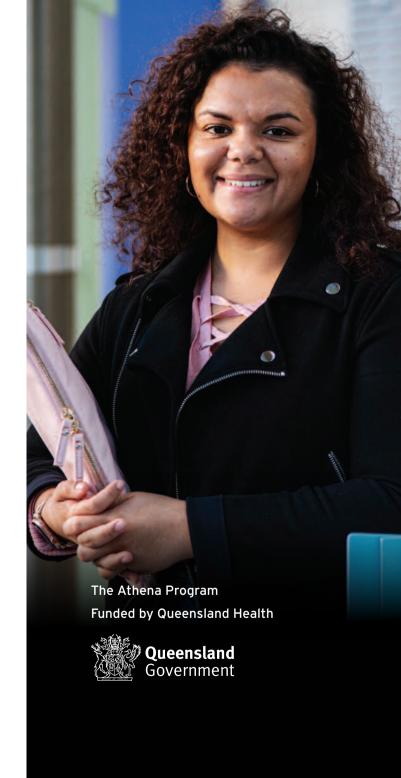


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REPORT SCOPE

The ATHENA Program (ATHENA) seeks to make clinical trials widely available and accessible to all interested and clinically relevant Queenslanders. It seeks to radically reduce the cost and time taken to recruit participants for clinical trials which across Australia and globally are plagued by the high cost and time needed to find and screen eligible participants to increasingly rigorous trial protocols. Queensland Health commissioned this report in April 2022 to evaluate the projected economic and health benefits for Queensland likely to arise from lifting the number of clinical trials conducted

in Queensland, and the value for money from investing in ATHENA to deliver these outcomes.

This Report also evaluates the unique benefits ATHENA offers to clinical trial sponsors. It is the uniqueness of this value proposition that will attract sponsors to undertake more clinical trials and medical research in Queensland.

The benefits ATHENA offers to clinical trial sponsors build on the findings of a worldwide literature search and over 50 separate engagements¹ with industry stakeholders and Sponsors² of clinical trials since 2016.

This Executive Summary includes four sequential Reports which outline the:

Report 1:

The ATHENA Program

Report 2:

The Benefits for Sponsors

Report 3:

Economic Benefits for the Queensland Economy and Health Benefits for the Community

Report 4:

Rollout Plan, Cost Model and Measures of Success

DISCLAIMERS

The views expressed in the ATHENA Economic Modelling Report (the Report) are based solely on the sources of information and data referenced therein. This Report is solely for the purpose set out in the Report and is not to be used for any other purpose or distributed to any other party without the prior consent of Triple Innovation. Triple Innovation accepts no responsibility arising in any way from reliance placed by a third party on this paper. Any reliance placed is that party's sole responsibility.

¹ Available on request.

² A Sponsor means a Commercial Sponsor (international and local developers of drugs, vaccines, and other therapies, and medical device companies) and Non-Commercial Sponsors who initiate clinical trials. Non-Commercial Sponsors include General Practitioners or specialist Clinician Non-Commercials employed in hospitals or private practice and Researchers employed in not-for-profit medical research institutions. For the purposes of this Report, Non-Commercial Sponsors also include Medical Researchers such as epidemiologists who can answer their medical research questions solely by interrogating large-scale anonymised health data and do not require access to individual participants.



EXECUTIVE SUMMARY

Advances in medical research leading to new medicines, procedures and diagnostics that benefit the Community cannot occur without human clinical trials. Clinical trials drive the application of evidence-based medicines. Participation in clinical trials offers free access to new therapies that may help to treat or manage disease progression and/or improve survival rates. Increasing participant access to and participation in clinical trials enables more trials to be undertaken to benefit more people and improve health outcomes for the general community.

Forty-eight percent (2.5M) of the Queensland population live with one or more chronic diseases but only 12,366 Queenslanders (0.5% of those with a chronic disease) participate in clinical trials. The participation rate in clinical trials is similar across Australia, yet it is estimated to be one-quarter of the participation rate in the United Kingdom. This suggests that there is significant potential to increase community participation in clinical trials in Queensland and across Australia.



The healthy economy

A healthier population generates quantifiable direct and indirect benefits

A healthier population generates quantifiable direct and indirect benefits for the economy. Most illnesses and deaths in Australia are caused by chronic conditions which are becoming more prevalent due to an aging population and changes in lifestyle. The 2021 Australian Institute of Health and Welfare Report on Chronic Disease found that 51% of hospitalisations in 2017–18 and 89% of deaths in 2018 were associated with a chronic disease. Chronic conditions make up almost half (46%) of all potentially preventable hospitalisations.

The persistent nature of chronic disease places significant pressure on individuals,

families, the health system, and the economy through its impact on quality of life, workforce participation, and productivity. The Commonwealth Government Intergenerational Report 2021 noted that by 2062 health expenditures are projected to represent 26% of Commonwealth Budget expenditures driven by spending on public hospitals. Over the next 40 years, as the population ages and combined with lower fertility rates, the number of people of working age for every person aged over 65 is expected to fall from 4.7 to 2.4. This projection highlights the importance of investing in preventative measures to protect the physical and productive health of the population.





The healthy economy

In 2013, the McKeon Report³ recommended that Governments invest more in medical research to develop preventative health and better treatment therapies for prevalent chronic conditions. That Report made clear the dependent relationship between the impact of medical research and clinical trials on average life expectancy, productive years spent in good health, and economic outcomes. The National Preventative Health Strategy 2021-2030 estimates that if action were taken to invest in preventative health, particularly in regional, rural and remote communities, and in lower socioeconomic and indigenous populations, 170,000 extra Australians could enter the workforce generating \$8Bn in extra earnings. Additionally, \$4Bn annual savings

could be made in welfare support payments and 60,000 fewer people annually would need to be admitted to hospital, saving \$2.3Bn in hospital expenditure. Furthermore, 5.5M fewer Medicare services would be needed each year generating annual savings of \$273M, and 5.3M fewer PBS scripts would need to be filled each year generating annual savings of \$184.5M.

In 2020, McKinsey⁴ noted that developed economies like Australia are exposed to a high prevalence of lifestyle and age-related health conditions that can only be addressed by investing in preventive health and improved treatment options. McKinsey calculated that 70% of the potential gains arising from investment in preventative health will accrue to working-age populations.

³ Australian Government Department of Health and Ageing (2013), Strategic Review of Health and Medical Research: Summary Report

⁴ Prioritising Health, A Prescription for Prosperity, McKinsey Global Institute 2020. These include chronic conditions like diabetes, cardiovascular disease, cancer, Alzheimer's disease and other dementias, vision, and hearing loss. Healthy life expectancy-years lived in good health—is not keeping pace with rising life expectancy in many developed countries. Additional years gained at the end of life are increasingly spent in poor health.

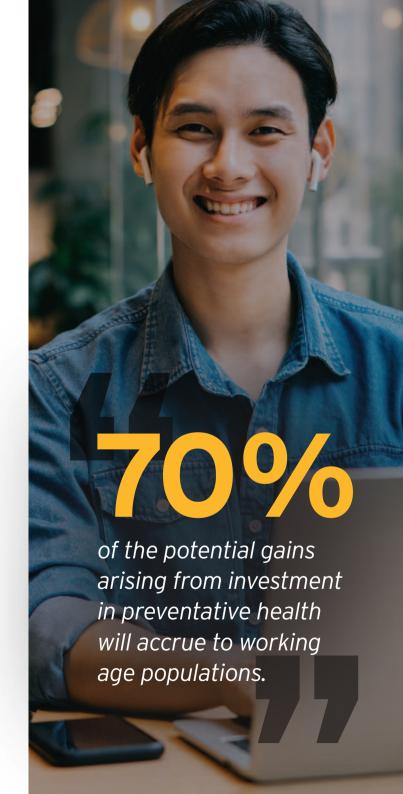
The clinical trial challenge

Multiple Reports since 2000 have documented the frustrations multinational clinical trial Sponsors experience in conducting clinical trials in Australia. Sponsors identify access to eligible participant populations as the major barrier to increasing the intensity of clinical trial activity in Australia. Participant recruitment processes are inefficient and embed high cost and time inefficiencies into a system where the cost of developing new therapies for chronic and rarer diseases is already expensive.

The ATHENA program aims to remove this barrier by engaging 4.1M Queenslanders to consent to contribute a comprehensive set of their personal health information (primary health care data, biosamples, genetic data and lifestyle data) to Queensland Health's Population Health Database for medical research. ATHENA will also ask Queenslanders' to consent to be recontacted to participate in

clinical trials. This will form a mass cohort of willing subjects that can be screened quickly to determine their eligibility to take part in a clinical trial or other research. Clinical trial Sponsors will engage ATHENA to screen participants for clinical trials and to contact eligible participants to start the recruitment process, while Medical Researchers will engage ATHENA to access anonymised participant data held by the Qld Population Health Database.

Sponsors have indicated that this will be a game-changing innovation that will allow them to undertake more clinical trials in Queensland more cost-effectively and faster and enable more Queenslanders to gain access to additional new therapies to improve the diagnosis, treatment, and management of diseases prevalent in the Queensland population.⁵



⁵ This includes clinical trial design for target populations, reduced time to market for new therapies, more efficient lower-cost clinical pathways, post-market surveillance, and cost-benefit assessment to inform health system payments.



The clinical trial challenge

This Report models the economic and health benefits for Queensland generated by increasing the number and value of clinical trials undertaken in Queensland.

The function of the ATHENA Program as an enabler of the Qld Population Health Database, which has a discrete asset value, also deserves recognition and cannot be understated. When patient-level records are normalised and consolidated into a single longitudinal population scale digitised data set, they provide a comprehensive history of individual health, diagnosis, treatments, medical procedures, and outcomes that Sponsors can interrogate to identify predisposition to disease, factors affecting disease onset, disease biomarkers for faster and earlier diagnosis, and therapies to manage disease progression. It also enables operational and cost-effectiveness of health care delivery and workforce planning and, with appropriate measurement, can address observed socioeconomic disparities in health, wellness, standards of care and access to new therapies. In 2020, EY⁶ estimated the commercial value of the NHS could be as high as £5Bn per year and deliver £4.6Bn to patients if the 23M EMR records it currently holds are linked to primary care GP records and a subset of these records are combined with the subset of 100,000 patients that in 2020 had undergone genome sequencing, via the UK Biobank. The asset value of the Qld Population Health Database accelerates over time as patient records become more complete and large data analytical and scientific tools, including AI, become more sophisticated.

The more Queensland invests in the Qld Population Health Database, the faster its asset value accumulates as a foundation asset, and Queensland becomes more attractive as a location to undertake medical research enabled by ATHENA with access to the health data assets held in the Qld Population Health Database.

⁶ Realising the value of healthcare data: a framework for the future, EY, 2020

ATHENA unlocks substantial economic and health benefits for Queensland

This Report models the increase in clinical trial activity over a 6-year forecast period from 2023 to 2029 above a baseline growth forecast of 1% per year by reference under two growth scenarios: a base case forecast (the ATHENA Base Case) and an accelerated case forecast (the ATHENA Accelerated Case). This period includes 2023 as a pilot year, so that Base Case and Accelerated Case forecasts cover the shorter period 2024-2029. The ATHENA Base Case projects a compound annual growth rate (CAGR) of 5% for Commercial trials and 3% for Non-Commercial trials above the projected baseline growth rate over this period. The ATHENA Accelerated Case projects a CAGR of 10% for Commercial Sponsors and 5.5% for Non-Commercial Sponsors, above the projected baseline growth rate over this period.7

Relevant multipliers are applied to calculate the additional economic, employment and health benefits to the Queensland economy generated by the increase in clinical trials projected in both scenarios.

In 2022, Queensland Health advised that 393 clinical trials were initiated in Queensland, of which 192 were Commercial and 201 Non-Commercial. The estimated value of all trials in Queensland in 2022 was \$177M comprising \$130M from Commercial trials and \$47M from Non-Commercial trials. It is assumed that each Commercial trial Site includes 10 patients, and each trial includes on average 1.5 Sites. It is assumed that each Non-Commercial trial includes a single Site and an average of 50 patients. Each Commercial trial is assumed to be worth \$825,000 and each Non-Commercial trial is \$235,000. An estimated 12,366 Queenslanders participated in a clinical trial, and it is estimated that 695 Queenslanders were directly employed in clinical trial activity.



⁷ Non-Commercial Sponsors are assumed to be less responsive to the clinical trial efficiencies ATHENA can deliver than Commercial Sponsors for several reasons: time to undertake additional clinical trials given other clinical responsibilities, access to funding, and appetite to devote more time to clinical trials.



ATHENA unlocks substantial economic and health benefits for Queensland

The baseline growth rate forecasts that 417 clinical trials will be conducted in Queensland in 2029, from a baseline of 393 trials in 2022.

Given these baseline assumptions, this Report projects that ATHENA will generate the following economic benefits over the period 2023-2029 under its Base Case and Accelerated Case growth scenarios:

ATHENA Base Case growth scenario

320 additional clinical trials, comprising 229 Commercial trials and 91 Non-Commercial trials (Figure 1).

Additional direct external investment in clinical trials of \$210M, comprising \$189M in Commercial trials and \$21M in Non-Commercial trials. On average, ATHENA would enable additional investment in clinical trials of \$35M per year, comprising \$31M from Commercial trials and \$4M from Non-Commercial trials.

Gross value-added of \$472M or \$79M per year, based on applying a value-added multiplier of 2.5 to the value of the projected additional investment in Commercial trials.

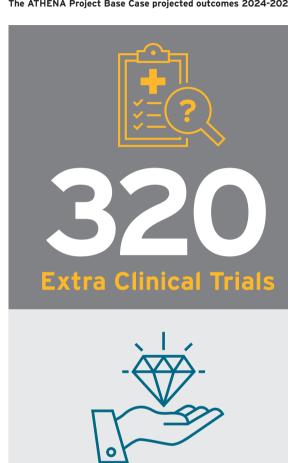
Additional direct employment of 153 clinical trial workers by 2029, or on average 25

clinical trial workers every year from 2024 to 2029. ATHENA forecasts that by 2029, the clinical trial industry in Queensland will directly employ 848 workers. Applying an employment multiplier of 2, the ATHENA Base Case would generate a further 153 clinical trial workers by 2029, (i.e. extra 306 direct and indirect jobs) or a further 25 jobs per year in the clinical trial supply chain. By 2029, ATHENA forecasts that 1,001 workers will be directly and indirectly employed in the clinical trial sector in Queensland.

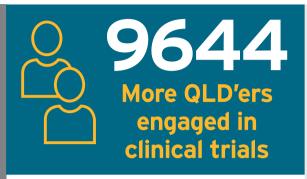
More Queenslanders engaged in clinical trials. ATHENA's Base Case would engage an additional 9,644 Queenslanders in clinical trials between 2024-2029 or, on average, an additional 1,607 Queenslanders per year.

Avoided health costs of \$52M. Queensland Health would otherwise incur, or on average, \$8.7M each year, of which \$3.5M relates to avoided drug costs.

Health benefits to the Queensland Community of \$902M, comprising \$334M multiplied by 2.7, which is the health benefit multiplier identified by KPMG in 2018 in relation to Australian medical research, or an average of \$174M per year over the period 2024-2029.



\$472M+



\$210M

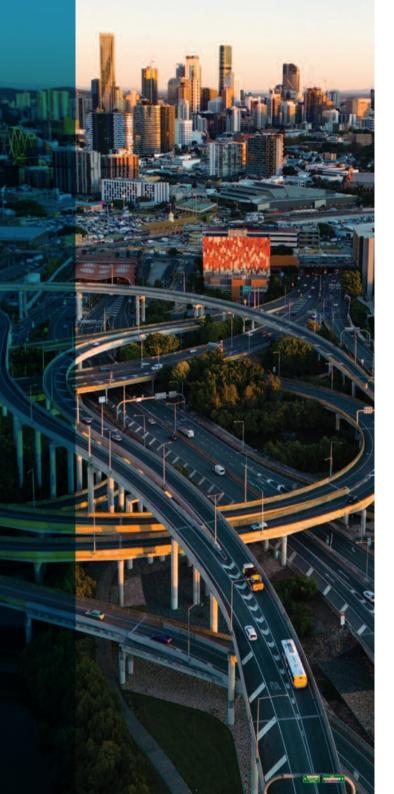
Direct External Investment



306
Extra Jobs







ATHENA unlocks substantial economic and health benefits for Queensland

ATHENA Accelerated Case growth scenario

712 additional clinical trials, comprising 498 Commercial trials and 214 Non-Commercial trials (Figure 2).

Additional direct investment in clinical trials of \$481M, comprising \$411M in Commercial trials and \$70M in Non-Commercial trials. On average, ATHENA would enable additional investment in clinical trials of \$76M per year, comprising \$70M from Commercial trials and \$6M from Non-Commercial trials.

Gross value-added of \$1Bn or \$170M per year, based on applying a value-added multiplier of 2.5 to the value of the projected additional investment in Commercial trials.

Additional direct employment of 375 clinical trial workers by 2029, or on average 63 every year from 2024 to 2029. ATHENA forecasts that by 2029, the clinical trial industry in Queensland will directly employ 1,070 workers. Applying an employment multiplier of 2, the ATHENA Base Case would also generate a further 375 jobs (i.e. an extra 750 direct and

indirect jobs), or 63 jobs, each year in the clinical trial supply chain. By 2029, ATHENA forecasts that 1,445 workers will be directly and indirectly employed in the clinical trial sector in Queensland.

More Queenslanders engaged in clinical trials.

ATHENA's Accelerated Case would engage an additional 19,829 Queenslanders in clinical trials between 2024-2029 or, on average, an additional 3,304 Queenslanders per year.

Avoided health costs of \$114M Queensland Health would otherwise incur or, on average, \$19M each year, of which \$7.7M relates to avoided drug costs.

Health benefits to the Queensland Community

of \$1.63Bn, comprising \$605M x 2.7 (the health benefit multiplier identified by KPMG in 2018 in relation to Australian medical research), or an average of \$272M per year.

The cumulative economic and health benefits to Queensland are substantial under either the ATHENA Base Case or the ATHENA Accelerated Case growth scenario and remain significant even if the Base Case scenario is reduced by 50%.

Figure 2: The ATHENA Program Accelerated Case projected outcomes 2024-2029







\$481M

Direct External Investment









The cost to deliver ATHENA

The cost to deliver ATHENA is modest by comparison. ATHENA plans to commence rollout to Queensland Health's 15 Hospital and Health Services (HHS) via an initial pilot program in the Sunshine Coast HHS at the Sunshine Coast University Hospital Campus. The pilot budget is \$2M and will run for up to 2 years between 2023 to 2024 or until ATHENA is fully operational at all public hospitals and supporting medical centres in the Sunshine Coast HHS. The pilot program includes a planning and preparation period of 3 months with a progressive rollout to prioritised participant cohorts from 2023 with all cohort implementation completed to allow for 4 months of live operation. The objective is to engage Commercial Sponsors and initiate clinical trials to evaluate end-to-end processes and fee-for-service revenue options so that ongoing operating costs are covered and

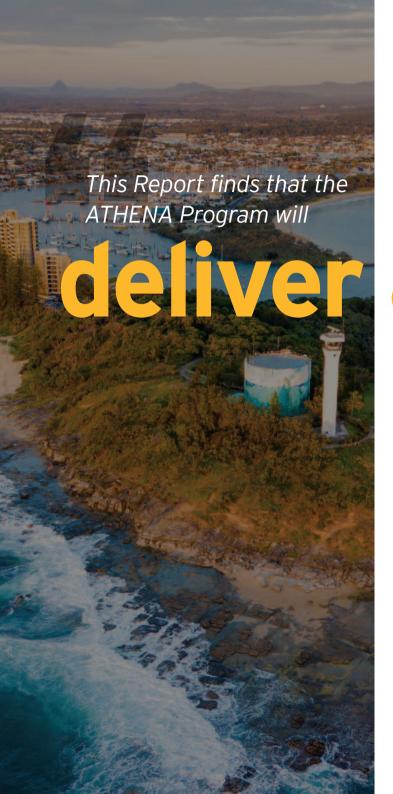
ATHENA's expansion is supported over time. The pilot program will assess Community engagement and eConsent rates and establish procedures for rapid growth. Rollout to the other 15 Queensland HHS Districts will cost \$4M per year for the first 2 years of operation, declining to \$2.5M per year thereafter to support ongoing operations.

This Report finds that the ATHENA Program will deliver a return on investment that increases significantly over time from 2024. The ATHENA Program also satisfies the REDS framework⁸ used by the Queensland Government to prioritise investment in impactful R&D, and the alternative formula proposed by the Office of the Chief Scientist, Queensland to evaluate R&D investments by their capacity to deliver projected outcomes for Queenslanders cost-effectively.⁹

⁹ A return-on-investment approach for public good research investment and partnerships, Hugh Possingham, Queensland Chief Scientist - 27 March 2022.



REDS means Real future impact - delivering economic, environmental, and social benefits that are measurable and translate to enduser benefit; External commitment - attracting and leveraging funding and resources from collaborators; Distinctive angle - targeting comparative advantage and uniqueness, and Scaling towards critical mass - addressing the global opportunity. Refer REDS decision rules, Office of the Chief Scientist, Queensland



The cost to deliver ATHENA

a return

on investment that increases significantly over time.

This formula is denoted by BPS/C where B means benefits, P means the likelihood that the project would not be undertaken without Queensland Government support, S means the investment is likely to succeed and delivers the benefits, and C means the cost to deliver the project. This Report finds that the ATHENA Program has a high chance of cost-effectively delivering the benefits this Report identifies for Sponsors and the economic and health benefits modelled for the Queensland economy and the Community.

During its pilot phase, ATHENA will investigate opportunities to implement fees for service charges to Commercial and Non-Commercial Sponsors. This will enhance the costeffectiveness of the ATHENA Program under the above formula, the REDS framework and enhance its ROIC. This Report suggests that a competitive fee structure that recovers capital and operating costs is small compared to the recruitment cost and time savings ATHENA offers. Fee for service charges are therefore unlikely to reduce demand from Commercial or non-Commercial Sponsors to access ATHENA to undertake clinical trials in Queensland.

THE ATHENA PROGRAM

The ATHENA Program (the Australians Together Health Initiative) aims to increase the number of clinical trials undertaken in Queensland and increase the number of Queenslanders (those with a chronic disease and the healthy) who have access to and choose to participate in clinical trials wherever they are located. ATHENA will do this by engaging Queenslanders to consent to provide their health data for medical research and to consent to be recontacted to participate in a clinical trial. ATHENA's ability to screen a pre-consented population scale cohort of willing participants will reduce the cost and time needed to find, screen, and recruit eligible participants adding greater certainty for Sponsors that recruitment targets can be achieved much faster and at a radically lower cost compared to best practice recruitment processes. Sponsors will choose to undertake more trials in Queensland to access the unique cost and time savings ATHENA delivers.

Figure 3: Qld Population Health Database (PHD)





Consenting participants

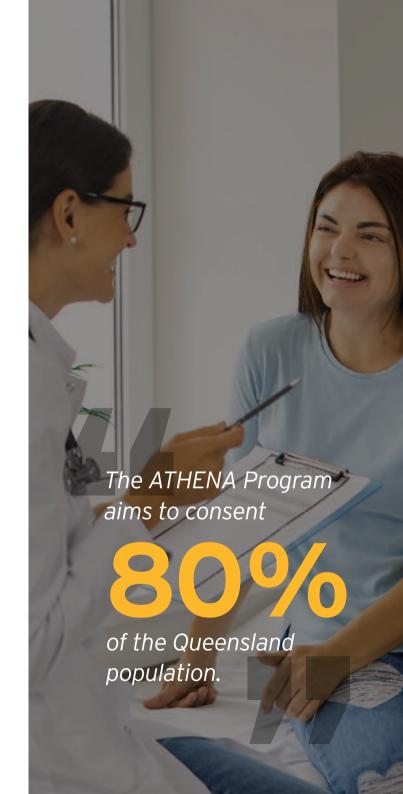
Multiple Australian studies indicate Australians understand the benefit of medical research and are prepared to contribute their personal health information to support that research and to participate directly in clinical trials. However, many Queenslanders find it difficult to access clinical trials or find the clinical trial process daunting. ATHENA aims to bridge this gap by becoming the primary Queensland Health sponsored gateway the Community uses to access clinical trials in Queensland.

Since 2018 ATHENA has been developing the data infrastructure needed to extract data from the digital primary care records held in general practice (GP) and link it to the state-wide 'data lake' Queensland Health has been establishing to integrate Emergency Medical Records (EMR) data and Health Registry records across all public hospitals in Queensland (the Queensland Population Health Database). GP data typically includes participant clinical risk factors (e.g., weight, blood pressure, ethnicity, family history, etc.) not routinely captured in hospital EMR systems. Multiple studies in the UK, US and Scotland have established the research utility and downstream benefits to public health of linking GP and hospital medical records.

ATHENA has successfully extracted participant GP data and linked it to other healthcare data sets in pilot studies and is exploring methods to scale this solution.
ATHENA has also developed and evaluated a universal digital eConsent platform (the Dynamic Consent Platform (DCP)) participants will use to consent to release their data to ATHENA for medical research and to be recontacted to discuss participation in a clinical trial.

ATHENA aims to consent 80% of the Queensland population or 4.1M Queenslanders to allow their GP records, biosamples, and genomic and lifestyle data to be stored in the Qld Population Health Database and used for medical research purposes approved by ATHENA (Figure 1).

Enabled by ATHENA, the Qld Population Health Database will be the first integrated population-scale health database in Australia. It will be one of the largest integrated public health databases of its type in the world. For comparative purposes, it will be 8x larger than the successful UK Biobank, which has a population base of 500,000.





Increasing the number of clinical trials by reshaping the participant recruitment process

Identifying and screening participants eligible to participate in clinical trials is a major frustration for Commercial Sponsors globally. Participants are hard to find, and participant data is fragmented across hospitals, GPs, specialists, and other health service providers. Identifying eligible participant populations is more difficult in smaller populations, where the statistical probability of finding enough of the right participants is reduced. Commercial Sponsors, therefore, prefer to locate trials in larger population centres where there is at least a statistically higher chance of recruiting eligible populations in target numbers to recruitment timelines.

Once on location, a Sponsor typically engages one or more CROs to undertake a clinical trial and find the participants to take part in the trial. The CRO then conducts a Feasibility Study to determine which Sites (based on their performance history and any new Sites they identify) might have eligible participants, experienced staff (PIs and clinical trial staff), expertise, technology, and cost to conduct the trial successfully and on time. Sites completely undertake a feasibility study to assess whether they can find eligible participants and resource the trial. The CRO often undertakes a Site visit to assess the accuracy of PI and Site recruitment estimates and adjust for over-estimation, their interest in the trial, their commitment to delivering recruitment targets and Site infrastructure to run the trial effectively. The Site and CRO negotiate a per-participant fee to cover the trial protocol standard of care and an administration fee to cover Site trial management calculated as a price per participant. The CRO assesses the number of Sites needed to recruit target participant numbers on time and negotiates a trial fee with the Sponsor.

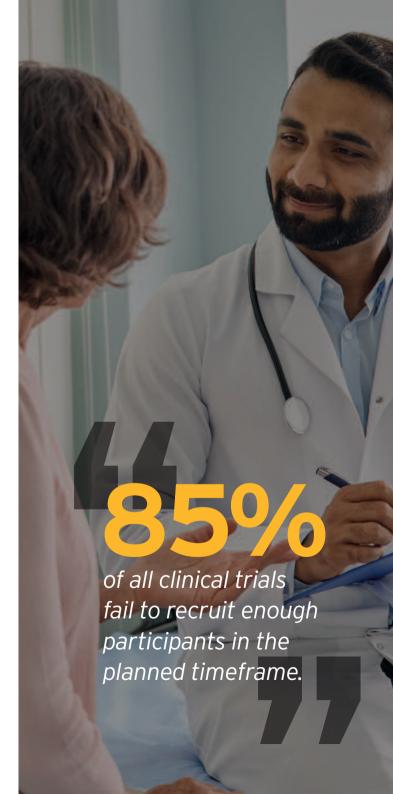
Increasing the number of clinical trials by reshaping the participant recruitment process

Sponsors and CROs depend on Principal Non-Commercials (PIs), typically clinical specialists in the trial field, and associated Sites to find participants and run the trial. PIs find participants from their participant lists supplemented by outreach to the local Community often supported by clinical trial marketing specialists.

85% of all clinical trials fail to recruit enough participants in the planned time frame and 80% are delayed because of recruitment problems. Pls often do not know how many participants they have on their books that could meet the trial protocol and tend to overestimate the available study population. CROs and Sponsors cannot support the recruitment process because they do not have direct clinical access to participants and have no direct or indirect way to determine the size of the eligible population they are seeking, where that participant population resides or how to identify potential Sites closest to participant populations. As a result, 37% of Sites under-enrol, and 11% do not enrol a single participant. CROs compensate for under-performance by progressively

activating extra PIs and Sites, as Sites report under-recruitment or engage multiple Sites competitively at the beginning to improve the chance of recruiting participant numbers within the trial time frame. This makes participant recruitment an uncertain, time-consuming, and costly hit-or-miss exercise for Sponsors. Under-recruitment also impacts Sites. Sponsors remunerate Sites on a perparticipant recruited basis, typically leaving Sites to absorb the cost of finding and screening participants.

Participant recruitment represents 25% of overall clinical trial costs and 30% (2.5 years) of total CT time across Phase I, Phase II and Phase III trials in development cycles of usually 7-10 years. This cost includes the following components: the cost to activate a Site, the cost to identify eligible participant populations for pre-screening, the cost to screen a participant, the cost of not meeting study timelines, loss of revenue from (patent protected) time that a successful product is not in the market, and the risk that a sponsoring entity runs out of funding and cannot complete a trial.





ATHENA solves the participant recruitment problem

ATHENA recognises that the inability of Sites to estimate the size of eligible participant populations they have access to and to prescreen them effectively are the central flaws in the participant recruitment process today. Providing regulated access to a comprehensive set of participant personal health information, consolidated in the Qld Population Health Database, that can be interrogated efficiently solves both challenges. This change cannot be understated. ATHENA revolutionises the current participant recruitment process by stripping out embedded costs and slashing the end-to-end time needed to screen and enrol participants from many months and sometimes years to weeks.

Saving cost and time by streamlining and restructuring the end-to-end participant recruitment process is at the heart of ATHENA's value proposition to Sponsors. ATHENA restructures this process by arming Sponsors for the first time with data about the size and location of eligible participant populations, which gives them visibility of the participant recruitment pipeline from start to finish. For the first time, Sponsors can

engage Sites to communicate their expected contribution to participant recruitment. In effect, ATHENA removes the responsibility to find eligible participant populations from PIs and Sites, allowing them to refocus resources on enrolling participants and conducting trials effectively and efficiently. ATHENA replaces a labour-intensive, time-consuming and unreliable site-specific participant selection and recruitment process with a fast, efficient, and reliable participant screening process.

If ATHENA can deliver this benefit, Commercial Sponsors will undertake more clinical trials in Queensland involving more participants and accelerate the time it takes to advance new therapies to market. Non-Commercial Sponsors experience the same frustrations as Commercial Sponsors and will benefit from a more efficient participant recruitment process even if at a smaller scale. Medical researchers also benefit significantly from the development of the Qld Population Health Database. Currently, their access to linked population-scale data is limited. Providing access to the Old Population Health Database will accelerate medical research in the same way it has for the UK Biobank.

The ATHENA engine

ATHENA works on the premise that a growing database (the Qld Population Health Database) of consented participants keen to participate in clinical trials, coupled with a radically more efficient participant recruitment process, will motivate more Sponsors to conduct more clinical trials in Queensland. The larger the size of the consenting population, the more diverse and geographically representative the Qld Population Health Database will become. Additionally, the larger the number, type, and complexity of clinical trials it can support, the more valuable it becomes to Sponsors as it enables a record of participant health and history of the onset and progression of disease as participants age. Furthermore, the easier it is for the Community to participate in clinical trials through ATHENA, and the faster it is to recruit participants, the more Sponsors will choose Queensland as a preferred clinical trial destination. This drives the ATHENA engine (Figure 4).

Figure 4: The ATHENA engine







The ATHENA engine

The faster the ATHENA engine cycles to increase the intensity of clinical trial activity in Queensland, the more therapies can be shipped to Queensland participants who can benefit from them.

The ATHENA engine depends on key Sponsor demand assumptions and Community participation assumptions, each of which has been validated by ATHENA in studies of up to 1,000 participants, and in relevant published clinical trial literature in other jurisdictions.

Assumptions about Sponsor demand rest on five foundations. First, Qld Population Health Database offers a unique scale and depth of participant health data and health history which Sponsors can interrogate usefully, that is not available elsewhere in Australia. Second, Queensland has a diversity of diseases and size of eligible participant populations to meet Sponsors' recruitment needs across all phases of clinical trial activity. Third, ATHENA can reduce recruitment costs

and achieve participant recruitment targets significantly faster for Sponsors than other participant recruitment methods they use today. Fourth, Sponsors will pay ATHENA to secure these benefits. Fifth, Sponsors choose to recruit more clinical trial participants from Queensland, recognising that ATHENA provides a unique cost-effective participant recruitment value proposition.

Assumptions about Community participation are based on multiple Australian studies indicating that the Community understand the need to invest in medical research and is prepared to contribute their personal health information to support that research and to participate directly in clinical trials, even if those benefits are not immediate. ATHENA has already consented 1,000 Queenslanders to ATHENA-related programs. Results show that 75-80% of participants approached consented to have their GP data accessed for medical research and to be recontacted to participate in a clinical trial.

THE BENEFITS FOR SPONSORS

ATHENA offers Sponsors two categories of benefits: savings in the cost of the recruitment process, and savings in the time needed to achieve participant recruitment targets (Figure 5).

Cost savings result from removing avoidable costs and recognised inefficiencies in the participant recruitment process. Time savings relate to the benefits Sponsors derive from accelerated recruitment timelines expressed in value terms as the additional revenue that a successful product could generate in the market under patent protection for each day a trial recruitment timeline is accelerated—the avoided opportunity cost of extended recruitment timelines. Accelerating recruitment time across each of Phase I-IV trials also reduces the internal cost of capital

otherwise needed to fund a trial. The cost of capital is measured by its opportunity cost if that capital could be redeployed productively.

This Report develops illustrative examples of a Commercial trial and a Non-Commercial trial to calculate the cost savings and recruitment time Sponsors might expect to secure by engaging ATHENA's participant recruitment services. The findings reported below, based on these examples, have been validated by Commercial and Non-Commercial Sponsors:

ATHENA saves on average 18% of the average cost of a Commercial trial and could accelerate a typical Phase II 30-month Commercial trial by up to 17 months by reducing the recruitment period from 18 months to 1 month, resulting in a time saving of 56%.

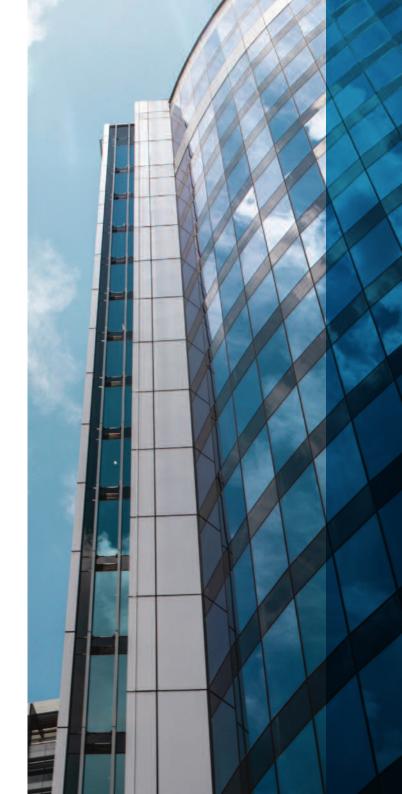
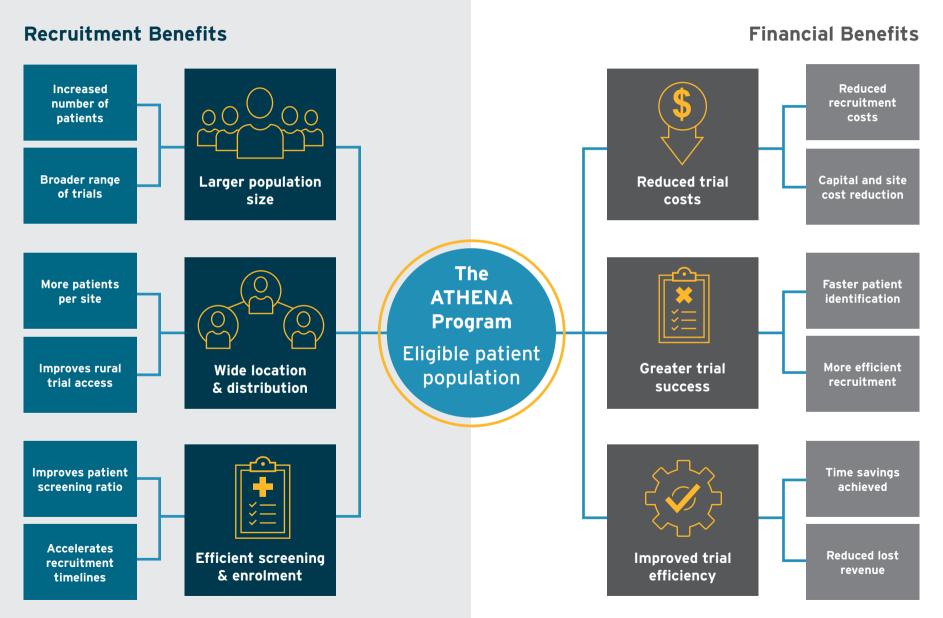


Figure 5:

The ATHENA Program value to customers





THE BENEFITS FOR SPONSORS

ATHENA saves on average 20% of the average cost and an average of 16 months (53%) of a grant-funded 30-month Non-Commercial trial.

The impact of these savings is better understood at scale. In 2022, Queensland Health reported 393 trials were undertaken in Queensland, of which 192 were Commercial trials and 201 Non-Commercial trials.

Applying these figures to the cost and time savings identified above -

ATHENA would save Industry Sponsors 18% of the \$130M invested in clinical trials in Queensland in 2022¹⁰ or \$23M of recruitment-related costs. ATHENA would save Industry Sponsors and Sites 53% of total trial time, reducing the average clinical trial from 30 months to 13 months.

ATHENA would save Investigator Sponsors 20% of the \$47M invested in clinical trials in Queensland in 2022¹¹ or \$9M in recruitment-related costs. ATHENA would

save Industry Sponsors and Sites 53% of total trial time, reducing the average trial from 30 months to 14 months.

These savings enable Sponsors¹² to undertake more trials involving more participants faster, but with the same resources. Recruitment efficiency lifts the intensity of clinical trial activity in Queensland. Faster trials mean more treatments can be shipped to more participants who need them sooner.

Sponsors also quantify the benefit of faster clinical trial cycle times by valuing the extra time a successful therapy has in-market to earn revenues whilst a patent protects it. The value of additional time in-market depends on the therapeutic area and its therapeutic benefits and typically starts for a successful therapy from \$600,000 per day. For all Sponsors, the revenue opportunity cost of inmarket time saved, and the Community health benefits that accrue by offering more patients faster access to needed therapies will always significantly dwarf the cost savings generated by an efficient process to recruit participants.

¹⁰ Refer Report 3 - Benefits for the Queensland Economy and Health Benefits for the Community

Refer Report 3 - Benefits for the Queensland Economy and Health Benefits for the Community

¹² It is assumed that Commercial Sponsors direct all time saved into new clinical trial activity. It is assumed that Non-Commercial Sponsors direct only 50% of the time saved into new clinical trial activity recognising that they are typically already busy with clinical responsibilities or other professional activity.

ECONOMIC BENEFITS FOR THE QUEENSLAND ECONOMY & HEALTH BENEFITS FOR THE COMMUNITY

A key premise of the ATHENA model is that it will unlock significant cost and time savings for Sponsors, enabling them to initiate more trials for the same investment and initiate new trials that require new investment. The additional economic benefits to the Queensland economy and the health benefits to the Queensland Community enabled by ATHENA are calculated

using 2022 as a baseline year¹³ and then comparing the ATHENA Base Case and Accelerated Case growth scenarios to forecast growth in baseline trial numbers. Additional gross value-added, additional employment and downstream health benefits are estimated by identifying and then applying relevant multipliers.

¹³ Where this Report refers to 2022 baseline data, it refers to data provided by Queensland Health for the 12 months period to 30 June 2022.



The baseline year 2022

The paragraphs below identify key baseline year assumptions that underpin the modelling of ATHENA's growth assumptions and the calculation of the resulting economic and health benefits this Report identifies.

The baseline number of clinical trials initiated in Queensland in 2022.

In 2022, Queensland Health advised that 392 clinical trials were initiated in Queensland, of which 193 were Commercial and 201 Non-Commercial.

The value of baseline clinical trials initiated in Queensland in 2022.

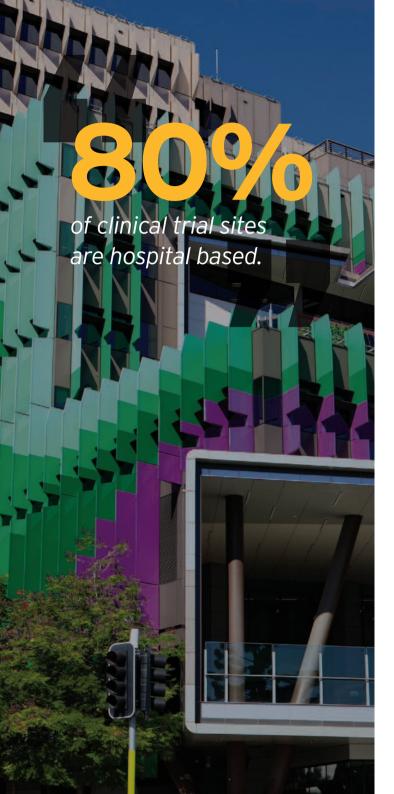
Based on the assumptions below, the estimated investment in clinical trials in Queensland in 2022 was \$177M, comprising \$130M for Commercial trials and \$47M from Non-Commercial trials.¹⁴

Queensland Health analysis of a random sample of the most recent Commercial Phase II and III trials initiated in Queensland in 2022 indicates that a Commercial trial in Queensland has a minimum average recruit target of 6 and a stretch target of 10 patients per Site. This is broadly consistent with global averages.

Queensland Health does not collect statistics on the value of clinical trials undertaken in Queensland. This has been estimated based on the assumption that each Commercial trial Site recruits on average 8 participants. Interviews with a Commercial Sponsor and a CRO suggest that the industry standard cost per patient for a Commercial trial is (av.) \$50,000 so that the average total patient cost per clinical trial site is \$400,000.



¹⁴ This number is broadly consistent with analysis undertaken by MTPConnect: Australia's Clinical Trials Sector, Advancing innovative healthcare and powering economic growth, MTPConnect, May 2021. Refer Report 3 - The ATHENA Program: Economic Benefits for the Queensland Economy and Health Benefits for the Community.



The baseline year 2022

The cost of Site activation, patient screening, Site administration, and margin is estimated to cost an additional \$50,000, so the total budgeted costs per Site is \$450,000. Each Commercial trial is assumed to engage 1.5 trial Sites so that, on average, each Commercial trial in Queensland recruits 12 participants. Queensland Health has validated these assumptions.

The baseline number of workers employed in the clinical trial industry in Queensland in 2022.

Based on the assumptions below, this Report estimates that 695 Queenslanders are therefore estimated to be directly employed in clinical trial activity in Queensland.¹⁵

Queensland Health and other data repositories do not collect data on the number of clinical trial workers employed in Queensland. In the absence of direct employment data, this Report applies the methodology outlined in the MTPConnect (MTPC) 2021 Report which estimated that on average 1.4 workers were required to support a clinical trial at a hospital site and on average 2.6 workers were required to support a clinical trial at a non-hospital Site. According to Queensland Health, 80% of clinical trial Sites are hospital-based Sites. This Report estimates that 595 workers were directly employed in the Queensland clinical trial industry in 2022 at an average of 1.5 workers per Site. It is estimated that Commercial Sponsors and CROs also employed an additional 100 workers in Queensland to manage and support the conduct of Commercial trial activity.

¹⁵ Both estimates have been discussed with Queensland Health as reasonable. For more detail refer Report 3 - The ATHENA Program: Economic Benefits for the Queensland Economy and

The baseline year 2022

This Report estimates that 12,366

Queenslanders participated in clinical trials in 2022.

The baseline number of Queensland residents that participated in clinical trials in 2022.

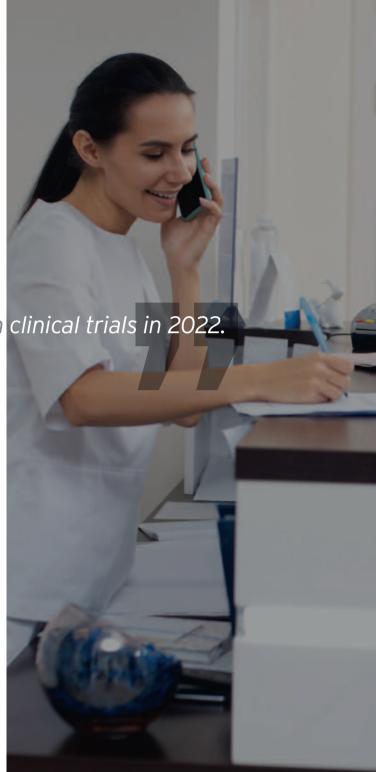
Based on the assumptions below, this Report estimates that 12,366 Queenslanders participated in clinical trials in 2022.

Queensland Health does not record the level of patient participation in clinical trials and there are no statistics or published literature that accurately record patient participation at an Australian level or state level. Bottom-up analysis undertaken by Queensland Health in 2022 suggests that a Commercial trial in Queensland involves on average 8 patients per Site and, on average, involves 1.5 Queensland Sites or 12 patients. This analysis

also suggests that a Non-Commercial trial in Queensland may involve from 35 to 70 participants. For the purposes of modelling, it is assumed that an average Non-Commercial trial involves 50 participants. Based on these assumptions, the 192 Commercial trials undertaken in Queensland in 2022 involved 2,316 patients (193 x 15), and the 201 Non-Commercial trials undertaken in Queensland in 2022 involved 10,050 participants.

The baseline growth in clinical trial numbers 2023-2029.

Queensland Health has advised that clinical trials in Queensland are expected to grow at 1.0% per annum over the period 2023-2029.



The ATHENA growth forecasts

The more valuable The ATHENA Program becomes, the more likely Sponsors will choose to locate their clinical trials in Queensland

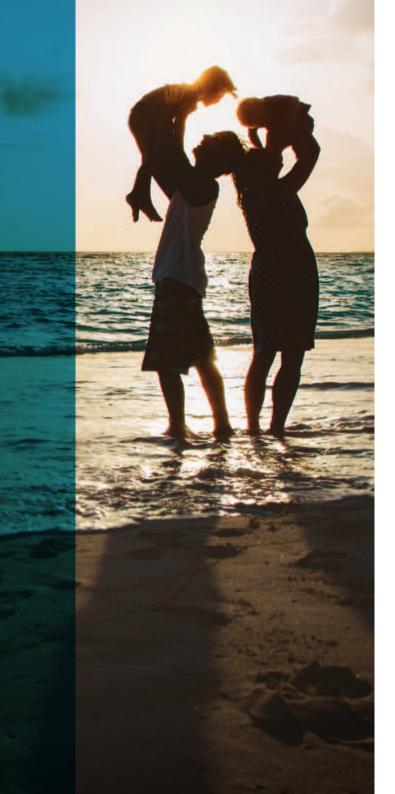
The ATHENA Base Case growth scenario starts in 2024 and projects a compound annual growth rate (CAGR) of 5% for Commercial trials and 3% for Non-Commercial trials above the projected baseline growth rate of 1% over the period 2023 -2029. The ATHENA Base Case growth forecast is based on the following assumptions:

Commercial Sponsors are price sensitive and will locate more clinical trials in Queensland because ATHENA offers comparative cost and time savings not available elsewhere in Australia or that are at least comparable to the cost and time to recruit participants in other clinical trial destinations. The cost and time savings are sufficient to support a CAGR of 5% above the baseline growth rate over the period 2024-2029.

Only 50% of Non-Commercial Sponsors will use ATHENA recognising that they may be less price sensitive because they have ready access to participants on their clinical lists, and do not have time or funding to devote to additional clinical trials given other responsibilities. A CAGR of 3% above the baseline growth rate is therefore assumed and is consistent with the impact Queensland Health expects ATHENA to generate.

Queensland Health will need to invest in Queensland's clinical trial infrastructure, transition its workforce to a full-time professional capacity, and expand it to accommodate increasing demand from Sponsors.





The ATHENA growth forcasts

The ATHENA Accelerated Case growth forecast CAGR of 10% for Commercial Sponsors is consistent with the additional clinical trial activity Commercial Sponsors expect to undertake in Queensland if ATHENA is implemented as intended. The forecast CAGR of 5.5% for Non-Commercial Sponsors reflects the upper limit of growth in Non-Commercial trials expected by Queensland Health. Athena's Accelerated Case growth forecast can be achieved if, in addition to the Base Case growth assumptions identified above -

ATHENA enhances its Patient Feasibility platform to support deeper pre-trial screening and analysis of eligible patient populations. The more valuable this platform becomes to Sponsors, the more likely it is that they will choose to locate clinical trial activity in Queensland to access these benefits.

Queensland Health invests to develop the scale and scope of the Qld Population Health Database to include patient biosamples, genetic, and lifestyle data akin to that collected by the UK Biobank. A richer, more comprehensive population-scale public health database will attract Commercial Sponsorship to fund and support its development and create new opportunities in the same way the UK Biobank has fostered new medical research in the United Kingdom.¹⁶

The ATHENA Program involves the Community in its governance framework so that the Community develops a sense of shared and active ownership of ATHENA. This includes promoting the benefits of Community and patient participation on clinical trial Patient Advisory Boards.

¹⁶ The UK Biobank has a population cohort base of 500,000. Since 2012, the UK Biobank has supported over 1,000 projects. Over 700 institutes worldwide have published using UK Biobank data including non-UK institutes with institutions such as the Broad Institute/ Harvard (USA), the University of Queensland (Australia), Erasmus University Medical Centre (Netherlands) and the Karolinska Institute (Sweden) - being heavy users. Many research groups collaborate. Researchers from the Broad Institute/Harvard and the Universities of Oxford, Cambridge and Edinburgh and Universities of Queensland and Edinburgh frequently publish together. The UK Biobank is an example of how the Qld PHD can develop with The ATHENA Program over time as a key component of Queensland Health's data infrastructure. Its development path is covered in more detail in Report 1 - Appendix A.

The ATHENA growth forcasts

Advances in molecular technology and delivery vectors are combining to unlock new frontiers in preventative and personalised medicine addressing chronic conditions.

The ATHENA growth assumptions are considered achievable for two reasons:

The ATHENA growth assumptions do not account for current or expected inflation of Site salary or medical consumables costs. The clinical trial industry is reporting Site costs 2-4x higher than 2019 levels primarily due to staffing shortages. The industry expects that higher costs will become embedded in the clinical trial system, leading to real increases in the cost of clinical trials through the forecast period 2023-2029. This will automatically lift the level of investment in clinical trial activity in Queensland.

At the same time, advances in molecular technology and delivery vectors are combining to unlock new frontiers in preventative and personalised medicine addressing chronic conditions. These advances are increasing the demand for clinical trials and measures to improve clinical trial efficiency and reduce cost.

A strong tailwind is driving the growth of the clinical trial industry globally that will accentuate the value to the Sponsors of the cost and time savings ATHENA can deliver.



Table 1: The ATHENA Program projected growth in clinical trial numbers 2023-2029, comparing baseline growth without The ATHENA

The paragraphs below show the growth in clinical trial numbers and the additional direct investment forecast under the ATHENA Base Case and Accelerated Case growth scenarios compared to project baseline clinical trial growth.

Base Case

The ATHENA Program Accelerated case

Program to The ATHENA Program Base Case and Accelerated Case scenarios

Non-Commercial trials

Non-Commercial trials

Commercial trials

,										Additional
Growth scenario		FY2022	2023	2024	2025	2026	2027	2028	2029	Trials
Baseline growth rate (without The ATHENA Program)		393	397	401	405	409	413	417	421	
The ATHENA Program base case				415	433	453	473	495	517	
The ATHENA Program Accelerated Case				429	465	504	546	592	643	
Added trials above baseline per	year (Panel A)									
The ATHENA Program Base Case				14	28	44	60	78	96	320
% above baseline				3%	7%	11%	15%	19%	23%	
The ATHENA Program Accelerated Case				29	60	95	133	175	221	712
% above baseline			7%	15%	23%	32%	42%	53%		
Added trials above baseline by Sponsor type (Panel B)										
The ATHENA Program C	Commercial trials			10	20	31	43	56	69	229

Total

Growth in clinical trial numbers

Table 1 shows the projected increase in the number of Commercial and Non-Commercial trials over the period 2023-2029 under ATHENA'S Base Case and Accelerated Case growth rates compared to 2022 forecast baseline growth rates. Table 1 shows that ATHENA'S Base Case delivers 320 additional clinical trials over this period, of which 229 are Commercial trials and 91 are Non-Commercial trials. ATHENA'S Accelerated Case projects an extra 712 trials of which 498 are Commercial trials and 214 are Non-Commercial trials. Table 1 also shows the growth in Commercial Sponsor and Non-Commercial trials for each growth case over the same period.



Growth of investment in clinical trials

Table 2 compares the additional investment in clinical trials in Queensland projected by

the ATHENA Base and Accelerated Cases to the baseline forecast growth of investment in clinical trials without ATHENA over the period 2023-2029. The additional clinical trials added under both ATHENA growth scenarios increase substantial investment in clinical trials over the period 2024-2029 compared to the project baseline growth without ATHENA.

Table 2: The ATHENA Program projected growth in clinical trial investment (\$M) 2023-2029, comparing baseline growth without
The ATHENA Program to The ATHENA Program Base Case and Accelerated Case scenarios

Total Additional

The ATTILINA Program to the ATTILINA Program base case and Accelerated case scenarios									Additional	
Growth scenario		FY2022	2023	2024	2025	2026	2027	2028	2029	Investment
Baseline growth rate (without The ATHENA Program)		177	179	180	182	184	186	188	190	
The ATHENA Program base case				192	211	233	256	269	284	
The ATHENA Program Accelerated Case			201	230	265	302	332	365		
Added trial investment abo	ve baseline by year (A)									
The ATHENA Program Base Case				12	28	48	70	82	94	334
% above baseline				7%	16%	26%	38%	44%	50%	
The ATHENA Program Accelerated Case			21	48	81	116	144	175	586	
% above baseline				12%	26%	44%	62%	77%	93%	
Added trial investment abo	ve baseline by Sponsor type (B)								
Value from extra participants per Commercial baseline trial			3	10	20	30	31	31	124	
The ATHENA Program Base Case	Commercial trials			8	17	26	35	46	57	189
	Non-Commercial trials			1	2	3	4	5	6	21
The ATHENA Program Accelerated case	Commercial trials			16	34	54	76	101	129	411
	Non-Commercial trials			2	4	7	9	12	35	70



ATHENA forecasts that the total investment in clinical trials under its Base Case scenario will increase to \$284M in 2029-\$96M above the baseline growth forecast of \$190M without ATHENA. The ATHENA Accelerated Case projects a total investment of \$365M in 2029-\$175M above the baseline growth forecast. Commercial trials contribute over 90% of the additional investment under both ATHENA growth cases.

Modelling assumes that a Commercial Sponsor invests on average \$825,000 per trial (10 patients x \$50,000 per patient and activates on average 1.5 Sites to support the trial). Modelling also assumes that a Non-Commercial Sponsor invests on average \$235,109 in a clinical trial and on average activates one Site to undertake the trial. From 2024, ATHENA has two impacts based on these assumptions:

ATHENA enables an extra 3 patients to be recruited for each Commercial trial, which increases investment per baseline Commercial trial by \$150,000 from \$675,000 to \$825,000. To account for the gradual rollout of ATHENA across Queensland, it is assumed that only 10% of baseline Commercial trials are impacted in 2024 and that ATHENA impacts an increasing proportion of baseline trials in each subsequent year until 2027—the first full year in which it is assumed that all Commercial trials in Queensland are undertaken with the support of ATHENA.

ATHENA increases the number of trials undertaken in Queensland at a higher investment of \$825,000 per trial.

Table 2 (A) shows the additional value enabled by ATHENA under its Base Case and Accelerated Case scenarios above the forecast baseline growth rate without ATHENA. In 2024, the ATHENA Base Case enables \$12M in additional investment in clinical trials comprising \$8M additional investment in Commercial trials and \$1M in Non-Commercial trials. The ATHENA Base Case and Accelerated Case growth scenarios also include \$3M from recruiting an additional 3 participants for 10% of baseline Commercial trials (Table 4(B)).

Table 2 also shows the proportion of additional value represented by Commercial and Non-Commercial trials under each growth scenario. The ATHENA Base Case projects that an additional \$210M will be invested in clinical trials in Queensland over the forecast period 2024-2029. This comprises an additional \$189M in Commercial trials and \$21M in Non-Commercial trials. On average, ATHENA would enable additional investment in clinical trials of \$35M per year, comprising \$31M in additional Commercial trials and \$4M in additional Non-Commercial trials per year.

The ATHENA Accelerated Case projects that an additional \$481M will be invested in clinical trials in Queensland over the period 2024-2029. This comprises an additional \$411M in Commercial trials and \$70M in Non-Commercial trials. On average, ATHENA would enable additional investment in clinical trials of \$80M per year, comprising \$69M in additional Commercial trials and \$11M in additional Non-Commercial trials per year. The difference in

additional investment reflects the difference in the projected growth of Commercial and Non-Commercial trials.

The economic and health benefits discussed below can be applied directly to this investment to calculate the additional value ATHENA generates for the Queensland economy over the period 2023-2029. Economic benefits include the direct and indirect value-added benefits arising from the additional direct investment in clinical trial activity in Queensland, which is commonly expressed as a value-added multiplier, and health costs paid for by sponsors as part of their clinical trial protocol that would otherwise be incurred by Queensland Health (avoided health costs). Health benefits to the Queensland Community arise from participation in more trials that accelerate the number of beneficial therapies that are approved for use and widely adopted to prevent, treat, or manage patients with chronic disease.



The economic value-added multipliers

ATHENA generates economic benefits for Queensland in three ways:

direct benefits arising from Commercial sponsored investment in clinical trials conducted in Queensland, including additional direct employment,

indirect downstream benefits for businesses that supply products and services to the clinical trial industry and industry suppliers in the form of increasing demand, and

induced effects generated by workers directly and indirectly employed in the clinical trial sector who spend a proportion of their wages or contract payments in the economy (the Type 1 multiplier) and induced effects from businesses who invest in new equipment or premises to support higher demand for their goods and services (the Type 2 multiplier).

Given the difficulties of estimating induced investment, this Report uses a Type 1 multiplier and measures its impact by reference to gross value-added consistent with international and Australian literature. The Type 1 multiplier is typically expressed as (i) a gross value-added ratio (Direct: Indirect + Induced effects), and (ii) an employment ratio (Direct: Indirect + Induced employment).

This Report finds that the gross valueadd economic multiplier for clinical trial activity is between 1.9 and 2.8, based on an extensive literature review focusing on developed economies with comparable health infrastructures, including the UK, Europe, and the United States. The median multiplier identified from literature studies is 2.5. The employment multiplier is 2.0 based on an analysis of relevant literature studies so that for every person directly employed in clinical trials, another person is indirectly employed in a supply chain business.



Figure 6: The multiplier effect of investment in an Industry Sponsored clinical trial Industry **Sponsors** Additional investment in clinical trials Direct value added **Direct employment Indirect effects** (first order effects) Indirect value added Indirect employment SUPPLY CHAIN INDUSTRIES Induced Value-added (second order effects) **Induced consumption** Induced investment

(Type 2 value-added multiplier)

(Type 1 value-added multiplier)

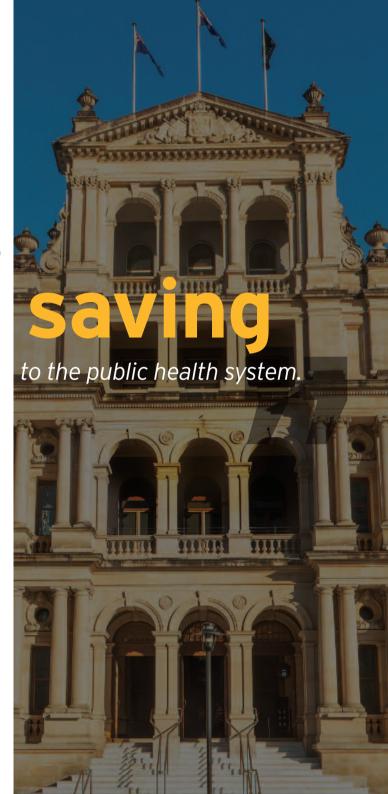
Avoided health costs

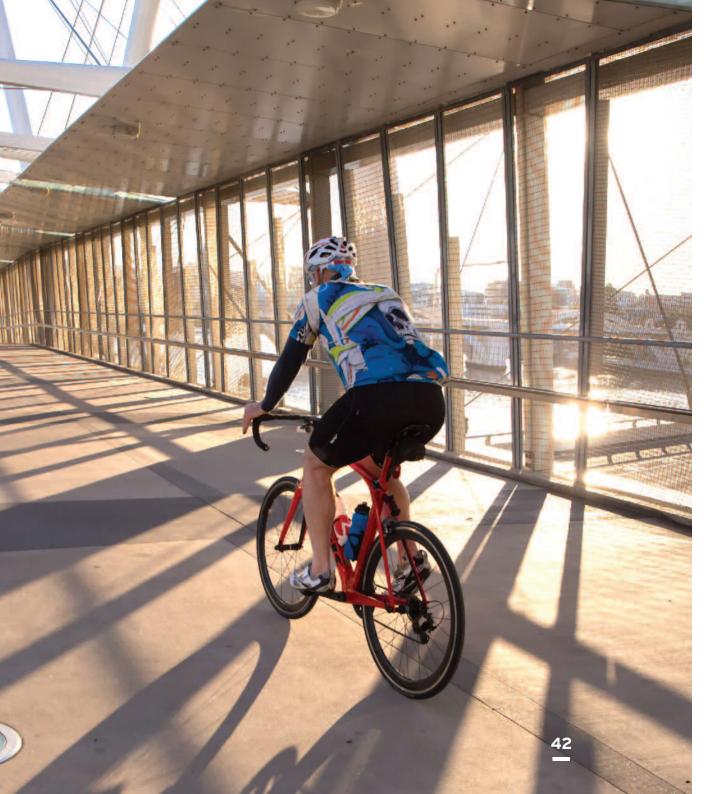
Avoided health costs represent a

direct

Avoided health costs include the cost of care and therapies that the public health system, private health insurers, and consumers would otherwise pay for as part of the standard of care for the participant's condition but are paid for instead by the Sponsor as part of the treatment regimen for the participant stipulated by the trial. They typically only arise in Phase II-IV trials and typically relate only to Commercial Sponsors who develop new drug therapies, not Non-Commercial Sponsors who typically do not have the financial and other resources needed to develop new drugs. Avoided health costs, therefore, represent a direct saving to the public health system.

Avoided health costs depend on the type of trial. A proportion of trials use new drugs or therapies in conjunction with the standard treatment drug, so the standard of care is still incurred by the public health system. In other cases, the standard of care may not use a drug. Avoided costs are therefore best interpreted as arising when the use of the study drug replaces the drugs used as part of the standard of care. In the absence of Australian empirical data, this Report assumes that avoided drug costs are \$20,000 per participant and that standard of care costs are \$49,500 per participant, which reflects avoided cost studies in the UK, Europe, and Canada.





Health benefits

Health benefits include improved patient outcomes and quality of life, including more years spent in good health and higher quality years living with disease, fewer early deaths, higher workforce participation and higher productivity, improved standard of care and higher efficiency as new therapies become accessible and improved culture and infrastructure in healthcare to support ongoing research. These benefits are additional to the gross value-added economic benefits described above.

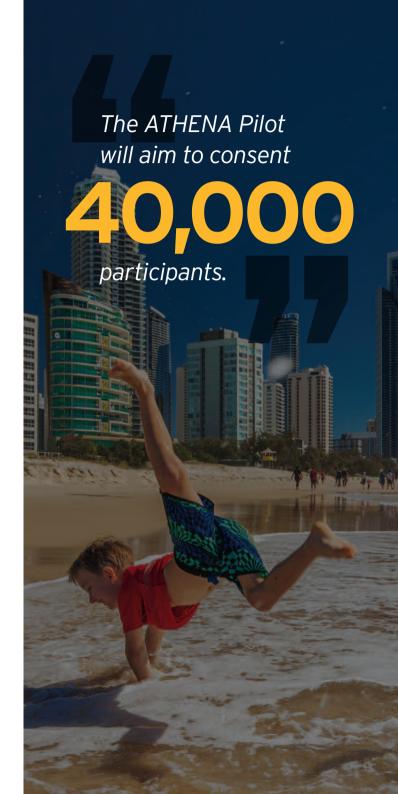
Health benefits are typically expressed as a health benefit multiplier and calculated on an economy-wide basis based on reported public investment in the wider medical research sector. Health benefit multipliers in Australia range from 2.7-3.9 based on a succession of commissioned reports over the last 15 years undertaken by Deloitte Access Economics and KPMG, and a 2022 McKinsey Report. All Reports apply the same methodology. A specific clinical trial health benefit multiplier is difficult to calculate without a detailed empirical analysis, which is beyond the scope and timeframe of this Report.

ROLLOUT PLAN, COST MODEL, AND MEASURES OF SUCCESS

ATHENA plans to begin rollout to Queensland Health's 16 HHS Districts via an initial pilot program in the Sunshine Coast HHS District at the Sunshine Coast University Hospital. The pilot will cost \$2M and will run for 22 months between September 2022-September 2024, the last year as a 'live' operation. The Pilot will aim to consent 40,000 participants or 80% of the 50,000 SCUH participant population over the operating period of 4 months. During this period, ATHENA will evaluate a range of fees for service structures with Sponsors and Medical Researchers.

The ATHENA Rollout program will implement the HHS engagement model, rollout procedures and operating model validated during the ATHENA Pilot. The rollout will proceed as an ongoing Queensland Health campaign akin to the Queensland Health Breast Cancer screening campaign using Queensland Health Hospital and allied clinical settings to promote ATHENA and encourage the Community to join ATHENA and make their health data available to support medical research and participate in Queensland-based clinical trials.

ATHENA estimates the rollout cost will be \$4M over 2 years to support ATHENA resourcing, rollout, and Community Campaign, after which it is expected to decline to \$2M to cover ATHENA resourcing. If ATHENA shifts to a feefor-service model, it hopes to at least cover annual ongoing operational costs.



ROLLOUT PLAN, COST MODEL, AND MEASURES OF SUCCESS

This Report includes a list of success metrics to measure the health of the ATHENA engine in relation to Sponsors, the Community and the Government, which are ATHENA's key stakeholders. These include input metrics that drive the ATHENA engine and ATHENA's revenue and Community engagement model, output metrics that target growth in the volume of Commercial sponsored trials undertaken in Queensland, the proportion of Queenslanders living in regional, rural, and remote areas of Queensland who participate in clinical trials, and growth in direct investment in clinical trials attributable to ATHENA from the 2022 baseline value. This Report includes an evaluation of the ATHENA Program against the Queensland Government REDS and Office of the Chief Scientist's alternative investment decision framework and the more traditional ROIC evaluation metric.



