

# The value of clinical trials

## BACKGROUND

### In 2019:

- The clinical trials sector employed 8,000 Australians
- More than 95,000 Australians participated in clinical trials
- Approximately 1,880 trials started
- 1.4 billion invested in clinical trials in Australia, with industry investment accounting for approximately 79% of this expenditure

(Source MTPConnect, Australia's Clinical Trials Sector, May 2021)

### Clinical trials play an important role in improving Australia's healthcare system because they:

- Lead to the development of **new and innovative treatments**
- Allow patients **early access** to potential life-saving medicines at no cost
- Help retain **specialised and highly trained researchers** in the country
- **Provide experience** with **novel and emerging therapies** for Australian clinicians
- Links Australia to **international scientific developments and the latest thinking**
- **Create employment** for research organisations, universities and hospitals

### Key challenges for clinical trials:

Clinical trial infrastructure and responsibility are shared across state, territory and federal levels. This makes it difficult to get new trials approved quickly.

Difficulties recruiting enough appropriate patients, due to lack of patient and clinician awareness about availability of trials and strict regulations on promoting clinical trial information.

Inconsistent and fragmented federal, state, institution environment for trials in Australia can act as a barrier to trial sponsors looking for efficient, timely and cost-effective locations.

Australia is less competitive than emerging and established markets on clinical trial measures of timely and efficient trial start-up, cost and the capacity to recruit trial participants.

## SOLUTION

**The Commonwealth Government has committed to a National One Stop Shop and National Clinical Trials Front Door. These separate but connected initiatives should deliver:**

- a single place where clinical trials will be submitted for review by a single ethics committee, thereby alleviating the inefficiency created by having multiple, jurisdictional-based systems;
- a single place where research governance applications are submitted using a standardised, single form (Site Specific Authorisation);
- administration of the CTN (and CTA) and the ability to submit to the TGA via the same single portal;
- the ANZCTR, or next generation clinical trials registry, will be embedded;
- ability to generate metrics and reports, in real-time, that describe the delivery of clinical trials across the country, accessible to researchers and sponsors; and
- support the accreditation of the National Clinical Trials Governance Framework.

## WHAT INDUSTRY NEEDS

**Full and speedy support for this initiative by all state and territory governments to protect existing, and maximise potential, investment in our clinical trials sector.**

The primary objectives of the One Stop Shop and Front Door should be to ensure the Australian clinical research environment is efficient, cost-effective and operates to world's best practice now and in the long-term. To achieve this, the following principles should be implemented:

1. **Efficient start up:** Clinical trials must be able to commence quickly and efficiently across many clinical trial centres around Australia.
2. **Capacity:** Australia needs to be able to connect participants with appropriate clinical trials in an efficient and timely manner.
3. **Competitiveness:** Australia must compete internationally with other countries on a cost basis.
4. **Continuous review:** To remain competitive over time, the One-Stop Shop and the Front Door will need to be continually reviewed against the needs of the clinical trials sector and the changing international environment.