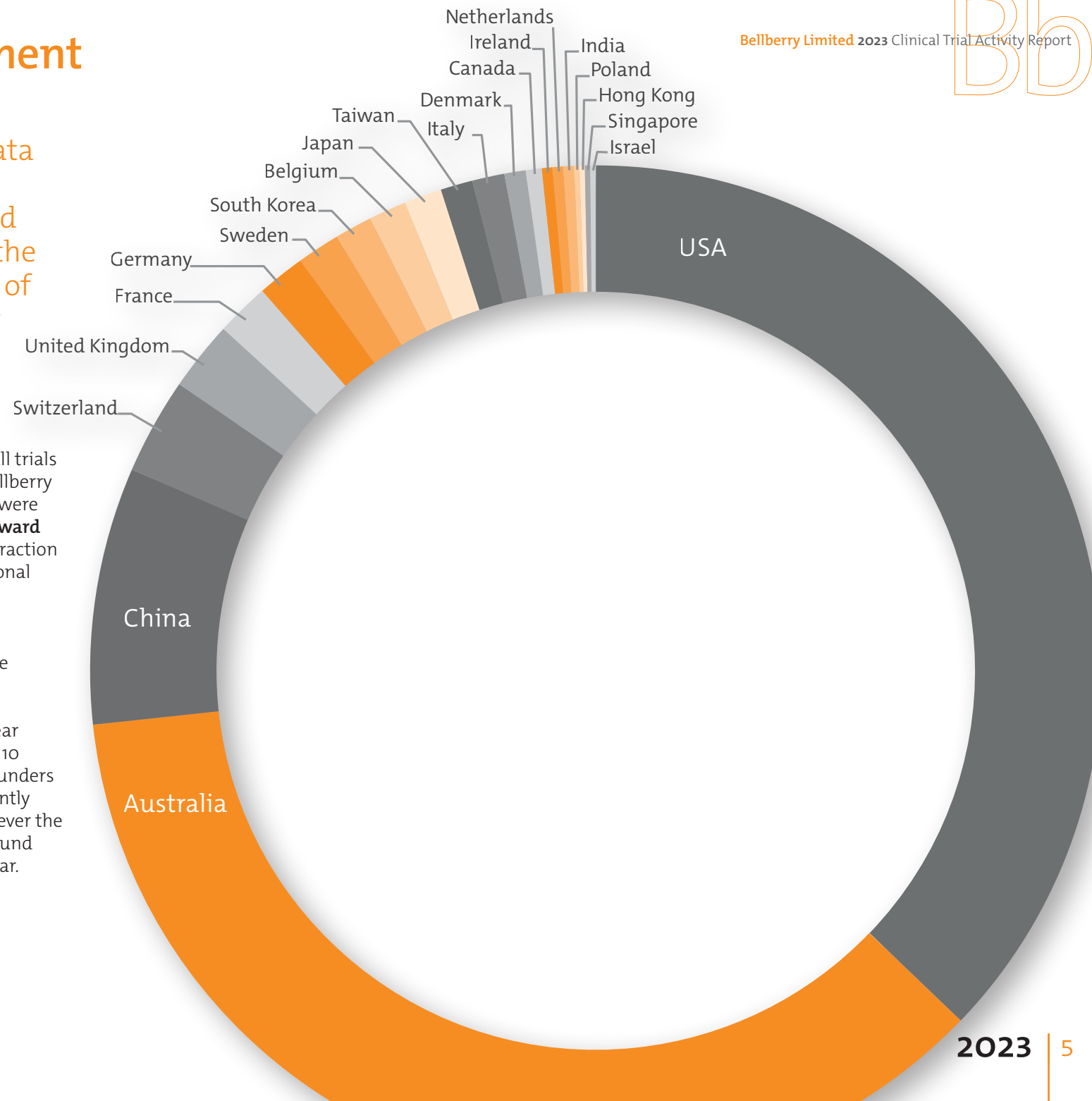
International investment in all trials



Bellberry data has been interrogated to identify the root source of funding for trials.

We found:

- **Two-thirds** of all trials reviewed by Bellberry HRECs in 2023 were the result of **inward investment** attraction from international jurisdictions.
- **Over one-third** of all trials were **US-sponsored**.
- Over the five year period, the top 10 International funders are predominantly the same, however the top 5 move around from year to year.



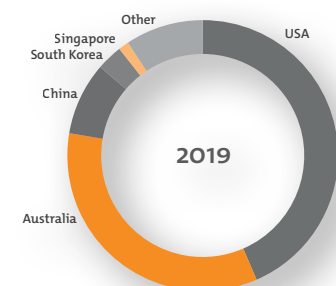
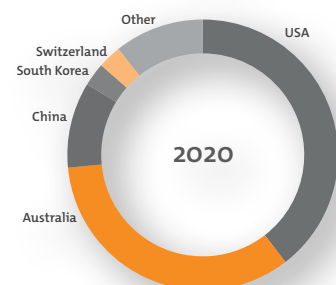
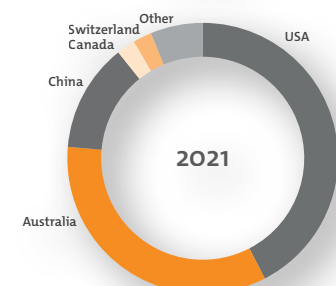
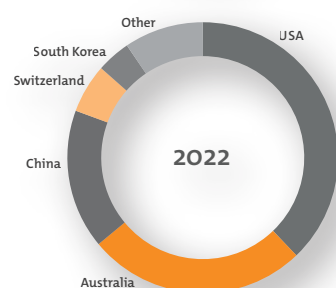
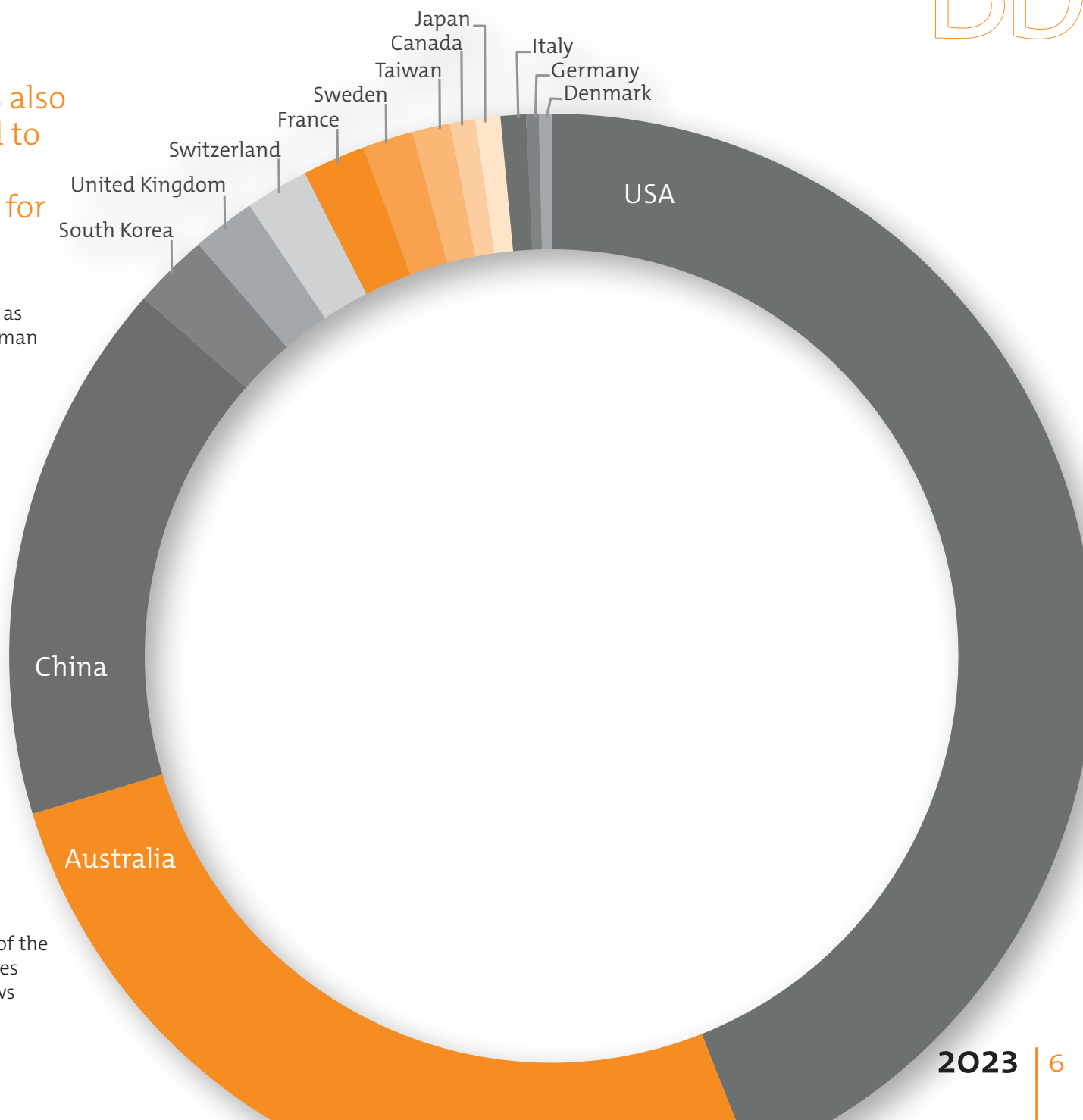
International investment in early phase trials

Bellberry data has also been interrogated to identify the root source of funding for early phase trials.

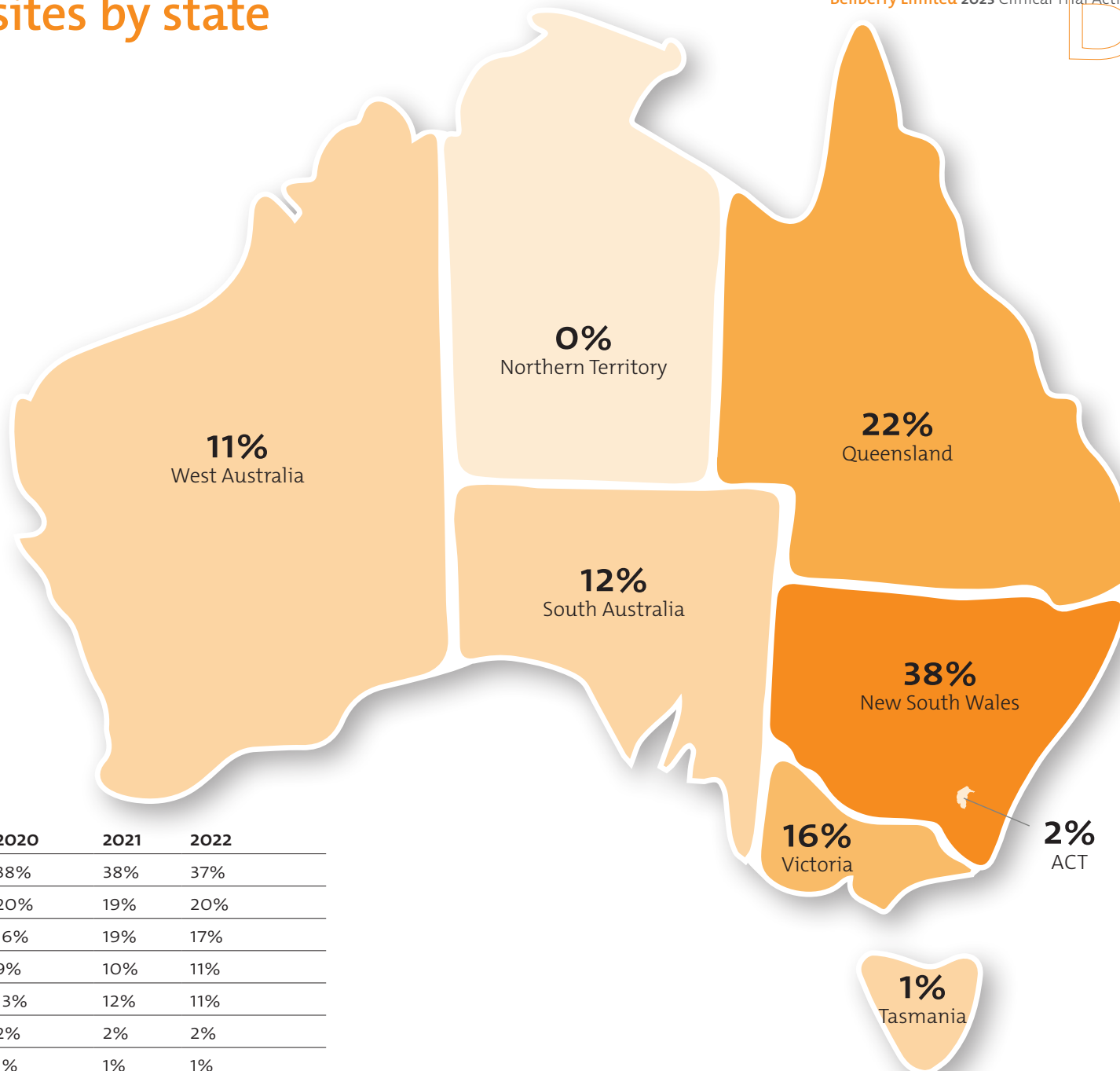
Early phase trials are classed as those including a First in Human (FIH) or Phase 1 component.

We found:

- Over two-thirds of early phase trials involved investment from **non-Australian sponsors**.
- Of that two-thirds, the **US** and **China** accounted for the most significant proportion, followed by, **South Korea, the UK, Switzerland, France, Sweden, Taiwan** and **Canada**.
- This trend of the US, Australia and China as top three has remained consistent for the last five years.
- International placement of the early phase trials continues to be a strength and shows further growth over that five-year period.



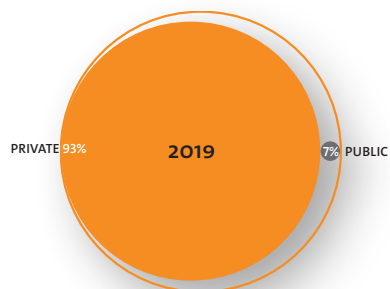
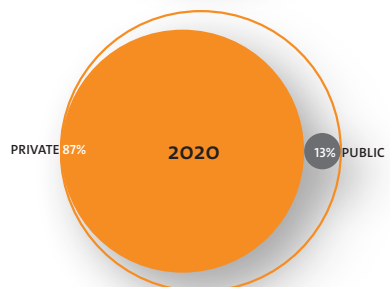
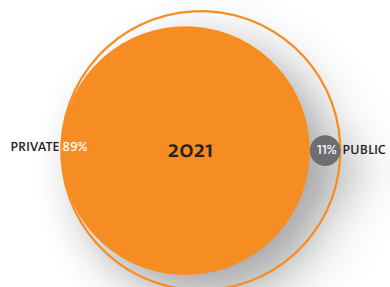
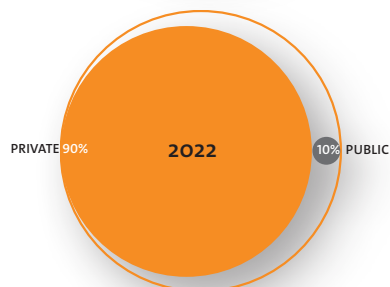
Distribution of trial sites by state



	2019	2020	2021	2022
New South Wales	33%	38%	38%	37%
Queensland	22%	20%	19%	20%
Victoria	21%	16%	19%	17%
South Australia	8%	9%	10%	11%
West Australia	12%	13%	12%	11%
Australian Capital Territory	2%	2%	2%	2%
Tasmania	1%	1%	1%	1%
Northern Territory	0%	0%	0%	0%

Note: Percentages are rounded and may not total 100%.

Distribution of trial sites by site type



Private sites range from small clinics through to hospitals, and also include university research; while public is defined as research based at public health funded sites.

We found:

- The majority of research reviewed by Bellberry HRECs continues to be with private sites.

PRIVATE 89%

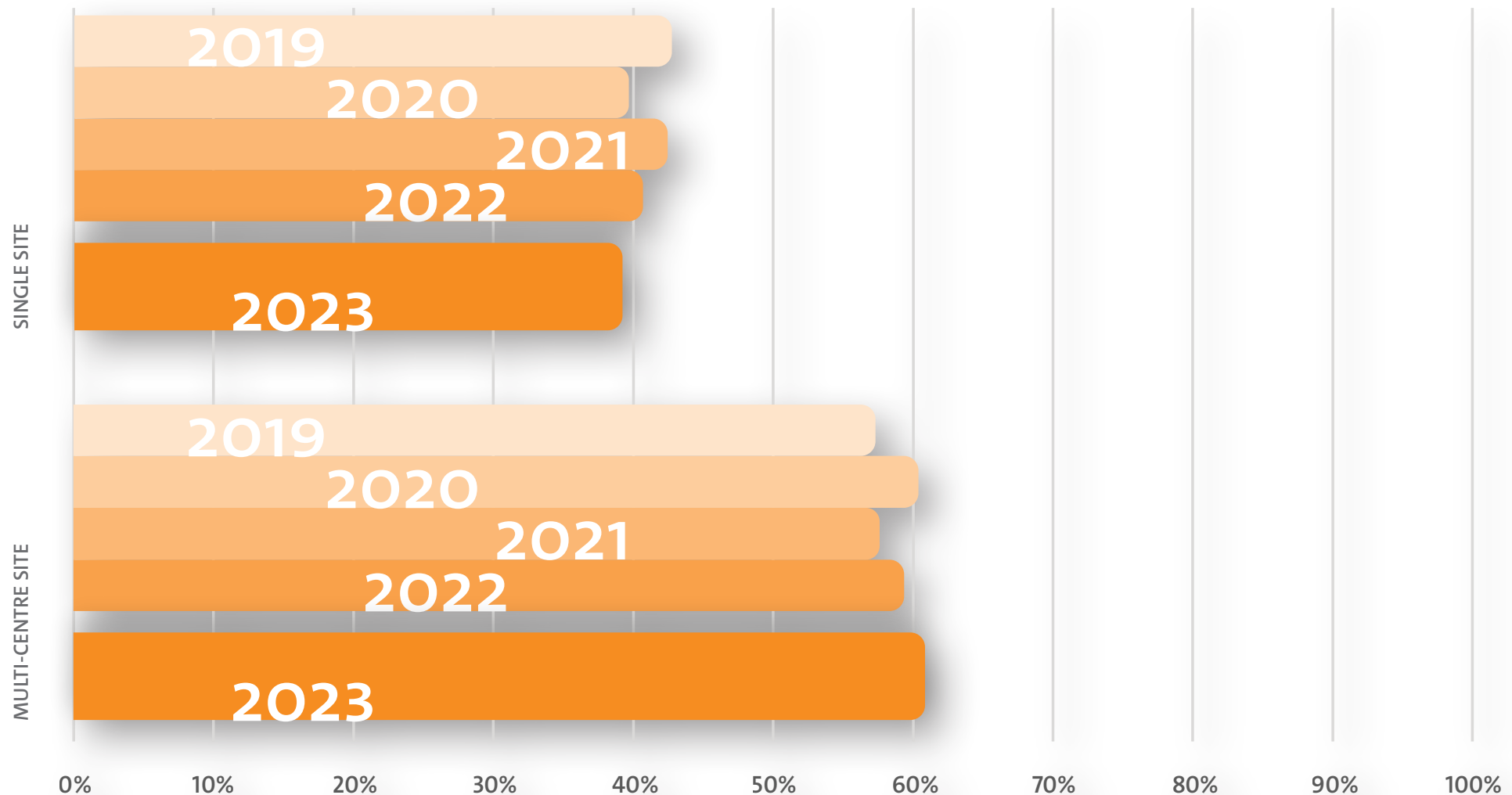
PUBLIC
11%

Multi-centre trials

Bellberry HRECs have been providing single ethical review for multi-centre trials since 2005.

Over the past five years, the proportion of research applications reviewed that were multi-centre studies has consistently been over half.

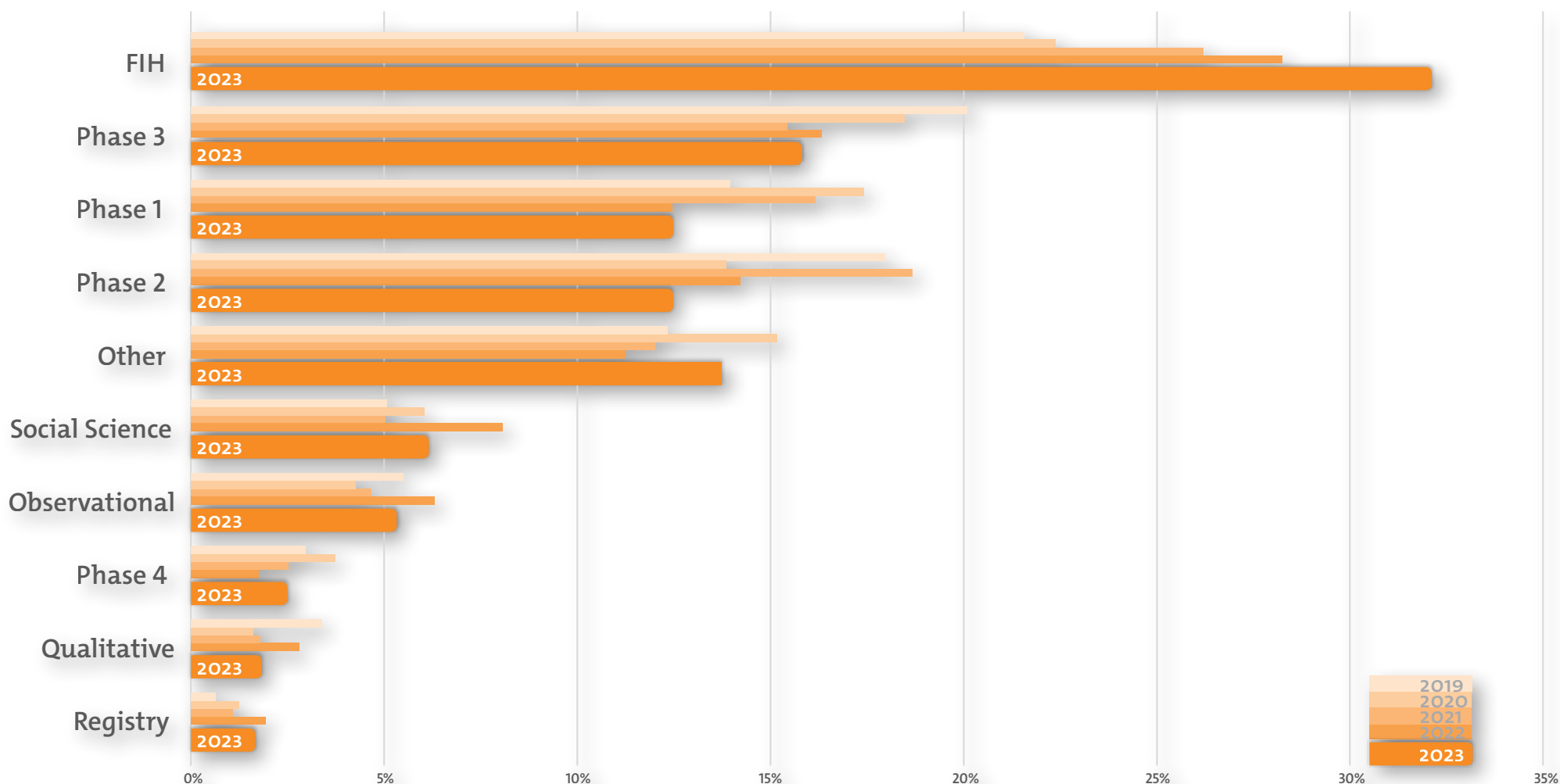
In **2023** the proportion of multicentre research is approaching **two-thirds**, reflecting the strength of Australia's capability in supporting multicentre research.



Distribution of trials by phases

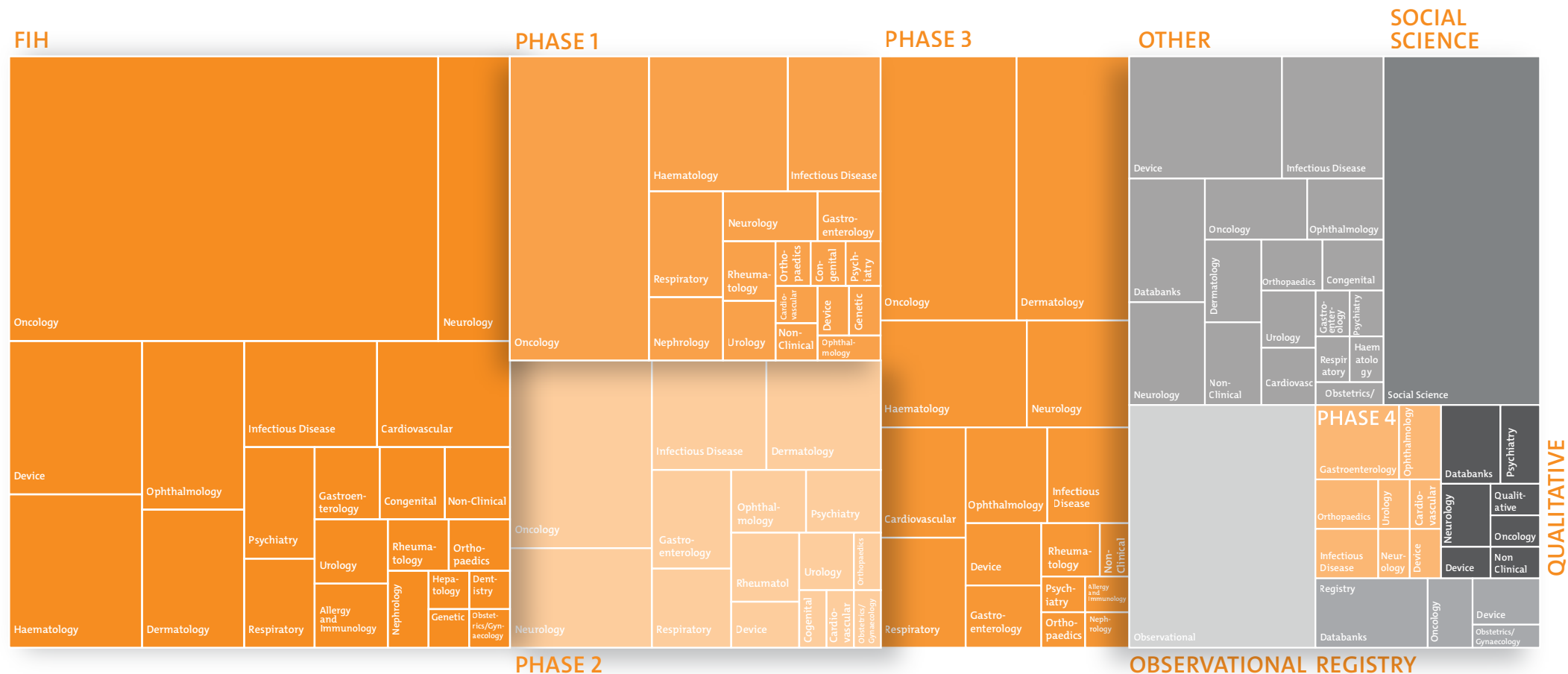
Bellberry applications reflect the continued strength of Australia in FIH and Phase 1 trials.

Additionally, the data demonstrates Australia's capability to take molecules from innovations from FIH through to phase three registration trials - and beyond.



Distribution by phases and therapeutic areas

Oncology for many years has been number one in most categories.



QUALITATIVE

Distribution of trials by therapeutic areas

The Australian research sector delivers trials across a broad range of therapeutic areas.

A long-standing trend, which continued in 2023, was oncology having the most substantial portion of trials overall.

