Why Australia for your Clinical Development Strategy

Australia offers the essential elements for success to any Emerging Biopharma (EBP): Speed, financial benefits, globally accepted quality data

Speed

of delivery with **Simple regulatory framework**

Rapid start up and fast approvals.

- **CTN* scheme** (No IND* Application Required)
- Ethics submission/ approval 4-6 weeks for healthy volunteer studies
- Required documents only: IB*/Protocol/PICF*

Cost saving Significantly cheaper than conducting Phase I in US

- **R&D tax incentive** from the AUS government (43.5% Tax refund)
- Favorable AUD exchange rate
- Save up to 60% compared to US/EU Phase I study

Quality

Globally accepted quality data in Australia can be used to support international regulatory applications, including the US FDA* and the EMA*

Local excellence, global thinking

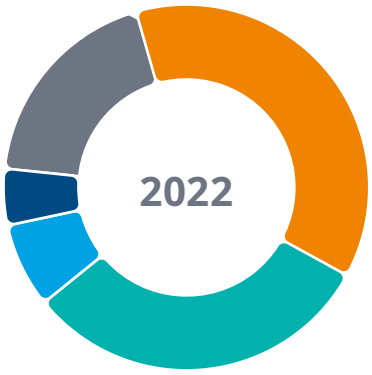
World leading investigator & KOLs*

* CTN: Clinical Trial Notification, IND: Investigational New Drug, IB: Investigator Brochure, PICF: Participant Information and Consent Form, FDA: Food and Drug Administration, EMA: European Medicines Agency, KOL: Key Opinion Leader

Australia is a leading global destination for early phase trials

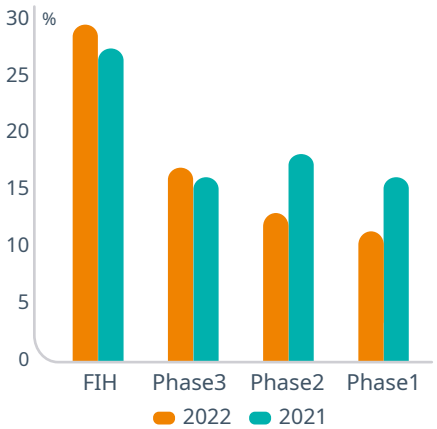
International investment in early phase trials

One-thirds of public early phase trials involved investment from **sponsors in Australia.**



Distribution of trials by phases

Data showed continued strength of Australia in **FIH* and Phase I trials.**



Source: Bellbery Clinical Trial Report 2022 Dataset; Research approved by Bellberry HRECs (2022 calendar year) and NSW Early Phase Clinical Trial (EPCT) Framework (2022 calendar year).

* FIH: First In Human

Growing trend for POC

There is a growing trend towards sponsors adding POC* cohorts.
Data from these POC studies can help inform go/no-go decision, helping EBPs avoid spending time and money on targets/molecules unlikely to succeed. This is a practice that Australia sites are familiar with and do very well.

* POC: Proof Of Concept

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