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Bellberry Limited

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supporting research and ethics

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Clinical Trial Activity Report

JANUARY 2020-DECEMBER 2020

Foreword

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

Our aim is to promote and improve the welfare of research participants and the quality, efficiency and effectiveness of research.

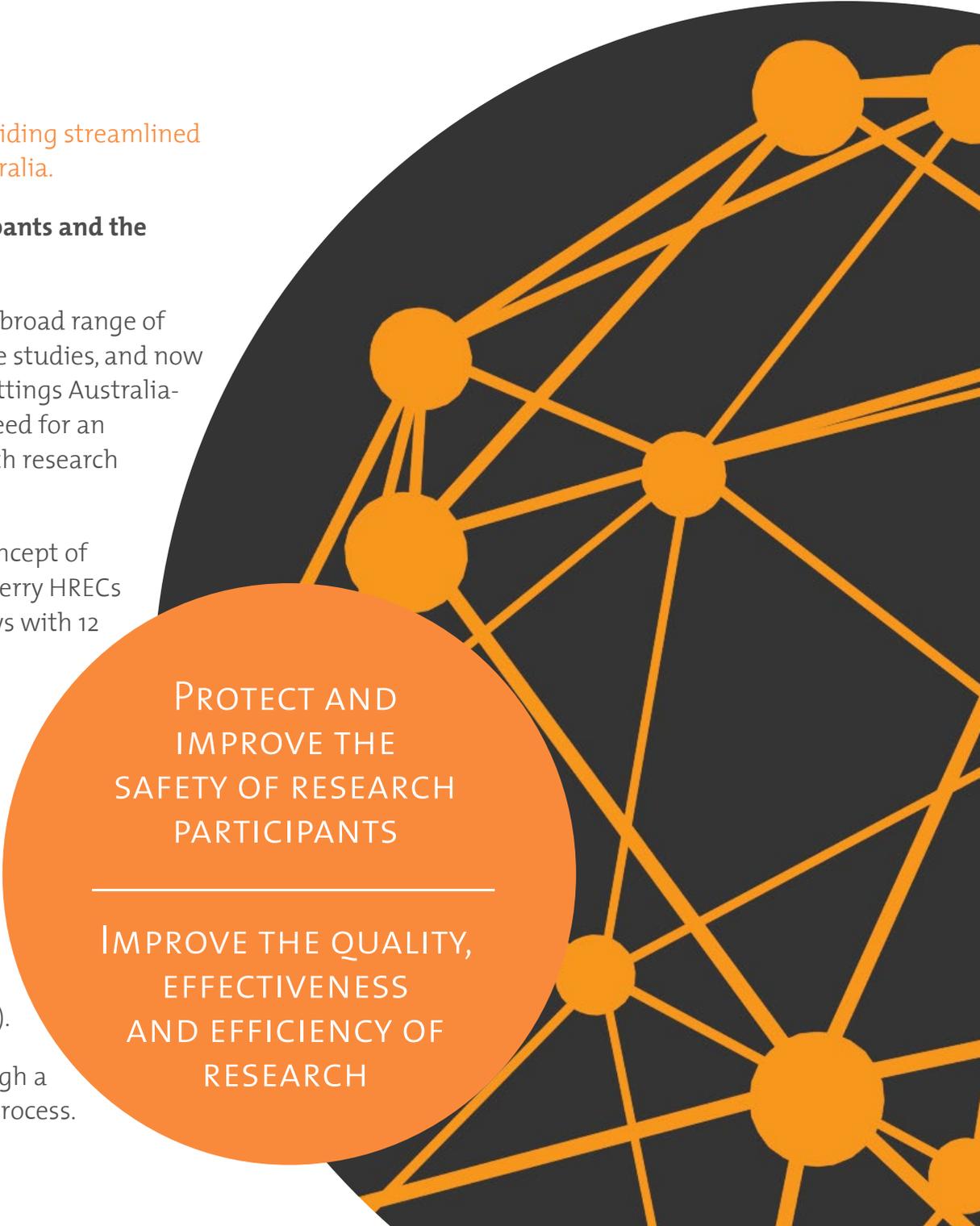
The **Bellberry Human Research Ethics Committees (HRECs)** review a broad range of research activity, from clinical trials to social and behavioural science studies, and now support researchers in private, public, academic and government settings Australia-wide. Bellberry was formed in 2004 following the recognition of a need for an independent HREC service to support the valuable human and health research being conducted within the private sector.

Bellberry started with one HREC offering a monthly meeting. The concept of the unaffiliated, non-institutional based HREC grew and today Bellberry HRECs are able to provide the same high quality, independent ethics reviews with 12 committees providing up to 3 meetings every week.

Bellberry reinvests proceeds in projects and initiatives that deliver on the objectives of the welfare of the participant and the quality, efficiency and effectiveness of research.

Bellberry HRECs comply with the strict guidelines for clinical trials as set by the NHMRC and ensure that *“all kinds of research involving or impacting on humans conform to the highest standards of ethical practice and academic integrity.”* Bellberry is also the first Australian organisation to achieve accreditation by the global Association for the Accreditation of Human Research Protection Programs (AAHRPP).

Bellberry HRECs are professionally managed and operate 24/7 through a dedicated electronic portal providing a paperless and secure HREC process.



PROTECT AND
IMPROVE THE
SAFETY OF RESEARCH
PARTICIPANTS

IMPROVE THE QUALITY,
EFFECTIVENESS
AND EFFICIENCY OF
RESEARCH

Data boundaries

Dataset:

- Research approved by Bellberry Human Research Ethics Committees (HRECs) (2020 calendar year).
- NSW Early Phase Clinical Trial Framework (EPCT) (2020 calendar year).

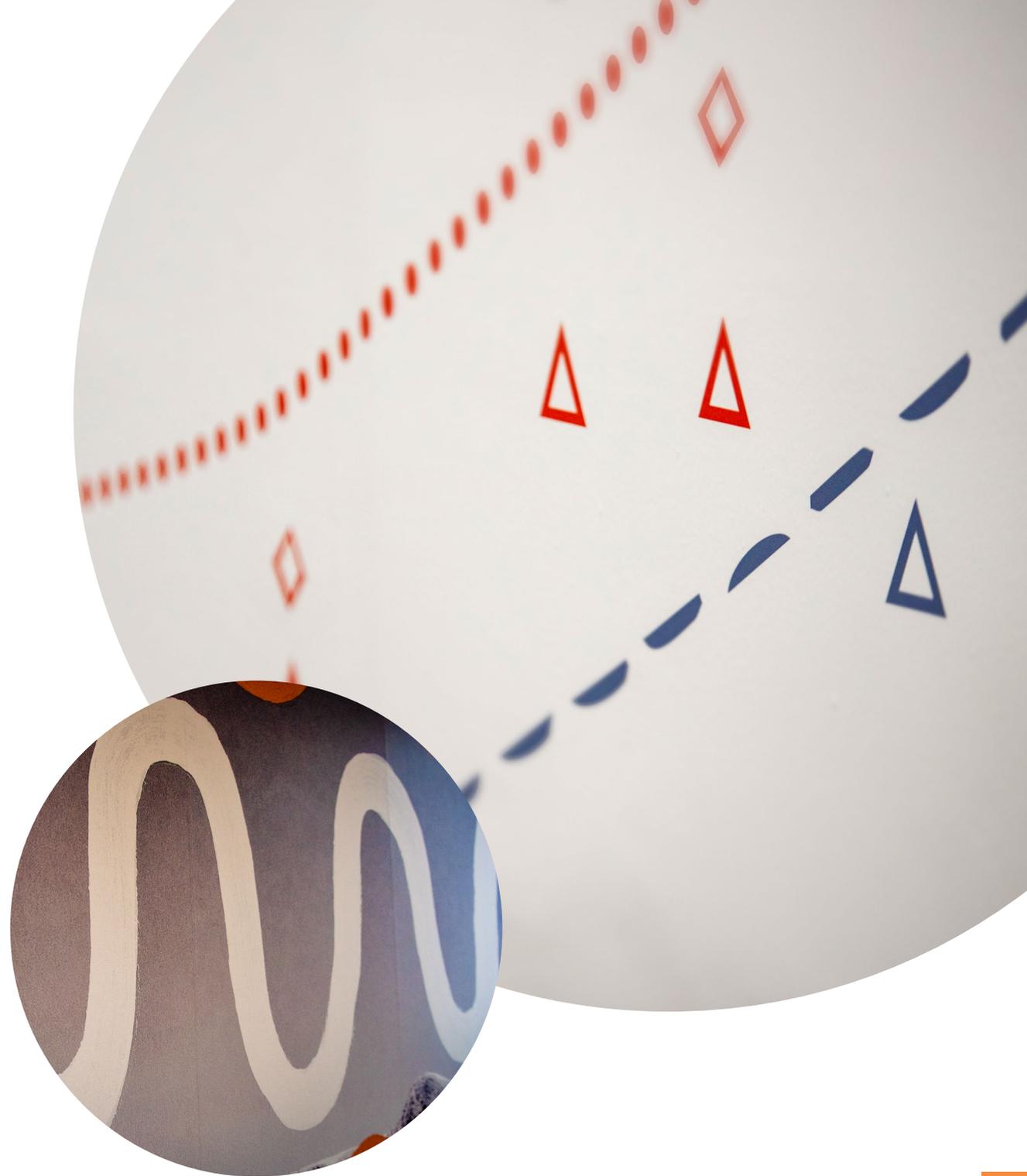
Includes clinical trials and other human research.

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

Diverse and broad user base, skewed towards the private sector:

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

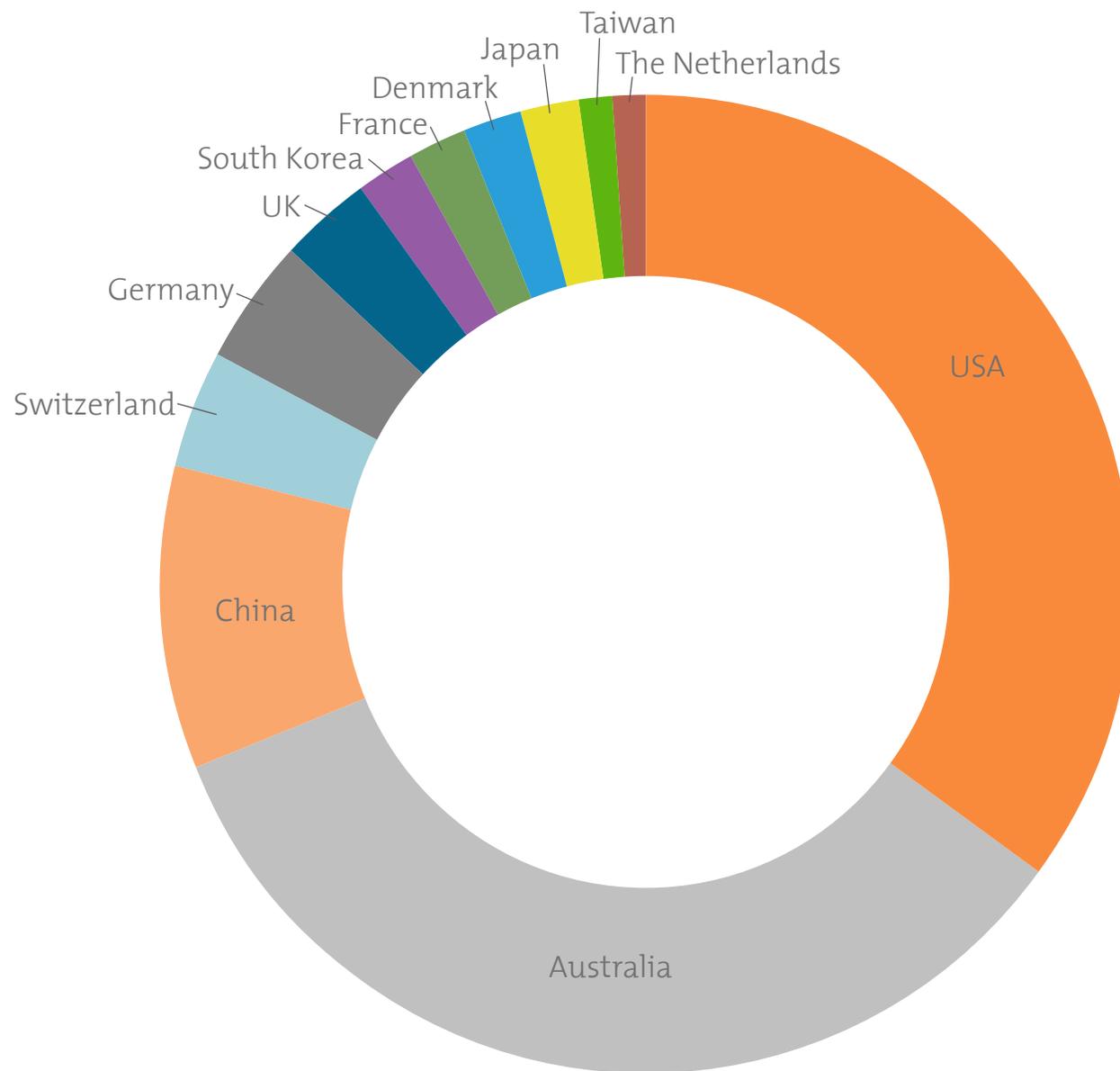
Public-based research includes studies from NSW (early phase) and SA Health.



International investment in all trials

Bellberry data have been interrogated to identify the root source of funding for trials. We found:

- 66 per cent of all trials reviewed by Bellberry Human Research Ethics Committee (HRECs) in 2020 were the result of inward investment attraction from international jurisdictions.
- 35 per cent of all trials were US-sponsored.
- The biggest movers from 2019 were Germany and France, which both increased from 2019 to 2020.
- USA, Australia, Switzerland and China were stable sources of funding, continuing at existing levels.

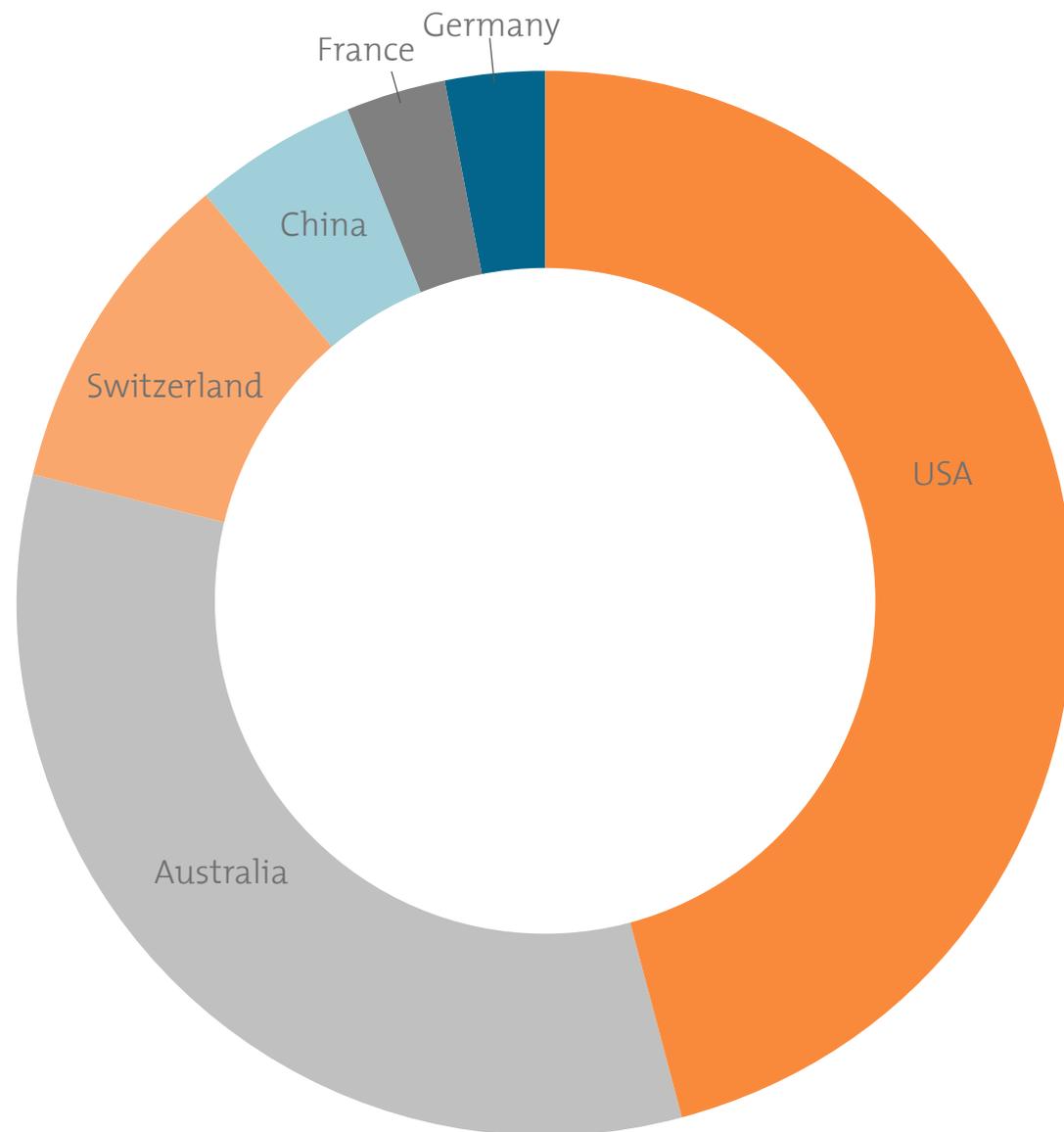


International investment in early phase trials

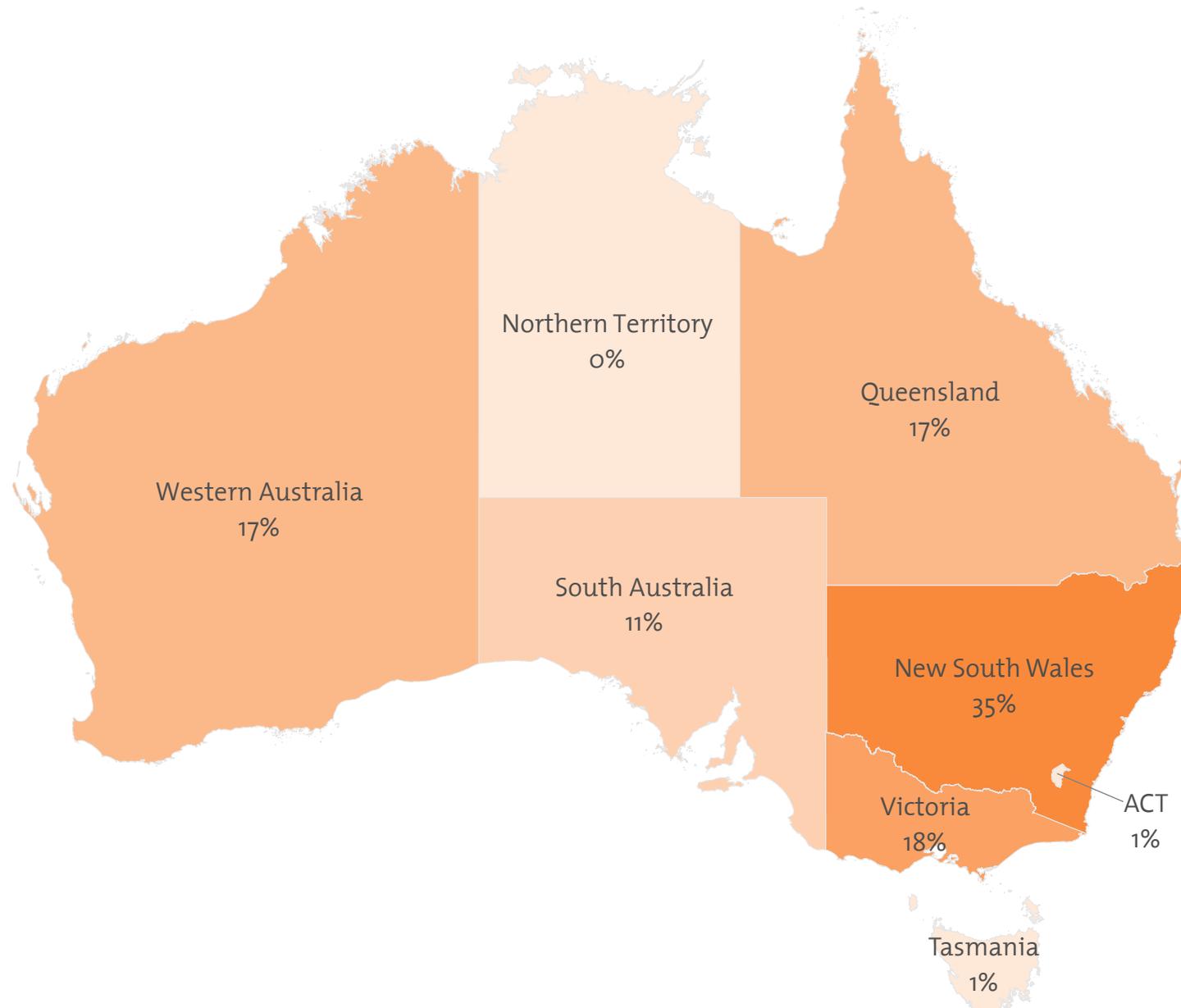
Bellberry data have been interrogated to identify the root source of funding for trials. Early phase trials are classed as those including a First in Human or Phase 1 component.

We found:

- 67 per cent of public early phase trials involve investment from non-Australian sponsors.
- 46 per cent of public early phase trials were US-sponsored.
- The biggest movers from 2019 were Germany and France, which both increased from 2019 to 2020.
- USA, Australia, Switzerland and China were stable sources of funding.

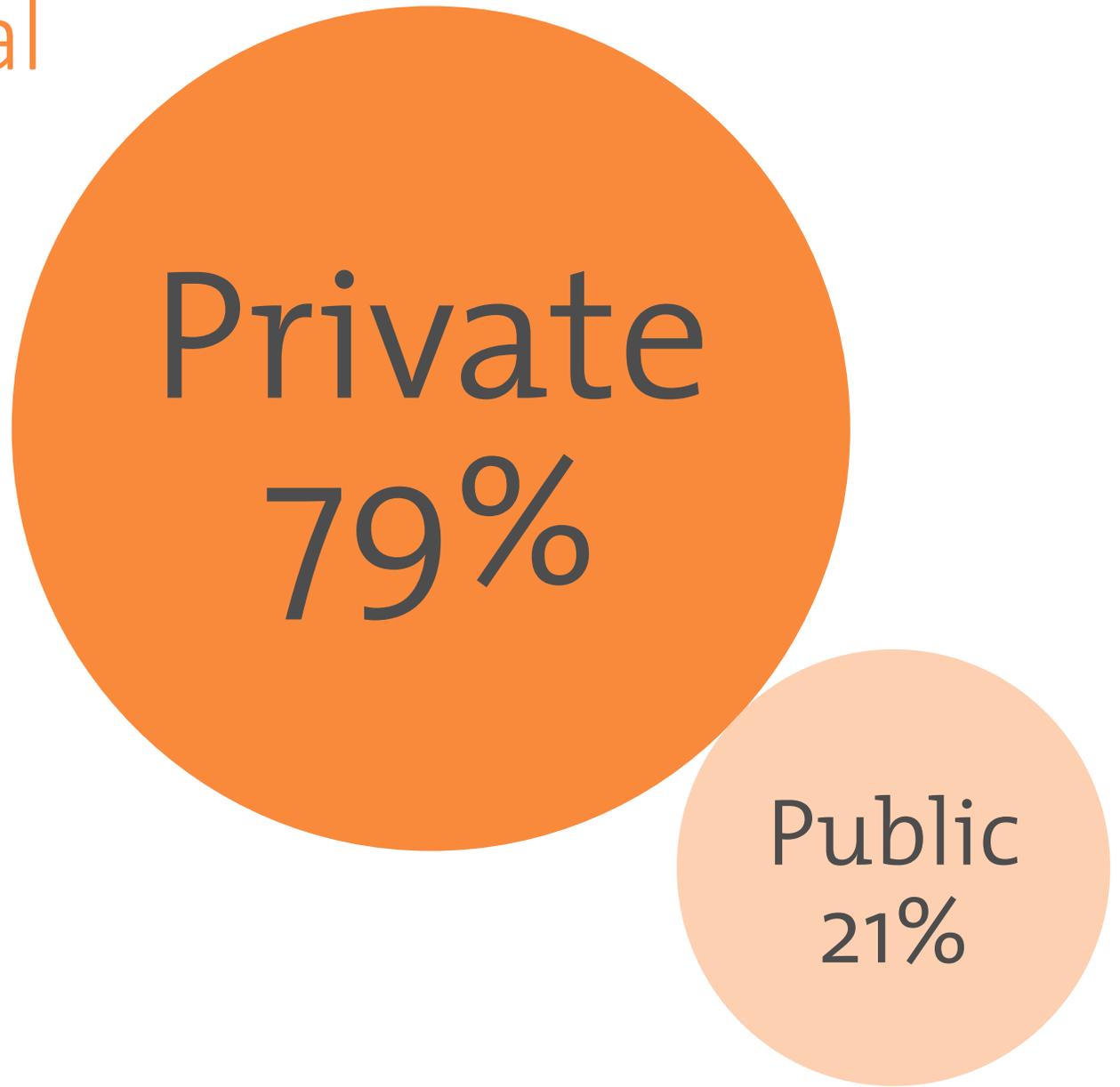


Distribution of trial sites by state



Distribution of trial sites by site type

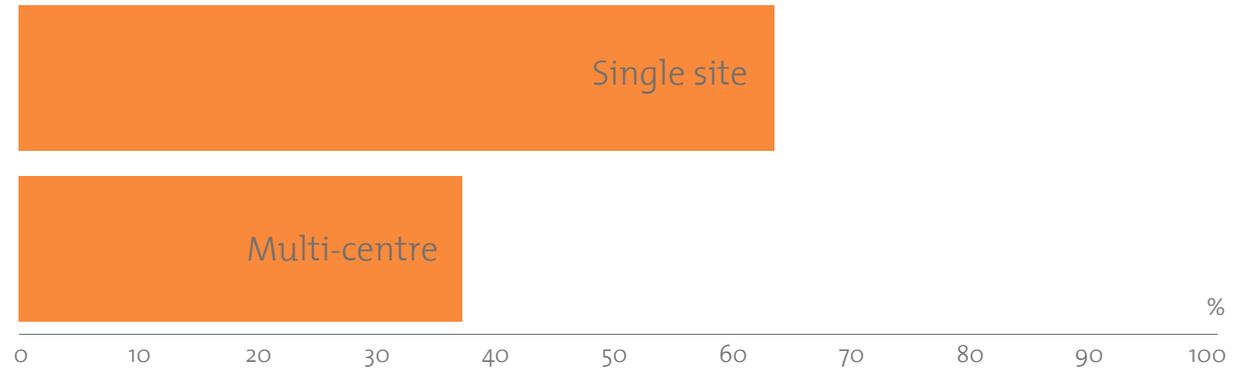
The majority of research reviewed by Bellberry HRECs is with private sites ranging from small clinics through to hospitals, and includes university research. Public is defined as research based at public health funded sites.



Multi-centre trials

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

About one-third of research reviewed by Bellberry is multi-centre, delivering a significant reduction in duplication in the research sector.

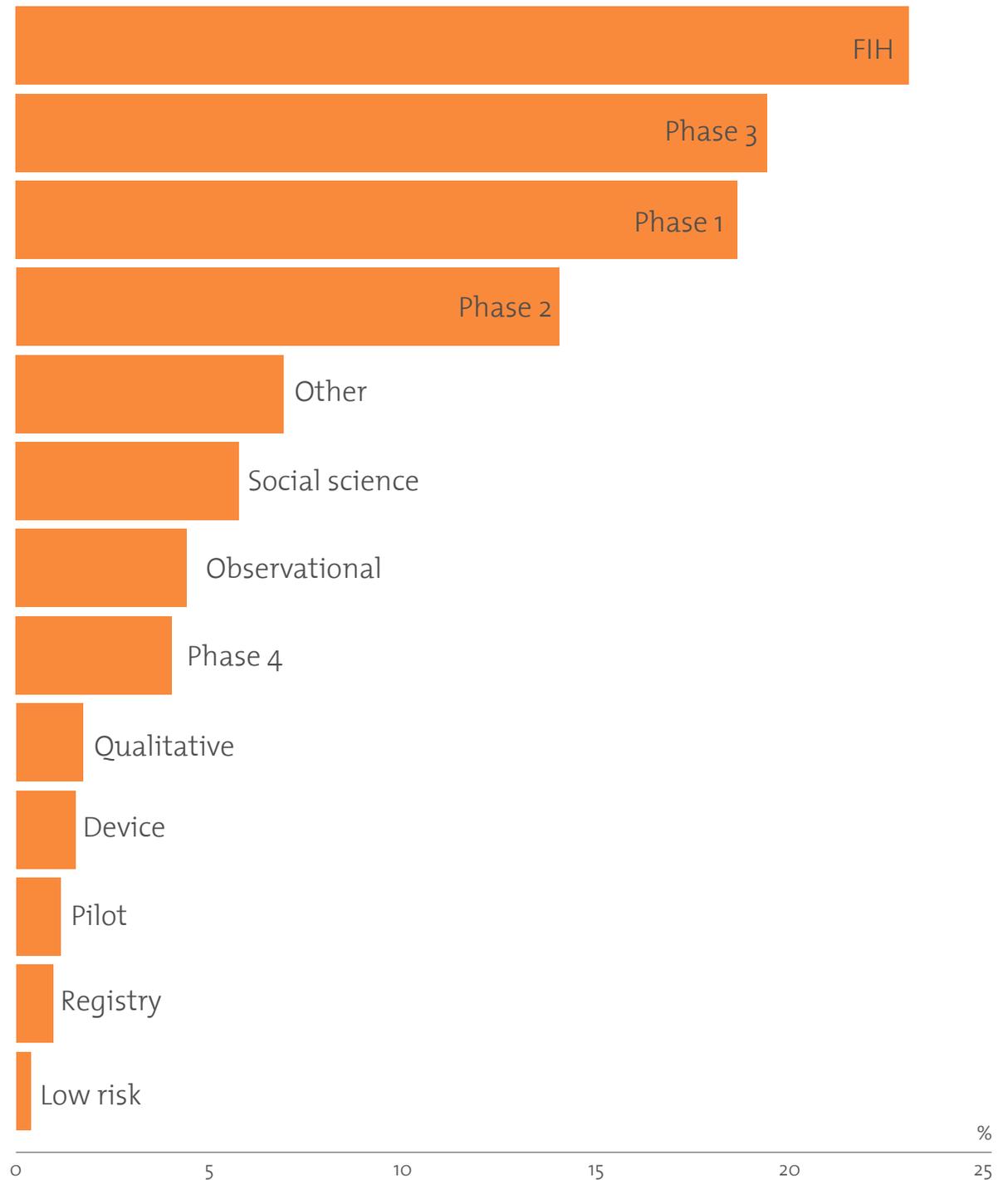


Distribution of trials by phases

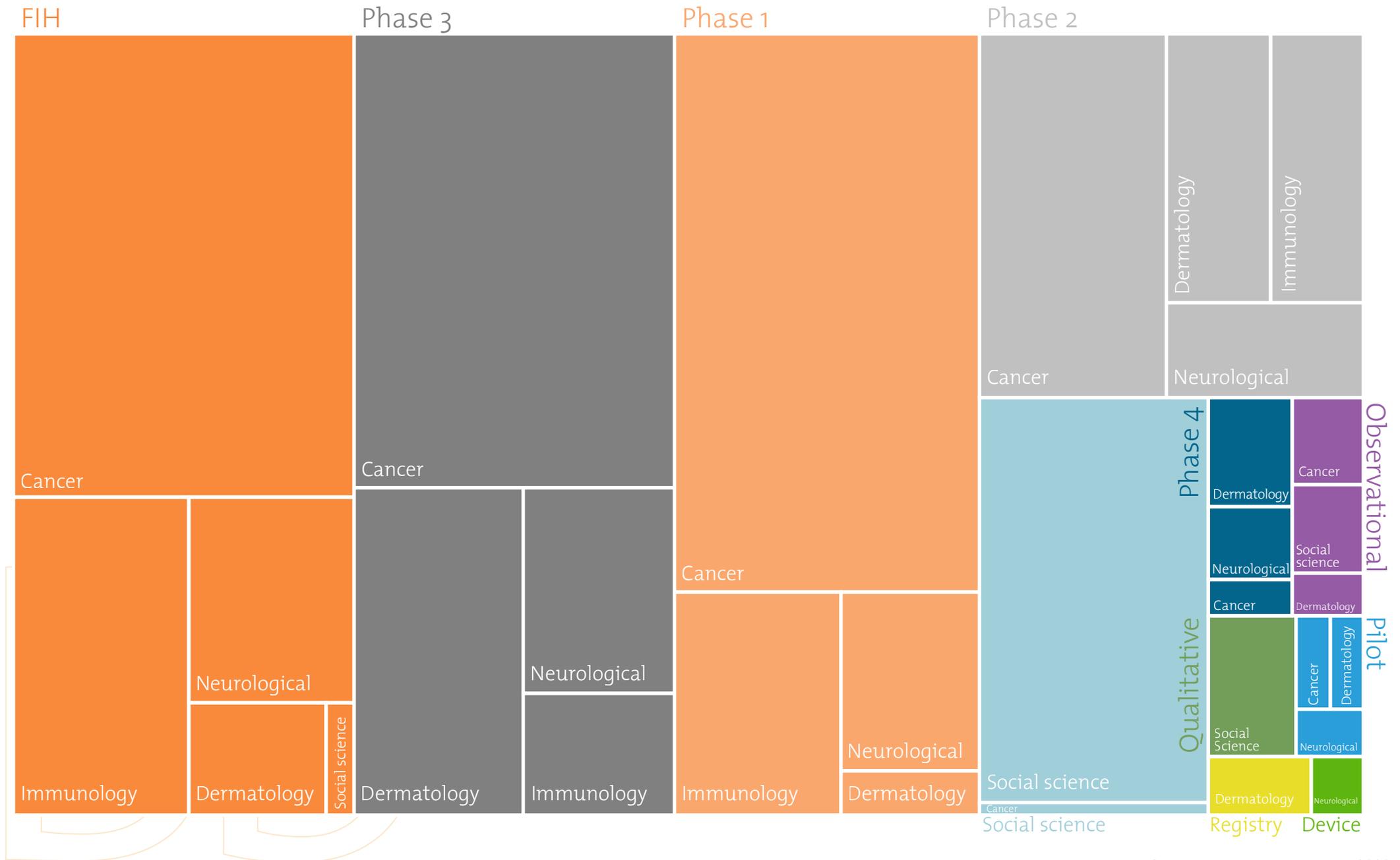
Bellberry data clearly confirms Australian strengths in First in Human (FIH) and Phase 1 trials.

Additionally, the data demonstrate established capability across the development life cycle at Phase 2, Phase 3 and beyond.

Australia is an experienced partner for global Phase 3 multi-centre research.



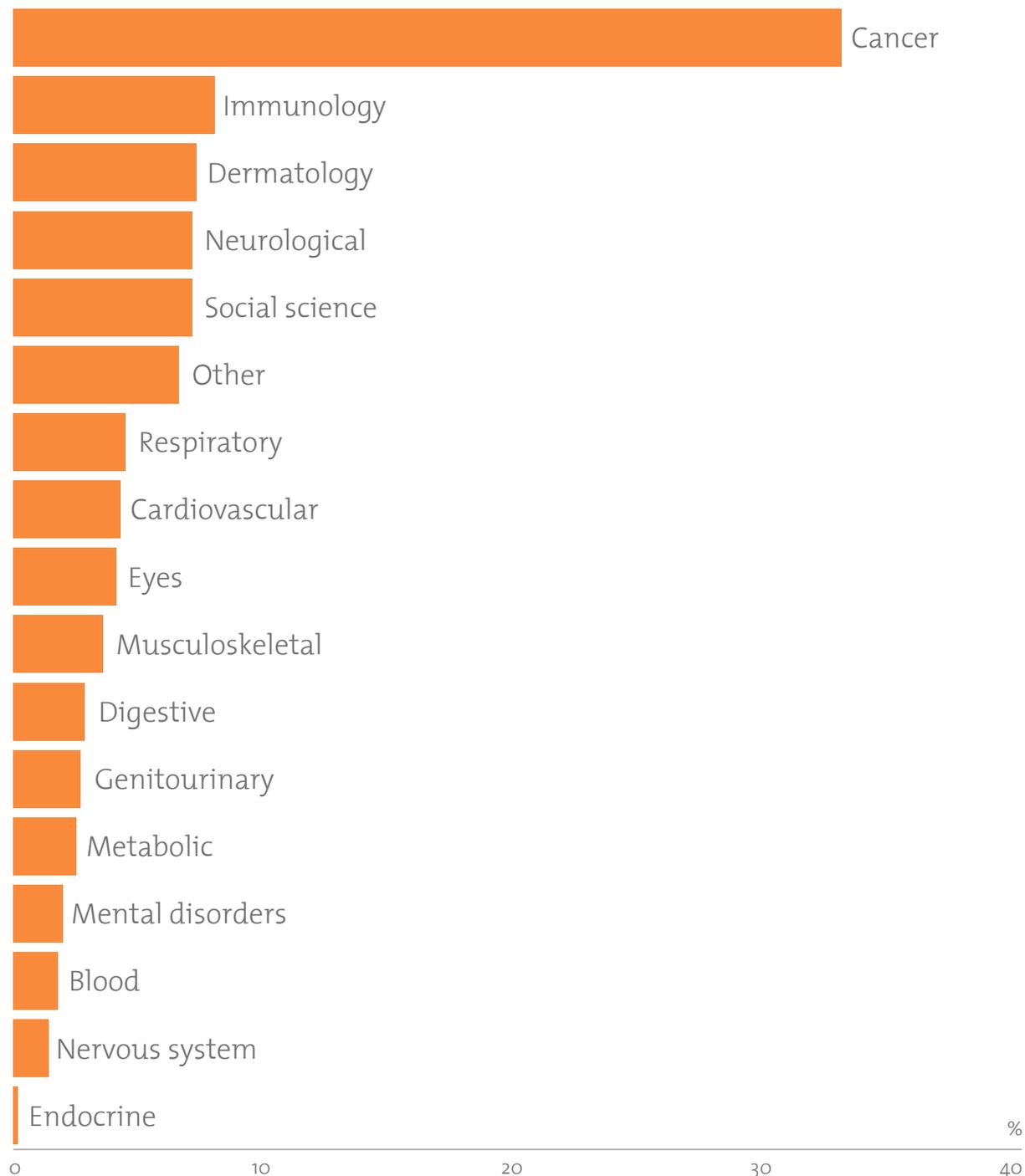
Distribution by phases and therapeutic areas



Distribution of trials by therapeutic areas

Australia has substantial strength in oncology research.

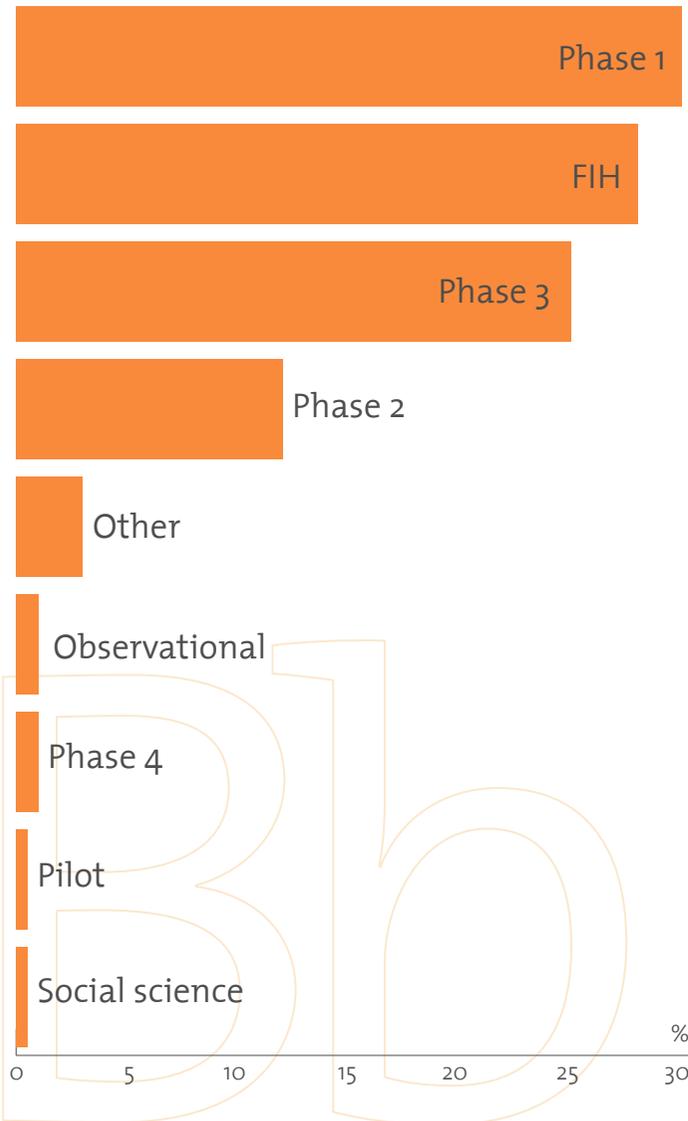
Australia has well-established capabilities in a broad range of therapeutic areas.



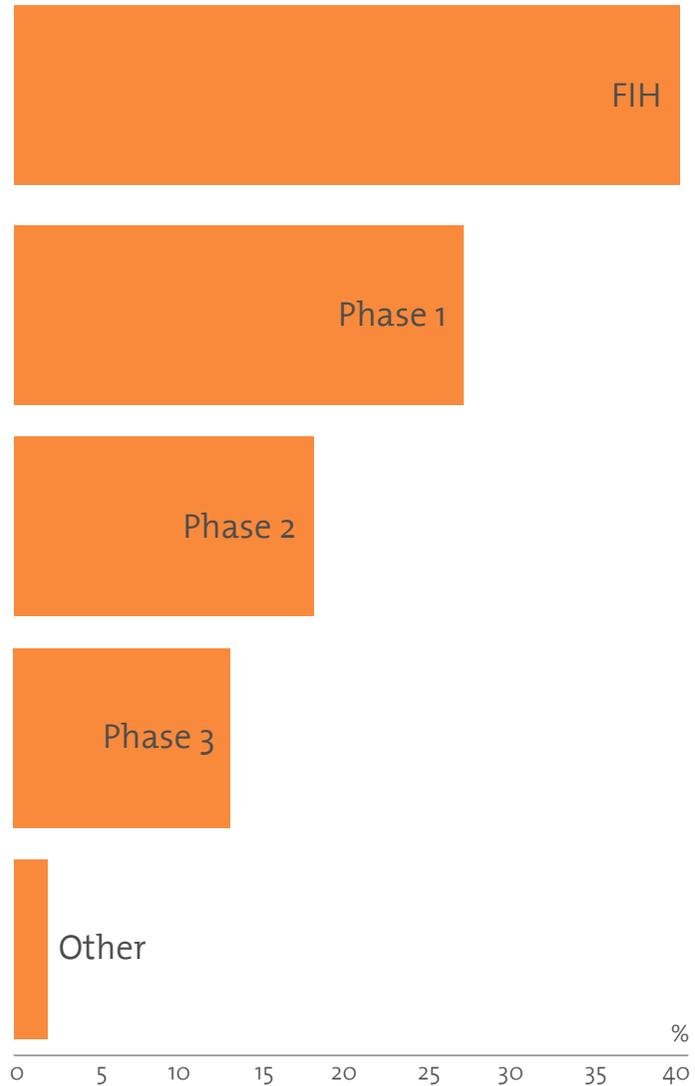
Top therapeutic areas by phases

The top 3 therapeutic areas reviewed by Bellberry HRECs in 2020 were cancer, immunology and dermatology.

Cancer by phases - 2020



Immunology by phases - 2020



Dermatology by phases - 2020

