

B Block, Hospital Ave
Perth, WA 6009

+61 (0) 8 6382 5100

enquiries@linear.org.au

www.linear.org.au

Linear Clinical Research Limited
ABN 43 142 055 749

26 June 2024

Mr Christopher Tallentire, MLA

Chair
Education and Health Standing Committee
Parliament House
4 Harvest Terrace
West Perth WA 6005
Email: thornlie@mp.wa.gov.au

Dear Mr Tallentire,

Thank you for the invitation to contribute to the parliamentary inquiry into health and medical research whereby you requested the following:

We invite you to make a written submission on behalf of Linear Clinical Research, addressing any or all terms of reference. Although not specified, term of reference 3 includes support for more clinical trials in WA as an area of Committee interest.

As Western Australia's main provider of clinical trial services, I am concerned that the level of funding from the State Government to support clinical trial infrastructure in WA is severely lagging that of other states. This is compromising the volume of clinical trials in WA and putting the WA community at a major disadvantage at a time when other states are investing heavily in this priority sector for the benefit of their patients, healthcare system and economies.

To outline the basis of my concern, I will highlight the following:

- 1. Linear's recent difficulty securing funding support that is commensurate with the activity and value that it provides for the state of WA**
- 2. The data that demonstrates investment by the WA State Government is severely lagging other states of Australia**
- 3. The lack of funding is inconsistent with the intent of numerous State Government strategic plans and initiatives**
- 4. Suggested actions the State Government can take to ensure adequate funding to support more clinical trials in WA**

This lack of investment is also inhibiting WA's capacity to secure national competitive funding (item 1 of the inquiry's brief), given state of the art clinical trial infrastructure will be a key driver of attracting greater national funding, which I will also refer to later in this submission.

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1. Linear's recent difficulty securing funding support that is commensurate with the activity and value that it provides for the state of WA

Linear is a not-for-profit contract research organisation and a wholly owned subsidiary of the Harry Perkins Institute of Medical Research. Linear was established in 2010 through a partnership with the State Government at the time which provided a \$9.5m grant to fit out and operationalise a dedicated, 24 bed, early phase clinical trial facility in the QEII Medical Centre. This was a direct response to **the absence of early phase clinical trial capacity within WA's public healthcare system**. Prior to the establishment of Linear, patients from WA had to fly to Melbourne or Sydney to access clinical trials. For many, this was not affordable or possible and patients suffered worse outcomes as a result.

Linear has grown to become internationally recognised for its early phase trial capabilities and a preferred partner for many of the world's leading biopharmaceutical companies. It has delivered over 400 clinical trials which has enabled thousands of people from WA to participate in medical research. This includes one of Australia's most active cancer trial groups **providing patients with advanced cancer access to the latest medical breakthroughs**. Linear has won state and national export awards and was listed in the AFR's most innovative companies list in 2020. It employs over 200 staff including doctors, nurses, trial coordinators and corporate staff. Linear is governed by a highly respected board of directors.

Linear self-funds operations by charging a fee for service model with its clinical trial customers (typically biopharmaceutical companies from the US, Europe and China). This model has created unique and substantial value for WA due to Linear's role as the key provider of early phase cancer trials for the State. This contrasts with every other state, where early phase cancer clinical trials are primarily **provided and funded by their respective State Government health departments** (refer to page 7 – supplementary information, for a list of the main early phase cancer trial providers in Australia). In WA, Linear not only funds this service, but it also carries the operational and financial risk of doing so, without any compensation from WA Health.

From the original investment of \$9.5m, Linear has generated extensive economic benefits for WA, with Deloitte indicating that the value add to the WA economy in 2019 alone was in excess of \$22 million. This would suggest **a cumulative return to WA from Linear's activities of well in excess of \$200 million**.

A report by Paxon Consulting in 2018 indicated that a proposed expansion of Linear services **could save the system in excess of \$400 million over a 20 year period** as costs are moved out of the public system. Whilst this analysis was conducted several years ago, the economic benefits today would be comparable, if not greater, due to the increasing cost of delivering healthcare and improving outcomes for patients on clinical trials which extends life and economic activity at an individual level.

The health impacts from Linear trials are even more profound. Patients with advanced cancers are observing response rates in over 50% of cases, including cases of complete response –

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equivalent to no detectable cancer. Linear's Haematology trial outcomes **rival that of the world's leading cancer hospital, MD Anderson Cancer Centre in the US** (refer to attached letter). Linear is also delivering world class outcomes in cardiometabolic disease and was one of the most active sites globally for COVID-19 vaccines and trials, contributing to an approved vaccine, antiviral and antibody treatment.

Despite the extensive economic and healthcare outcomes generated by Linear's activities, Linear has had difficulty securing ongoing funding support from the State Government outside of modest support for Linear's Joondalup site commissioned in 2022 (\$2.2 million from the Future Health Research and Innovation Fund) and Linear's Advanced Clinical Trials Centre commissioned in 2024 (\$3 million from WA Health). Collectively, these two sites have cost close to \$20 million.

While the funding support from the Future Health Research and Innovation Fund and WA Health was gratefully received, it was not commensurate with the healthcare activity and economic savings Linear provides for the State, nor the investment being made for comparable facilities by other State Governments (highlighted further below). This has resulted in Linear relying on philanthropic funding and commercial bank debt to complete much needed infrastructure expansion.

Earlier this year, Linear was unsuccessful in securing further modest funding support from WA Health of \$1.5 million despite having secured a matched funding commitment of \$1.5 million from the McCusker Charitable Foundation. This matched funding could not be accessed as the funding from WA Health was not secured.

This funding would have enabled Linear to significantly ramp up services, with the subsequent economic impact likely to see a payback period of less than 12 months. As an example of the demand for clinical trials that this expansion could have accommodated, I have attached a letter of support from IQVIA, the world's largest contract research organisation. This highlights **how Linear's infrastructure expansion will help attract more clinical trials to Australia and further differentiate Linear as one of the leading Asia-Pacific providers of clinical trials.**

The lack of funding support has resulted in Linear having to critically review its current portfolio of trial services and is likely to see reduced activity levels in the short term. In future years, Linear will need to consider the feasibility of supporting the frequent requests from local clinicians, companies and institutes who are reliant on Linear given its position as the sole provider for WA. A recent report from the federally funded industry body MTP Connect demonstrated WA's share of clinical trials (17%) already sits below that of NSW (31%), Victoria (30%), Queensland (22%) and South Australia (22%).

If Linear's contribution to the WA share were to be removed, **WA's contribution would be close to that of the ACT, Tasmania and the Northern Territory.** Given the current funding situation in WA and the strong support for clinical trials in other states, the WA share is likely to decline with reduced benefits for patients, the WA healthcare system and the WA economy.

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2. The data that demonstrates investment by the WA State Government is severely lagging other states of Australia

Linear's challenges accessing funding are clearly apparent when considering the investment by other State Governments in clinical trial infrastructure relative to WA.

Linear has received a total of \$14.7 million in State Government funding since 2010, with just \$5.2 million since 2020. This contrasts with the following investments by other Australian Governments in infrastructure and facilities:

- **The Victorian State Government has committed >\$100 million** into clinical trial infrastructure since 2020, including funding for 2 new clinical trial facilities that have opened in the last 12 months alone:
 - \$10 million for Cerulea Clinical Trials
 - \$2.5 million for Doherty Clinical Trials
- **The NSW Government has invested >\$40 million** in clinical trial facilities since 2014. This includes the recent opening of Precision Care Clinics, which offers molecularly targeted trials for cancer patients. Linear provides a similar service in WA.
- **The Queensland Government has recently provided >\$11 million** to the University of Sunshine Coast and is working to establish another clinical trial centre on the Gold Coast. This is in addition to millions of dollars of investment to attract global biopharma company Sanofi to Queensland as part of the \$280 million [Translational Science Hub](#), which will stimulate major clinical trial activity for Queensland.
- **The Commonwealth Government recently announced \$80 million** in funding for clinical trial initiatives.

If you were to include the investment by other State Governments in operating costs for early phase cancer clinical trials run through their public health systems (which is funded by Linear in WA), the disparity in funding support faced by WA becomes even more stark.

3. The lack of funding is inconsistent with the intent of numerous State Government strategic plans and initiatives

A wide range of strategic documents outline critical priorities for the WA health and research sector. Clinical trials are frequently highlighted as a competitive advantage of WA and the need to expand existing and new infrastructure is noted extensively across documents. Despite this, Linear's experience, and that of other key clinical researchers in WA, demonstrates these priorities are not being addressed. The lack of commitment to these priorities will cause groups such as Linear to re-assess their future growth plans and potentially reduce the volume of clinical trial activity in WA.

Examples where funding to support clinical trial infrastructure are clearly noted, however don't correspond with recent experience, is outlined below:

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WA Health and Medical Research Strategy 2023-2033

- Page 7 – strategic goal - Leverage the ecosystem
 - *Maximise and enhance existing research infrastructure to drive research excellence*
- **Future Health Research Innovation Fund Strategic Plan**
 - Future Health Research and Innovation Fund website – Priority Goals
 - *Enhance clinical trial capacity and expertise to improve the quality of clinical trials in WA and make the State more attractive to funders of clinical trials (grant funding and commercial sponsors)*
 - Future Health Research and Innovation Fund strategy on a page - Theme 3 Platforms
 - *Support new or existing infrastructure to elevate WA as an international leader in research and innovation*
- **JTSI Health and Medical Life Science Strategy 2021**
 - Page 21 - Government focus # 5
 - *The Western Australian Government will support the development of testing and manufacturing facilities to enable the scale up and commercialisation of local health and medical life sciences innovations.*
- **State Infrastructure Strategy 2022**
 - Page 229 – Recommendation
 - *Support health and medical life sciences industry development, research, innovation and commercialisation by co-investing in health and medical life sciences facilities, subject to business cases, including:*
 - *a. establishing local medtech and pharmaceutical manufacturing infrastructure and capabilities to support the implementation of the Health and Medical Life Sciences Industry Strategy to develop a world-class health and medical life sciences industry*
 - *b. identifying opportunities for the Future Health Research and Innovation Fund to partner with the Australian Government, academia and the private sector to realise the infrastructure-related aims of the fund.*
- **Sustainable Health Review**
 - Page 114 – Critical success factors for implementation of the strategy
 - *Focus investment on maximising value and outcomes that support consumer and WA health system priorities.*

Early phase trials (such as those conducted by Linear) represent a vital link in the medical research value chain. They are essential to enabling laboratory research to progress into human testing whilst presenting immediate and tangible results as new treatments are provided to patients. The lack of clinical trial infrastructure will therefore limit the ability of local researchers (many who are funded by the Future Health Research Innovation Fund) to progress into human clinical trials. High quality clinical trial infrastructure, such as that developed by Linear will

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support competitive submissions as it will demonstrate WA has the capacity to translate the basic research into human clinical testing and provide greater impact. World class research infrastructure is also a critical enabler to attracting leading clinical and academic talent which will support WA obtain a greater proportion of competitive funding.

4. Suggested actions the State Government can take to ensure adequate funding to support more clinical trials in WA

Whilst funding into basic research (which appears to be the focus of the Future Health Research Innovation Fund) is vitally important, the lead time to translation can take many years.

Comparable funding into clinical trial infrastructure will generate more immediate and on-going benefits to patients, healthcare systems and the economy. This includes:

- Shifting healthcare costs out of the public system as treatments are provided at trial sites and funded by the trial sponsors
- Helping to attract clinicians from national and international sources
- Providing a broader and more comprehensive range of options for patients and clinicians – moving closer to precision medicine
- Helping to equip healthcare systems for new treatment paradigms (eg: use of cellular therapy in cancer)
- Connecting local researchers with global industry to support better translation of WA's basic research

From the perspective of Linear, the following suggested actions provide opportunities to improve WA's funding to be on par with other states:

- Provide a dedicated pool of funding to support the capital and operational requirements of clinical trial sites in WA. This should be targeted in areas that help shift costs out of the public system (such as cancer and neurology where there is high trial activity). The successful Research Infrastructure Support (RIS) program for medical research institutes could be extended to include funding support to clinical trial sites. Given clinical trials capture clear operational metrics such as patient visits, outcome status and workforce development, it is possible to monitor the return on investment of any funding and ensure funds are deployed to the sources that provide the greatest value to the State.
- Ensure that opportunities for the State to partner and co-invest with philanthropic groups are executed upon (whilst this has been identified as a priority, the example of Linear's failed funding when McCusker Charitable Foundation funding was assured, has raised concerns about the practical commitment to this approach).
- Reduce barriers for independent trials group such as Linear to support WA Health's Health Service Providers (HSP) with the provision of clinical trials. WA has a complex research governance system relative to other states. This inhibits the ability of non-WA Health providers to easily leverage their specialist capabilities to support WA Health's

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trial needs. Overcoming this barrier would further leverage investment in clinical trial infrastructure by making it accessible to a wider range of clinicians, patients and providers. Furthermore, innovations piloted in clinical trial sites such as quality management systems (addressing the National Clinical Trials Governance Framework) and data capture technologies could be disseminated through HSPs to help drive wider innovation in the WA healthcare system.

Thank you for the opportunity to provide this submission. I would be pleased to assist the committee with any additional information you require. The clinical trial industry is a critical enabler to improving WA's healthcare and innovation ecosystem, driving economic growth and most importantly, changing lives.

Yours sincerely,



Jayden Rogers

BSc, MPhysio, MBA
Chief Executive Officer



B Block, Hospital Ave
Perth, WA 6009



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Supplementary information

1. Key providers of early phase cancer clinical trials in Australia:

- Melbourne: Peter MacCallum Cancer Centre, Austin Hospital, Alfred Hospital, Barwon Health, Monash
- Sydney: St Vincents Hospital, Chris O'Brien Lifehouse, Blacktown, Liverpool Hospital
- Brisbane: Princess Alexandra Hospital
- Adelaide: Royal Adelaide Hospital
- Perth: Linear

2. List of investments in clinical trial infrastructure by other state governments:

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- 2020: **The Victorian Government is boosting the number of clinical trials** run in regional Victoria through a Clinical Trial Research Support Service launched last year at Barwon Health as well as Bendigo Health, Ballarat Health, North East Health Wangaratta and Goulburn Valley Health [[source](#)]
 - Further supported by **\$2.5m** from Costa family grant to Barwon Health in 2021
- 2021: **\$17.5 million in funding through the state government's Victorian** Higher Education State Investment Fund, Monash University will establish Victoria's Health Innovation Centre, including a flagship cardiovascular disease-focused research accelerator, HeartLabs, and a new focal point for clinical trials, to create high-value jobs, intellectual property, start-ups, and attract and nurture new clinical trials
- 2022: **Victorian government \$50m** support for the Victorian Melanoma and Clinical Trials Centre in 2022 (total funding of >\$150m) [[source](#)]
- 2022: **Victorian government contributes \$35m** of a \$45 million investment over 5 years for Stage 2 funding earmarked for research, clinical trials and workforce development activities within the Victorian Paediatric Cancer Consortium (VPCC). [[source](#)]
- 2022: **The Victorian Government has committed \$16 million** in funding to support Brain-POP. The clinical trial program will deliver innovative, perioperative clinical trials with paediatric, adolescent and adult patients that will help researchers to create a holistic picture of brain cancer treatment that has so far been missing from research. [[source](#)]
- 2023: **\$10m from Victorian state government** to establish a phase I eye clinical trial centre [[source](#)]
- 2023 Victoria government support (as part of **\$400m funding** to establish Australian Institute of Infectious Diseases) the establishment of a phase I human challenge center - Doherty Clinical Trials [[source](#)]
- Victoria has invested **\$1.3 Billion** in medical research since 2014 [[source](#)]
- According to the Victorian Health and Medical Research Strategy 2016-2020, in 2016, Australian investment in clinical trials **exceeds \$1 billion, with Victoria's share accounting for approximately \$300 million** [[source](#)]

NSW

- 2014: Scientia (NFP clinical trial centre - similar to Linear) **cost \$23.8m**. This is being jointly financed through the Therapeutic Innovation Australia and the **NSW State Government**. [[source](#), [source](#)]
- 2023: NSW government provide **\$25m** to Omico to support their clinical trial program [[source](#)]
- 2023: NSW government **\$20m** to support broad paediatric research program (significant focus on clinical trials) [[source](#)]

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- The \$270.3 million investment in the 2022-23 NSW Budget includes: [[source](#)]
 - \$143.3 million for the Sydney Biomedical Accelerator Complex over four years, a state-of-the-art biomedical research complex co-located at the Royal Prince Alfred Hospital and the University of Sydney;
 - \$51.8 million over four years to accelerate NSW's commercial scale viral vector products for both research and clinical trials purposes;
 - \$49.6 million to build a commercially viable Viral Vector Manufacturing Facility (VVMF) which will manufacture viral vectors, essential components for most gene replacement therapies, and
 - \$25.6 million for 2022-23 for innovative and lifesaving gene-based therapies such as CAR T-cell therapy.
 - Stated aim of "These advanced therapeutics are cutting-edge and are offering new hope for remission and long-term survival for patients with rare, and previously untreatable, conditions," Mr Hazzard said. "It will also mean NSW patients have greater access to locally-based clinical trials and can receive highly innovative treatment options, to help ease the burden they face as they fight diseases which previously had very limited treatment options"
- Similar biotech investment that will drive clinical trial activity:
 - AU\$96 million RNA pilot manufacturing centre (based at Macquarie Park), and AU\$134 million to support the first GMP-grade clinical and commercial viral vector manufacturing facility in Westmead [[source](#)]

3. Findings from MTP Connect report on Australian clinical trial sector 2024

https://www.mtpconnect.org.au/images/MTPConnect_2024_AustraliasClinicalTrialsSectorReport.pdf

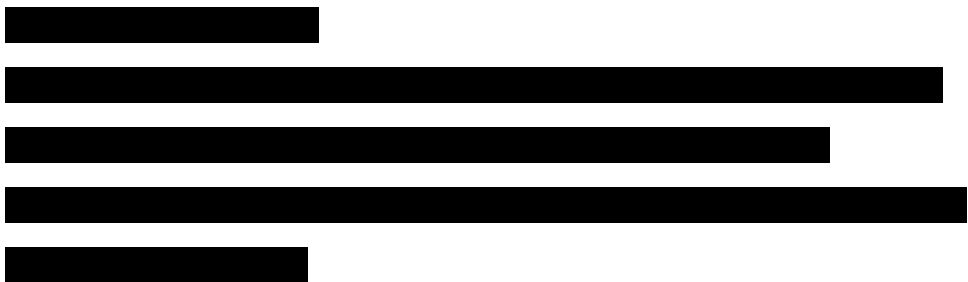
The latest report from the federally funded MTP Connect highlighted Australia's reputation as an attractive destination for clinical trials underpinned by the following factors:

- A strong reputation for the quality and global standing of its investigators and the networks that support them.
- Highly developed research infrastructure and systems that have enabled Australia to continue conducting clinical trials through disruptive global events such as the COVID-19 pandemic.
- High-quality data collection and overall compliance with Good Clinical Practice (GCP) guidelines, which ensures that data collected in Australian trials can support submissions to international regulators, including the United States' Federal Drug Administration (FDA) and the European Union's European Medicine Agency (EMA).
- **Specialised and dedicated early-phase infrastructure that enables the delivery of timely, high quality trials, supported by streamlined processes and private ethics committees.**

- The convenience and speed of the Therapeutic Goods Administration's Clinical Trial Notification (CTN) scheme, which enables the faster start-up times that are particularly crucial for early phase trials.
- The financial support provided by the Australian government's extension of its research and development (R&D) tax incentives, improving Australia's cost competitiveness.

This has led to the following outcomes (2022):

- >7,000 Australians employed
- >90,000 patients or volunteers participated in clinical trials
- 1850 clinical trials started
- \$1.6billion spent on clinical trials



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