



ARCS Australia

Pre-Budget Submission 2026–27

Building a Globally Competitive Clinical Trials System: Infrastructure and Workforce Must Advance Together

About ARCS Australia

ARCS Australia LTD is the national peak body representing life sciences professionals who are advancing innovation in healthcare. Our members are leaders in shaping the future of medical technology, pharmaceuticals, and healthcare delivery. ARCS represents professionals across industry, clinical research, academia and government, and plays a national leadership role in education, competency development and professional standards for Australia's clinical research workforce.

Executive Summary

Australia has made important progress in strengthening its clinical trials environment, including investment in the **National One Stop Shop (NOSS)** and initiatives to attract international clinical trials. These reforms are necessary and welcome. However, they will not deliver their intended economic, health and productivity benefits unless matched by deliberate and sustained investment in the **clinical trials workforce**.

This submission advances two inseparable priorities:

1. **Sustained funding and delivery of the National One Stop Shop (NOSS)** to ensure it moves from policy intent to fully implemented, nationally adopted digital infrastructure.
2. **Targeted investment in clinical trials workforce capability and capacity**, to deliver the people, skills and professional structures required to operationalise NOSS and absorb increased clinical trial activity.

Government investment in platforms, regulatory reform and international promotion will not succeed if Australia lacks a skilled, stable and scalable workforce to deliver trials. Infrastructure without workforce capability risks becoming an under-utilised asset.

Pillar 1: National One Stop Shop (NOSS) – From Reform to Realisation

The National One Stop Shop is a once-in-a-generation reform designed to address long-standing fragmentation in Australia's clinical trials approval and governance landscape. The intent of NOSS is to streamline approvals, reduce duplication, improve transparency and increase Australia's attractiveness as a global clinical trials destination.

Initial Commonwealth investment has enabled early design, stakeholder engagement and testing. However, the complexity of aligning Commonwealth, state and territory systems means that sustained funding and policy commitment are essential if NOSS is to move from concept to full implementation.

Without ongoing investment:

- Momentum risks stalling before full delivery.
- Jurisdictions may revert to divergent or non-interoperable systems.
- Industry confidence in Australia's reform agenda may weaken.
- Patients may experience delayed or reduced access to clinical trials.

International experience demonstrates that digital and regulatory reform must be backed by long-term commitment. Jurisdictions that have successfully improved clinical trial performance have paired platform development with sustained funding, national coordination and workforce investment.

ARCS strongly supports continued Commonwealth funding for NOSS in the 2026–27 Federal Budget to ensure the platform is fully built, implemented, maintained and continuously improved as national clinical research infrastructure.

Pillar 2: Workforce Capability – The Critical Enabler of Clinical Trials Reform

While regulatory and digital reforms are essential, clinical trials are ultimately delivered by people. Australia is currently facing a clinical trials workforce capacity challenge that threatens to undermine the return on investment in NOSS and international clinical trials attraction initiatives.

ARCS' *Strengthening Australia's Clinical Trials Workforce* White Paper, informed by the National Clinical Research Workforce Capacity Summit, identifies systemic challenges including:

- Persistent workforce shortages and high turnover
- Lack of clear career pathways and professional recognition
- Absence of nationally consistent entry standards and accreditation
- Fragmented education and training pathways
- Over-reliance on informal, on-the-job training and goodwill

These challenges are now directly affecting Australia's competitiveness. Sponsors increasingly cite workforce capacity as a constraint on trial placement. Clinical trial sites report difficulty activating and delivering trials despite strong investigator interest. Graduates enter the sector ill-prepared and exit prematurely due to limited progression and burnout.

Why Workforce Investment Is Essential to NOSS Success

The National One Stop Shop is designed to improve speed, coordination and productivity. However, these gains cannot be realised without a workforce capable of operating at scale and pace.

Without workforce investment:

- Faster approvals risk shifting bottlenecks downstream to sites.
- Increased international interest cannot be converted into delivered trials.
- Regional and public health sites struggle to participate, undermining equity objectives.
- Australia risks reputational damage if trials are approved but not delivered efficiently.

There is little value in Government expenditure on NOSS and international clinical trials attraction if Australia does not have a workforce with the capability and capacity to deliver the resulting trials.

Workforce capability must therefore be treated as core national research infrastructure, not an adjunct to regulatory reform.

What Is Needed: A National Clinical Trials Workforce Capability Program

ARCS calls for Commonwealth investment to support implementation of the recommendations in its Clinical Trials Workforce White Paper, including:

1. Nationally Recognised Competency and Accreditation Pathways

Support the establishment and scaling of competency-based accreditation for clinical trials professionals, building on existing frameworks already adopted across the sector. This will improve workforce quality, retention and professional identity.

2. Coordinated Education and Entry Pathways

Investment in aligned undergraduate exposure, postgraduate education and professional training to create a predictable pipeline of job-ready entrants into clinical research roles.

3. Structured Graduate and Internship Programs

Co-funded national graduate and internship programs to support transition from study to employment, particularly in public and regional trial sites.

4. Workforce Sustainability and Retention Measures

Funding mechanisms that enable protected development time, mentoring and ongoing professional development to reduce burnout and turnover.

5. Integration with NOSS and Research Funding

Workforce development should be embedded as a core component of NOSS implementation and Commonwealth-funded clinical trial activity, ensuring infrastructure and capability advance together.

Recommendations

ARCS Australia recommends that the 2026–27 Federal Budget:

1. **Provide ongoing and sustainable funding for the National One Stop Shop (NOSS)** to ensure full implementation, national adoption and long-term operation.
2. **Allocate dedicated funding to implement a National Clinical Trials Workforce Capability Program**, aligned to the ARCS Workforce White Paper.
3. **Embed workforce development as a core requirement within NOSS and Commonwealth-funded clinical trial initiatives**, recognising workforce capability as essential national infrastructure.
4. **Partner with ARCS to deliver nationally consistent workforce solutions**, leveraging ARCS' established role in education, competency frameworks and professional standards.

Australia has a genuine opportunity to strengthen its position as a preferred destination for clinical trials. The National One Stop Shop is a critical enabler of that ambition. But platforms and policy alone will not deliver success.

A skilled, recognised and sustainable clinical trials workforce is the foundation on which all reform depends. Investment in workforce capability is not optional or secondary; it is essential to realising the full economic, health and innovation returns from Government investment in clinical trials.

ARCS Australia stands ready to work with Government to deliver this agenda.

Yours Sincerely,



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References

Strengthening Australia's Clinical Trials Workforce: ARCS Clinical Research Workforce Capacity Summit Insights and Strategic Blueprint. ARCS Australia Ltd. (<https://www.arcs.com.au/news-item/21396/strengthening-australias-clinical-trials-workforce-white-paper>)

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