Bb Bellberry Limited
supporting research and ethics

Clinical Trial Activity Report

2022

January — December

Foreword

Bellberry Limited is an independent not-for-profit organisation providing streamlined scientific and ethical review of human research projects across Australia.

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



Association for the Accreditation of Human Research Protection Programs, Inc.
Full Accreditation

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 2022 Clinical Trial Activity Report is the third in a series of reports.



Data boundaries

Dataset:

- Research approved by Bellberry HRECs (2022 calendar year).
- NSW Early Phase Clinical Trial (EPCT) Framework (2022 calendar year).

Includes both clinical trials and other human research.

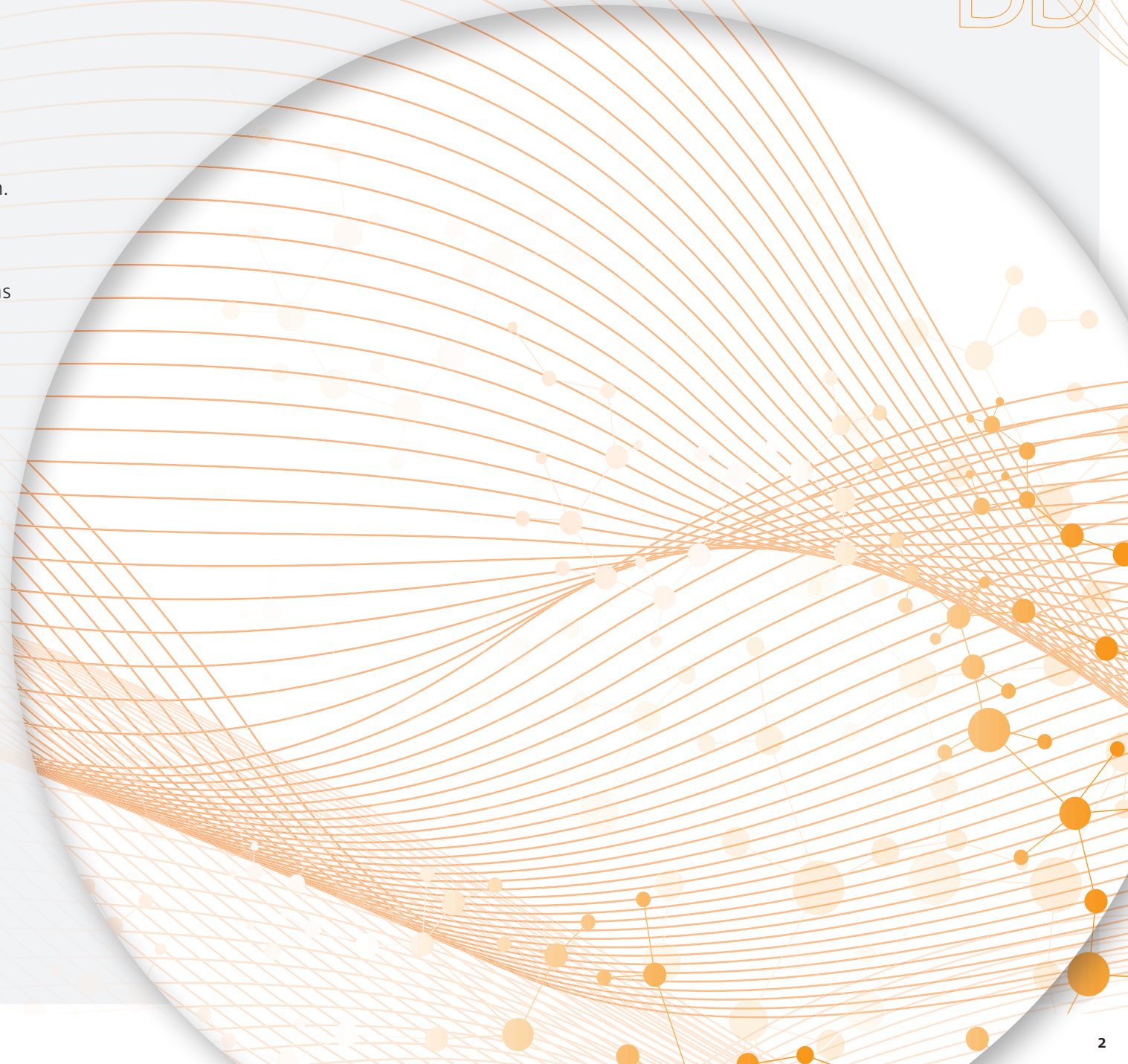
Approximately one-third of TGA Clinical Trial Notifications (CTNs).

Includes reanalysis of dataset from 2021.

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.

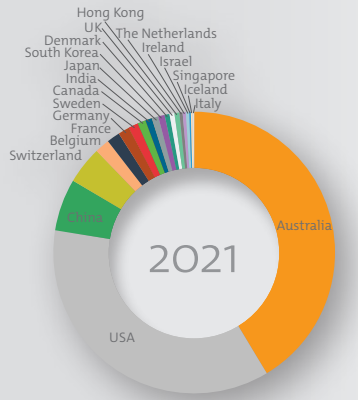


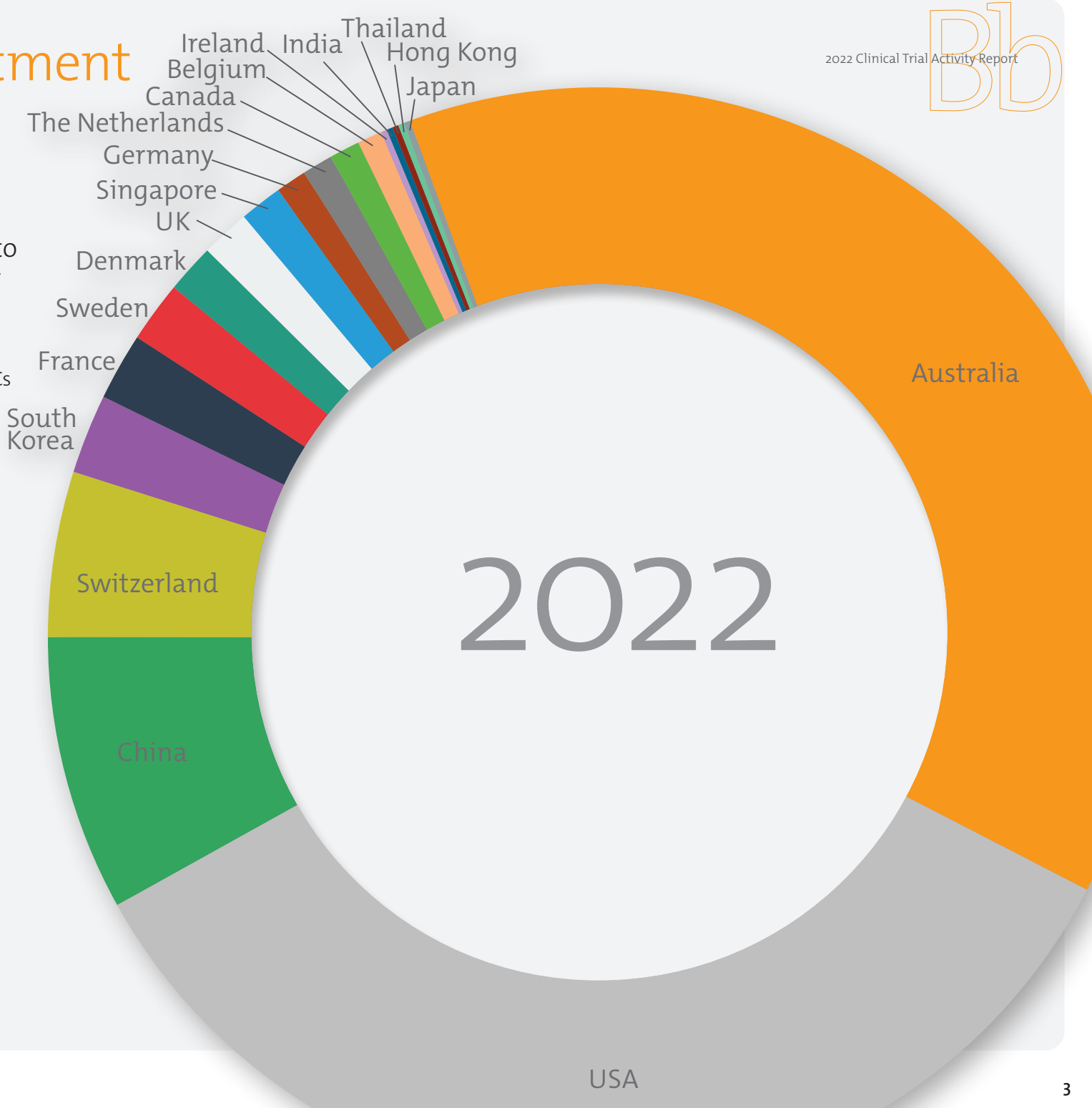
International investment in all trials

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 2022 were the result of **inward investment** attraction from international jurisdictions.
- **Around one-third** of all trials were **US-sponsored.**



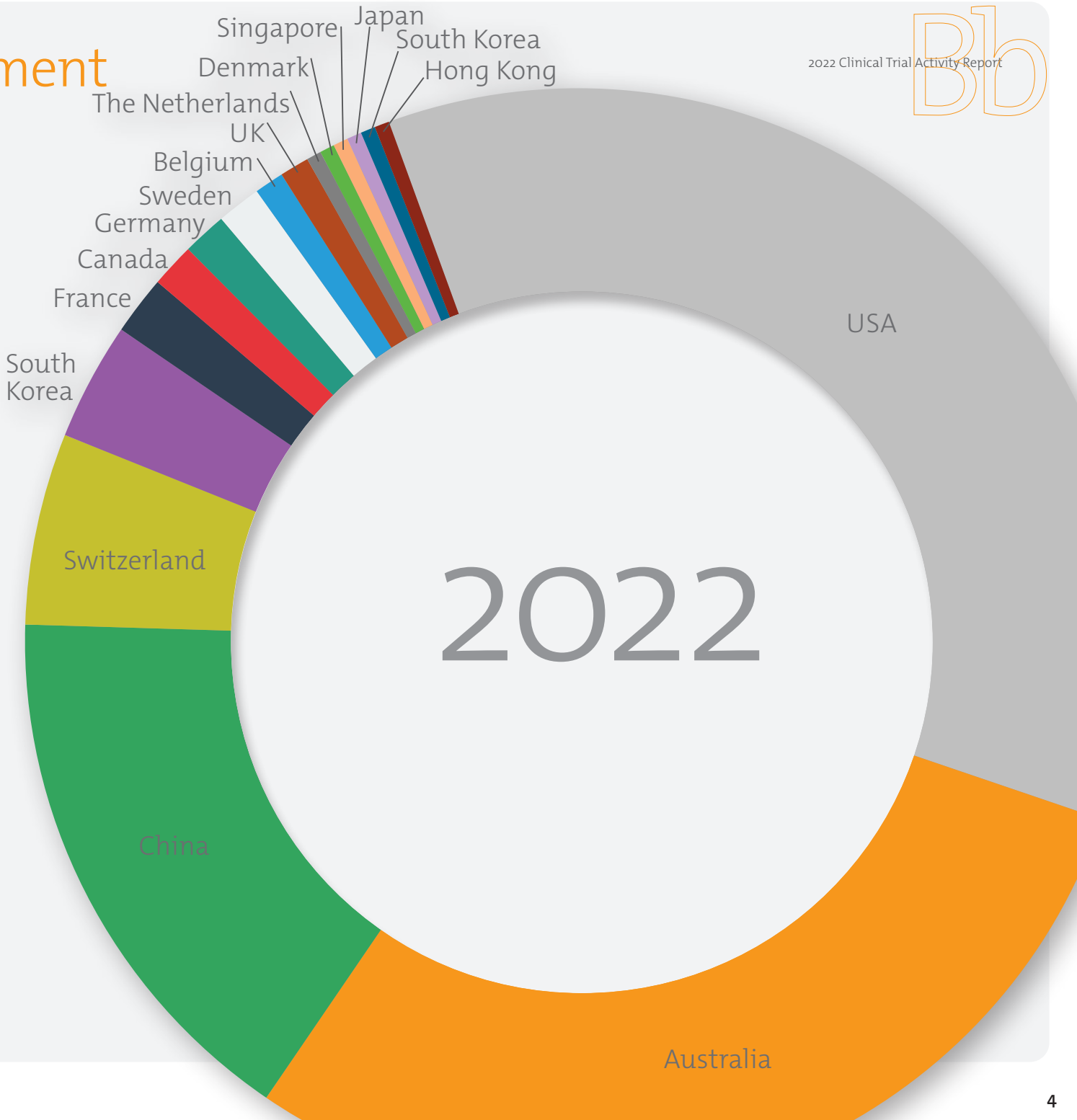


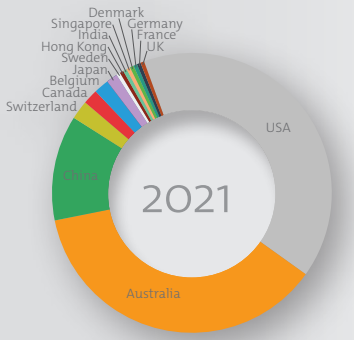
International investment in early phase trials

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.

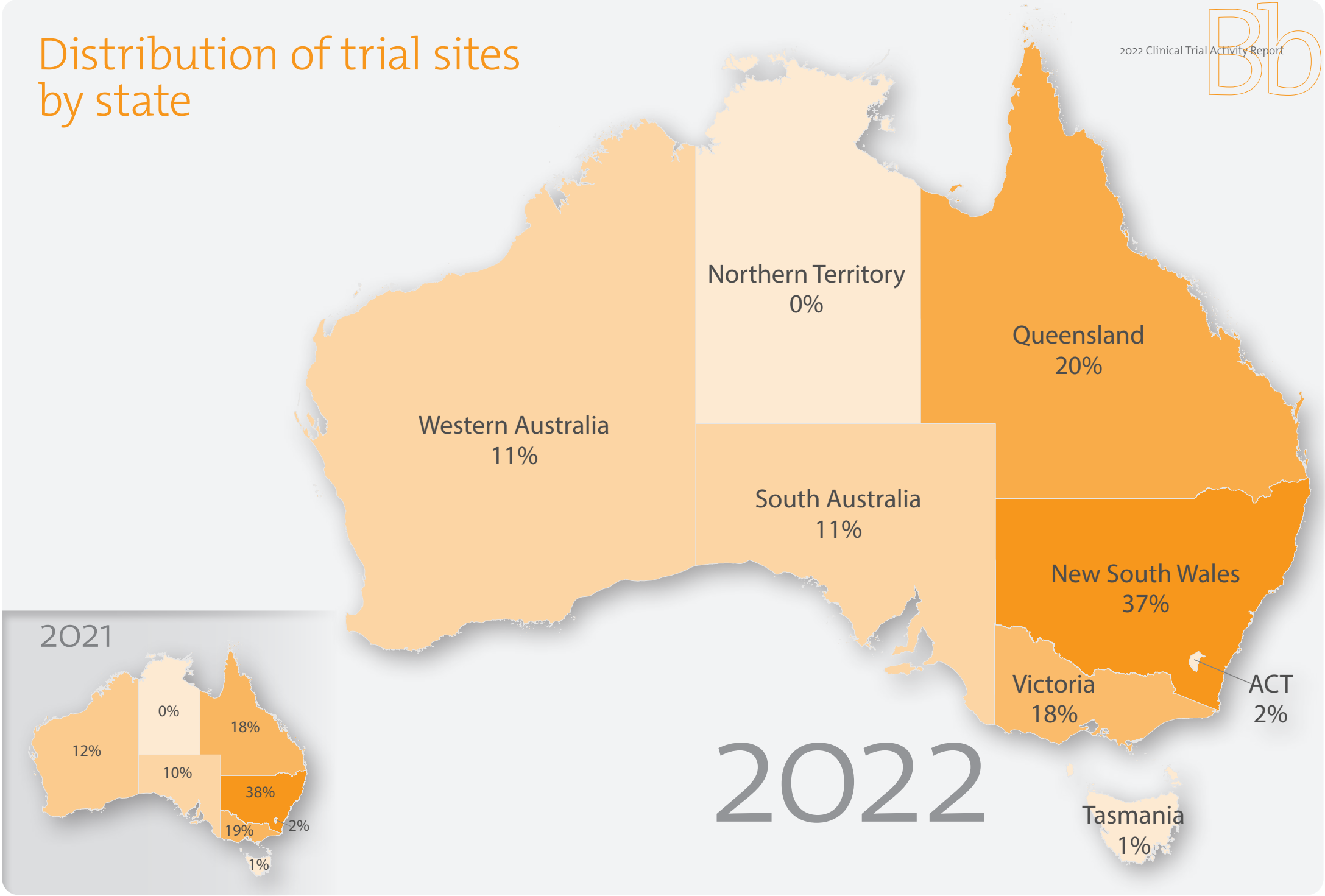
We found:

- **Two-thirds** of public early phase trials involved investment from **non-Australian sponsors.**
- Of that two-thirds, the **US, China** and **Switzerland** accounted for the most significant proportion.





Distribution of trial sites by state



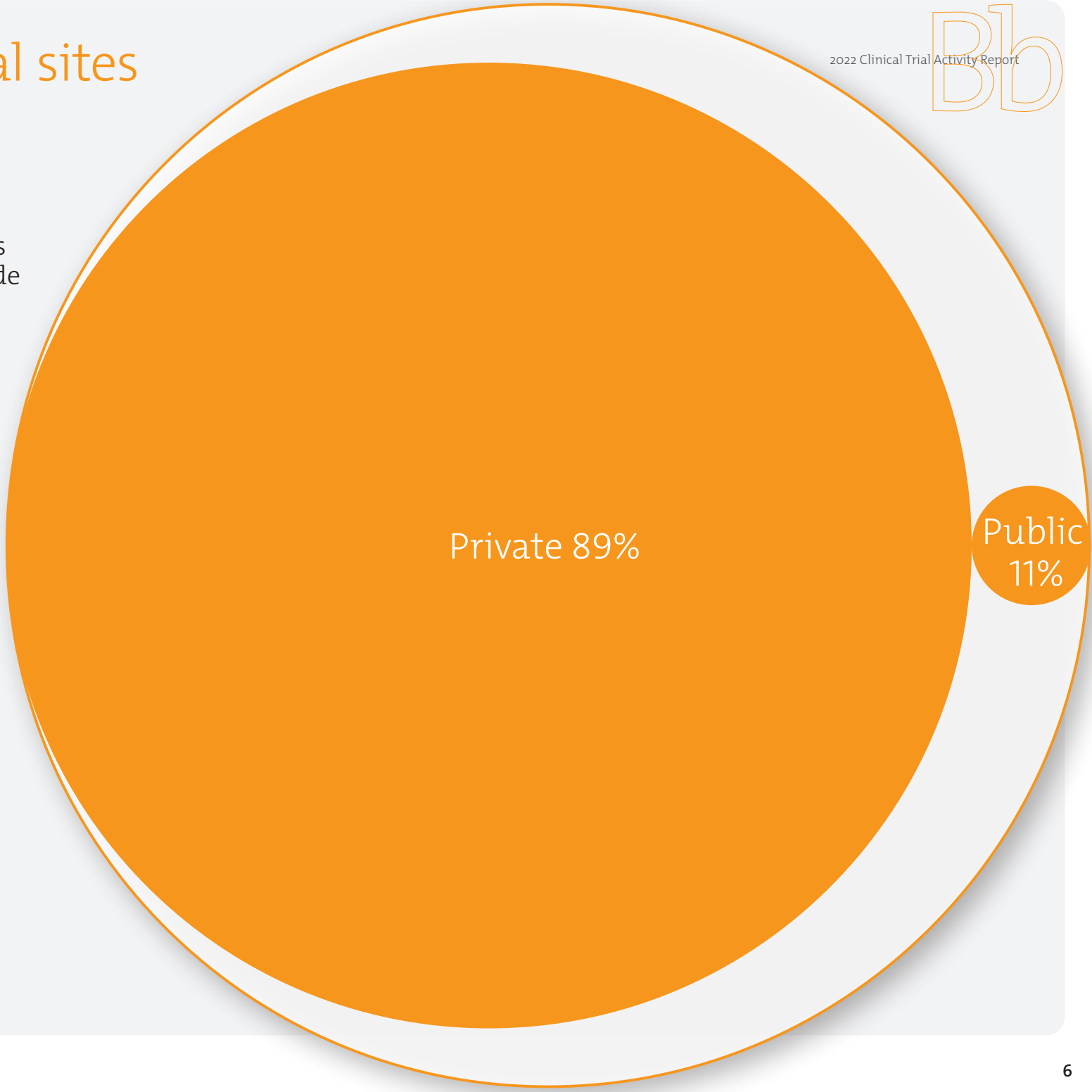
Distribution of trial sites by site type

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.

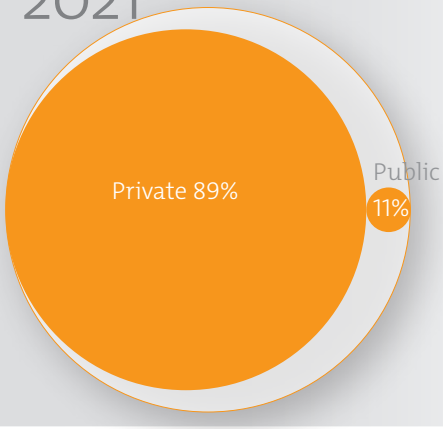
We found:

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

2022



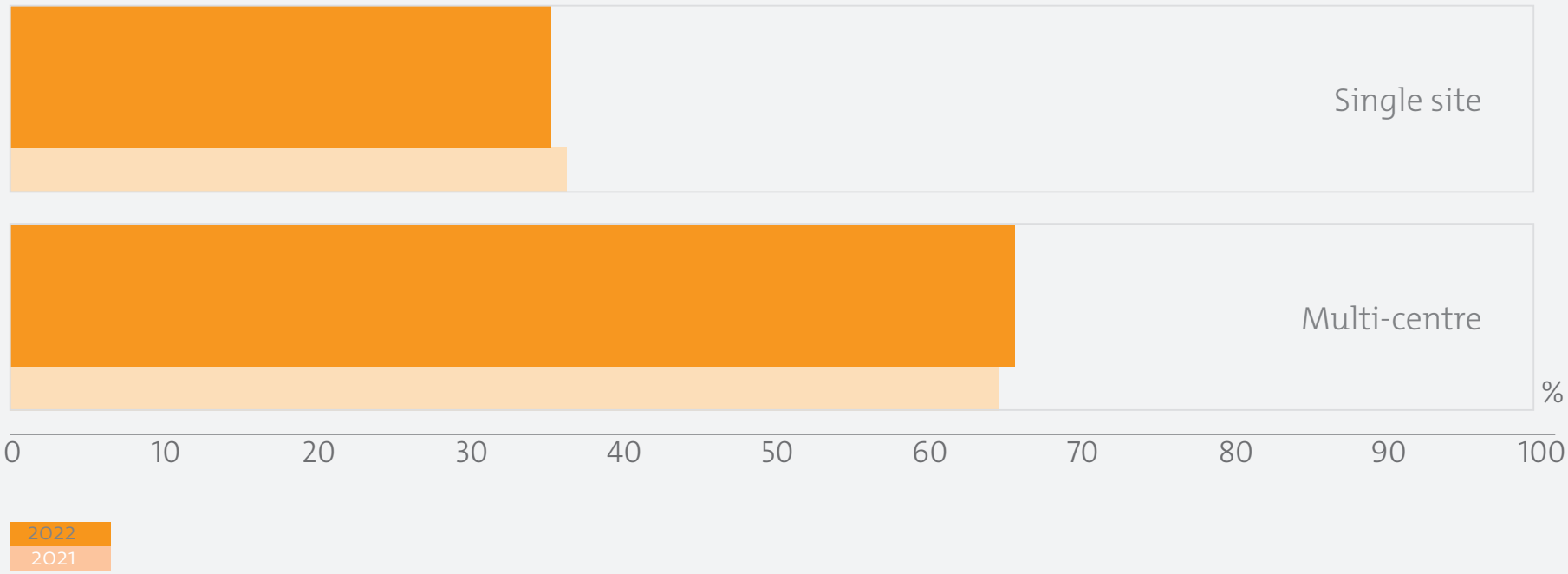
2021



Multi-centre trials

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

Similar to 2021, more than half of research applications reviewed in 2022 were multi-centre studies.

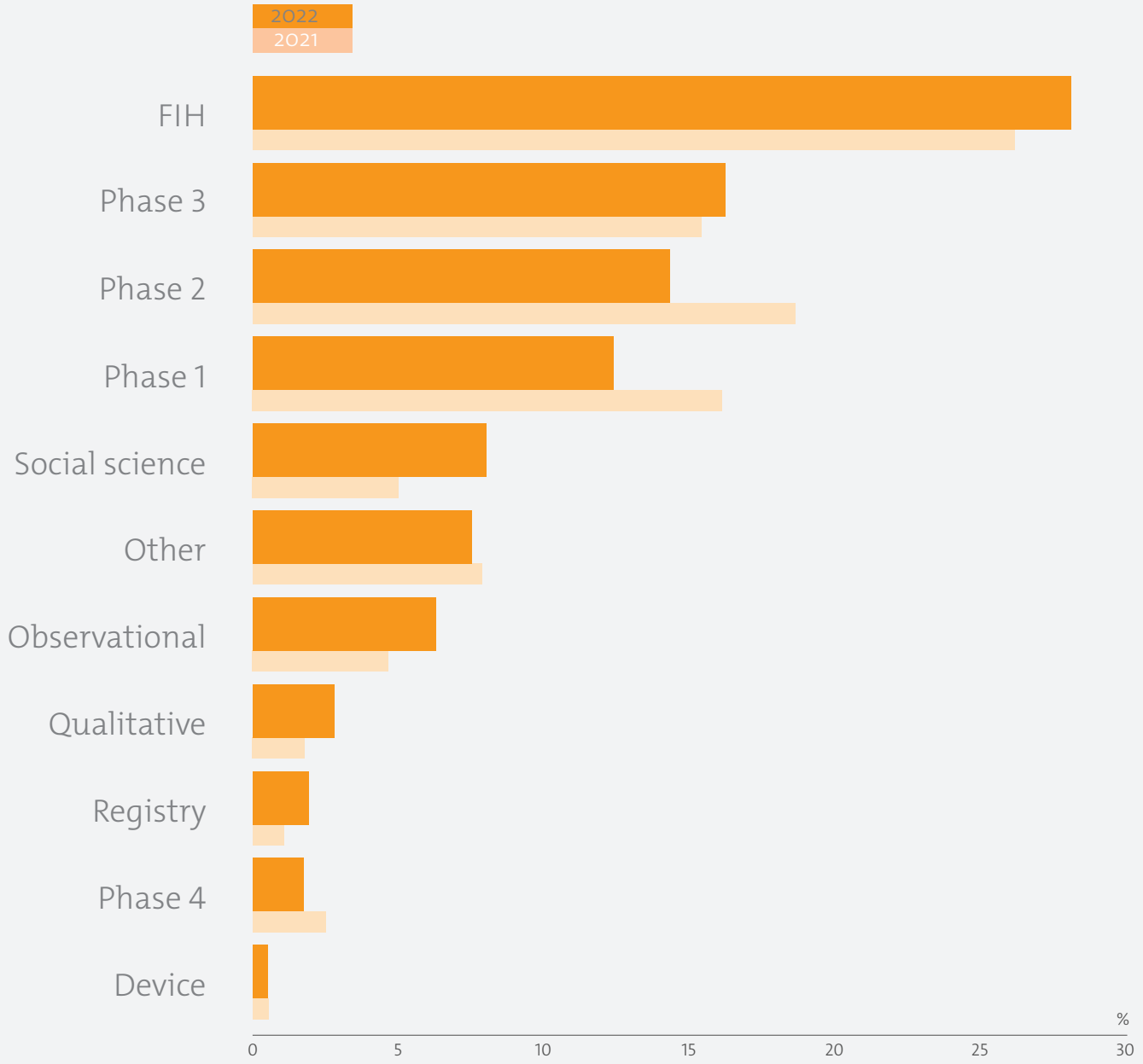


Distribution of trials by phases

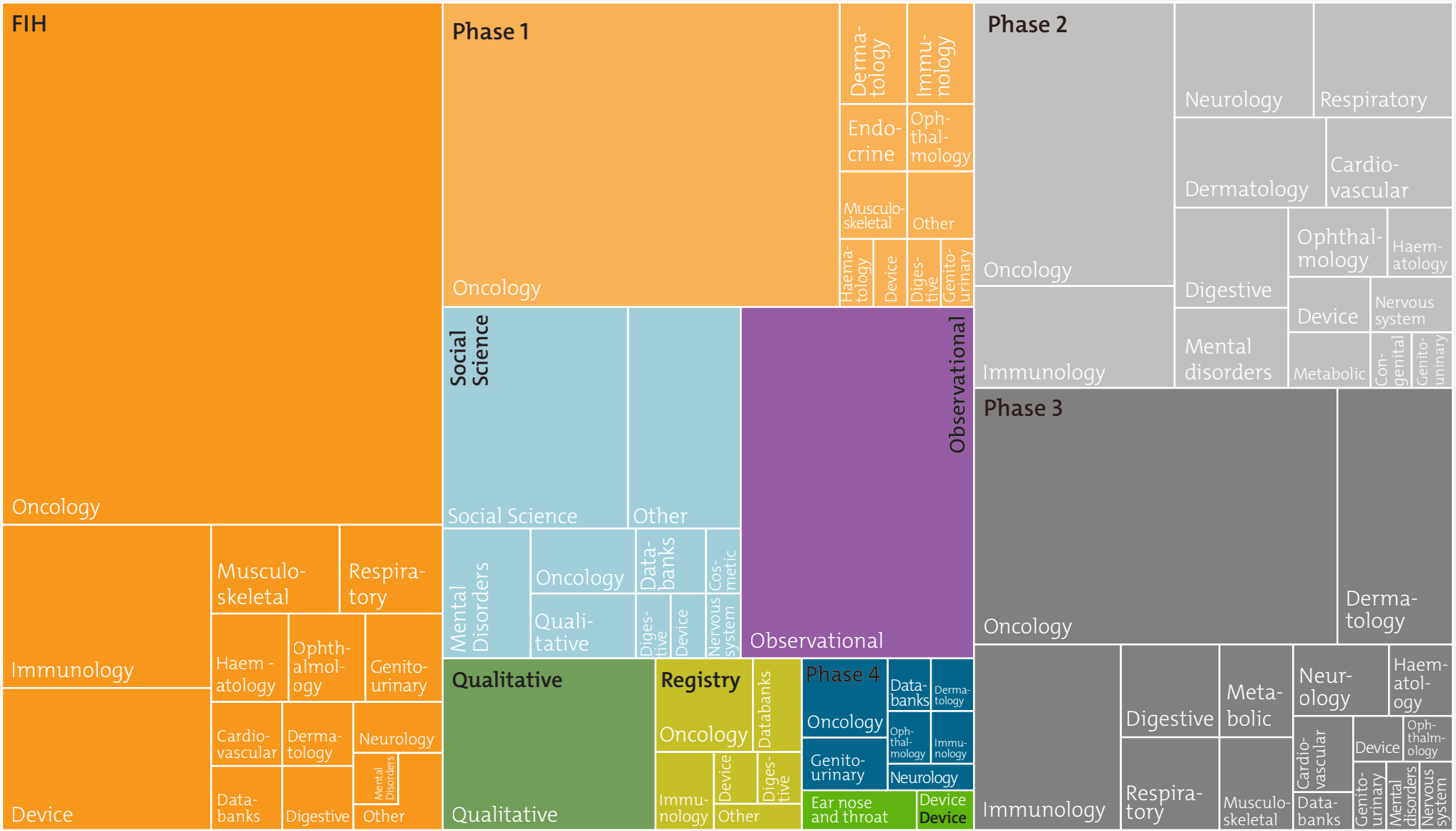
Bellberry applications reflect the continued strength of Australia in FIH and Phase 1 trials.

Additionally, the data demonstrates established capability across the development lifecycle at Phase 2, Phase 3 and beyond.

Australia is an experienced partner for global Phase 3 multi-centre research, with a notable increase in Social Science, Observational and Qualitative applications in 2022 compared to 2021.



Distribution by phases and therapeutic areas



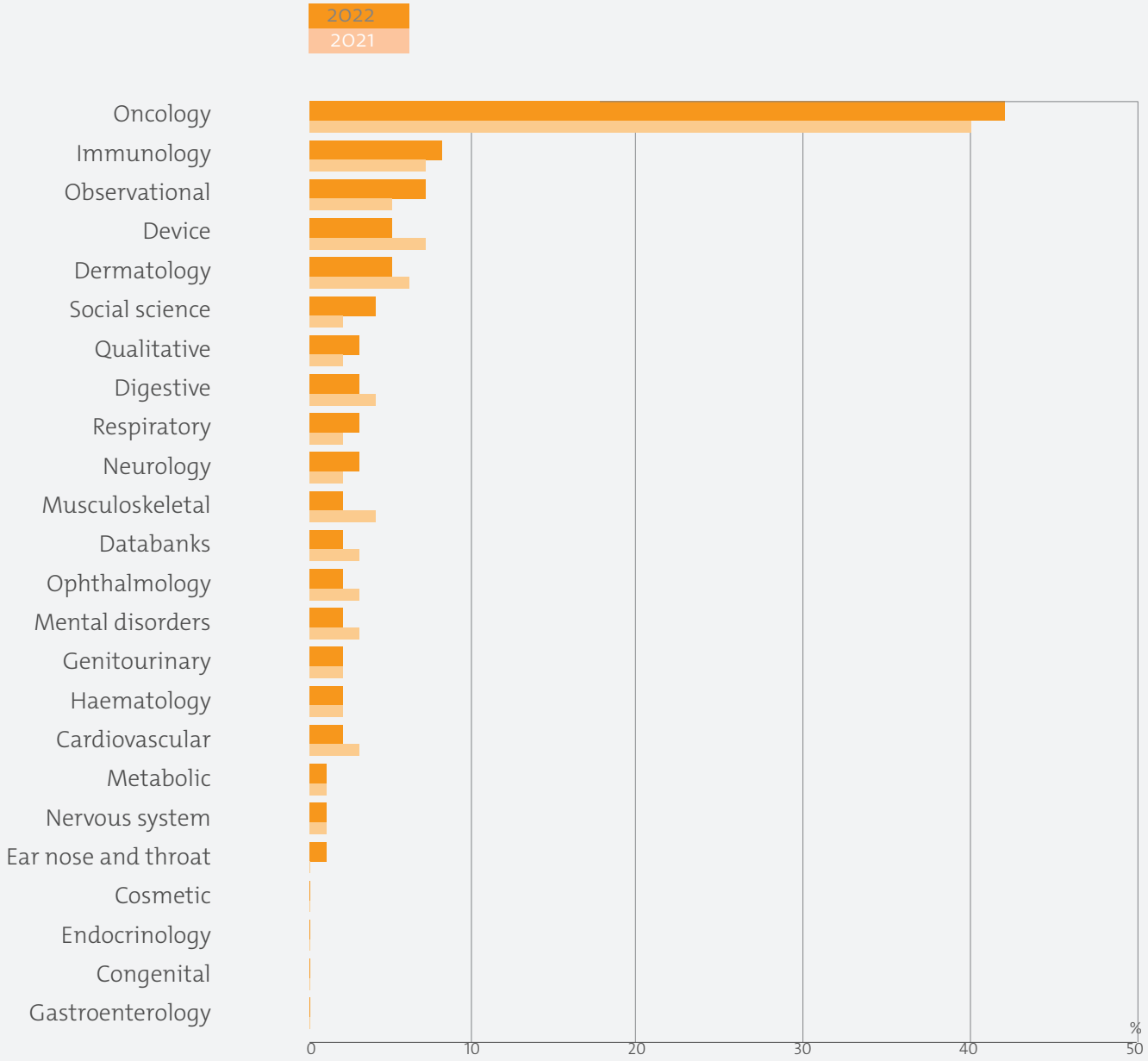
Distribution of trials by therapeutic areas

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

A long-standing trend, which continued in 2022, was oncology having the most substantial portion of trials overall.

A proportional increase in trials across a number of therapeutic areas was observed in 2022 compared to 2021, with the biggest lift occurring in Observational, Social Science, Qualitative and Ear, Nose and Throat studies.

Additionally, Cosmetic and Endocrinology research were two areas of research that began to emerge in this period.



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