



Nucleus Network

UNDERTAKING PHASE 1 CLINICAL TRIALS IN AUSTRALIA DURING A TIME OF UNCERTAINTY

10 steps to successfully navigating your clinical trial

In the presence of the challenges facing our industry as a result of COVID-19, Nucleus Network is committed to supporting our clients to the highest degree possible over the coming months. We have developed this comprehensive ten-step action plan to help you navigate your Phase 1 therapeutic trials through the current headwinds. (COVID-19) pandemic.

INTRODUCTION

NUCLEUS NETWORK: ON THE FRONTLINE OF VACCINE DEVELOPMENT

Nucleus Network (Nucleus) is continuing to monitor and respond to the evolving challenge of the global COVID-19 pandemic. As Australia's largest provider of phase I services, with approx. 150 Phase 1 beds of the total approx. 250 Phase 1 beds available in Australia, we provide this re-assurance to our clients and the wider Pharmaceutical and Biotechnology community of the pro-active steps undertaken by Nucleus in this time of uncertainty.

It is essential that development of new potential vaccines and therapies continue. Nucleus has implemented strict adherence to the Australian Government Department of Health, Victorian Health Department and Queensland Health Department recommendations for COVID-19, as well as instituting additional precautions and risk mitigation strategies. We are foremost committed to the safety of our staff, trial participants, and the broader community. The ripple effect of temporarily reducing the Phase 1 industry capacity would jeopardize COVID-19 vaccine development and delay development of potential new treatments from being available to global communities.

This pandemic has brought to the forefront of the world's general population the importance of drug development. Until the rate of infection can be slowed – or a vaccine or effective treatment is available – the world's health system will continue to be challenged, and potentially overwhelmed, by COVID-19. With the potential shortage of capacity in the health care system to treat the critically infected the continuing of drug development is more important than ever.

It is these therapeutic developments that can potentially improve the health outcomes of patients and reduce the future burden on the health system.

On an annual basis Nucleus conduct approx. 60 Phase 1 studies in healthy volunteers and patient populations, including FIH SAD and MAD, drug interaction, TQTc, ethnopharmacology, and biosimilar trials. Crucially, we regularly conduct vaccine clinical trials.

We have been awarded several first in human COVID-19 vaccine trials, which are due to commence shortly, and our preparedness as a business to continue to operate is guided by 10 key pillars:

- 1 **Multi-Site reach in Australia**
- 2 **Size, scale and savings**
- 3 **World-class medical precincts**
- 4 **Social distancing measures**
- 5 **Robust participant pipeline**
- 6 **Rigorous participant screening**
- 7 **Dedicated trial teams**
- 8 **Gold standard infection control**
- 9 **Cross-functional response team**
- 10 **Supply chain surety.**

These 10 key pillars underpin our processes, behaviors and values as Australia's largest Phase 1 clinical trials provider. They also ensure we can continue to support our clients' clinical trials requirements during this pandemic crisis and prepare them well for the next large-scale challenge.

Nucleus is the vital first step in unlocking the next generation of vaccines.

NUCLEUS NETWORK AT A GLANCE

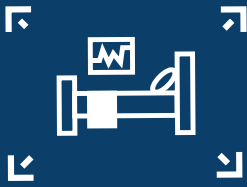
- + **Accelerated Clinical Development path**
- + **Quality Standards & Audit history**
- + **Financial Incentives**
- + **Unrivalled Excellence**
- + **Specialist Capabilities**
- + **Premier Locations**
- + **Diverse Participant Pool**
- + **High Repeat Clients**
- + **500 + Staff**

10 STEPS TO SUCCESS



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1 MULTI-SITE REACH IN AUSTRALIA



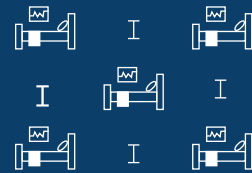
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2 SIZE, SCALE AND SAVINGS



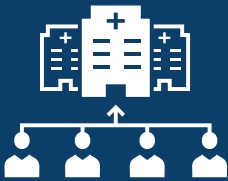
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8 GOLD STANDARD INFECTION CONTROL



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9 CROSS-FUNCTIONAL RESPONSE TEAM



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10 SUPPLY CHAIN SURETY

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WITH A WORKFORCE OF
OVER 400 SPECIALISTS,
... **NUCLEUS NETWORK**
IS UNIQUELY POSITIONED
TO PROVIDE CLIENTS
WITH A RANGE OF PHASE 1
CLINICAL TRIAL SERVICES.

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1 MULTI-SITE REACH IN AUSTRALIA

To succeed in today's global economy, more and more companies are relying on a geographically dispersed workforce. They build teams that offer the best functional expertise from around the world, combined with deep, local knowledge of the most promising markets. They draw on the benefits of international diversity, bringing together people from different cultures with varied work experiences and diverse perspectives on strategic and organizational challenges.

All this helps multinational companies compete in the current business environment.

As the coronavirus pandemic spreads globally, the mobilization of skilled resources has become a critical consideration. Availability of valued experts, combined with travel restrictions and isolation periods, is placing increasing pressure on the life sciences sector.

Nucleus is the only Phase 1 provider with multiple clinical units in different states in Australia and with access to a population of 7.5 million people to draw upon for clinical trial participation. Nucleus two-site solution across multiple states is proving to be a unique valuable solution for Biotechnology, Pharmaceutical companies and CROs with specific study requirements.

With a workforce of over 400 specialists, which includes 250 clinical personnel, and physical assets in the capital cities of Melbourne and Brisbane, Nucleus is uniquely positioned to provide clients with a range of Phase 1 clinical trial services. First-in-human studies can be conducted at either of the two clinical units with specializations available at each clinic. Both locations are governed by the same Australian guidelines for approving a Phase 1 study.

The key advantages of Nucleus during the COVID-19 pandemic include:

Infrastructure: The ability to offer our sponsors a dual site strategy to conduct their clinical trial under one HREC application and approval, at a reduced start-up cost. As a risk mitigation strategy, we offer a multi-site pathway which allows sponsors to initiate the conduct of their clinical trials at both units, where one site acts as the primary unit. This approach enables the ability to actively recruit a high volume of participants over a short duration at either clinical unit. In the scenario that one clinical unit is ever compromised, we are able to swiftly shift the study activity with little to no impact on study timelines to either clinical unit.

Medical Expertise: The Senior Medical Team are all Nucleus employees and include:

- *Five Principal Investigators*
- *Chief Medical Officer, Medical Oncologist,*
- *Medical Director, Infectious Disease Physician,*
- *Three Associate Medical Directors, Clinical Pharmacologist.*

Infectious Disease Expertise: Access to infectious disease expertise for trial development and oversight, by Dr. Paul Griffin, Nucleus Medical Director and Director of Infectious Disease at Mater Health Services. Dr. Griffin is actively involved in the research and development of vaccines including COVID-19. This, along with his advocacy work in the community, uniquely positions Nucleus to leverage his expertise and advise sponsors on their COVID-19 programs.



KEY TAKEAWAYS

- + **Nucleus has geographical spread with Phase 1 facilities in Melbourne and Brisbane**
- + **Infectious Disease Expert to advise on the rapidly evolving landscape of COVID-19**
- + **Risk mitigation strategies should a facility become compromised**



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NUCLEUS NETWORK IS
AUSTRALIA'S LARGEST PHASE
1 CLINICAL TRIALS PROVIDER
OWNING 150 BEDS OF THE
TOTAL APPROXIMATE 250
DEDICATED PHASE 1 BEDS
AVAILABLE IN AUSTRALIA.

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2 SIZE, SCALE AND SAVINGS

The FDA recognizes that the COVID-19 pandemic “may impact the conduct of clinical trials of medical products. Challenges may arise, for example, from quarantines, site closures, travel limitations, interruptions to the supply chain for the investigational product, or other considerations if site personnel or trial subjects become infected with COVID-19. These challenges may lead to difficulties in meeting protocol-specified procedures, including administering or using the investigational product or adhering to protocol-mandated visits and laboratory/diagnostic testing. FDA recognizes that protocol modifications may be required, and that there may be unavoidable protocol deviations due to COVID-19 illness and/or COVID-19 control measures.”¹

Access to clinics with medical experts and an appropriate number of beds has become a top line consideration for clients.

Nucleus is Australia’s largest Phase 1 clinical trials provider owning 150 beds of the total approximate 250 dedicated Phase 1 beds available in Australia.

All data produced through Nucleus clinics is FDA and EMA ready. As well as adhering to ICH preclinical toxicology and safety pharmacology guidelines, Nucleus has been audited by the FDA, inspected by the EMA and has previously held ANVISA certification.

Speed to market for therapeutic solutions is a priority. Clients benefit from Australia’s simplified and efficient regulatory process and to support the current climate in the development of

COVID-19 treatments, the Alfred HREC has developed an expedited review process pathway for COVID-19 applications.

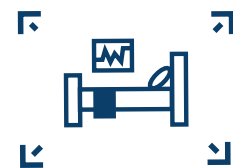
All COVID-19 applications will be reviewed out of session with a three-business day review cycle. This is currently the fasted review pathway for COVID-19 applications available to sponsors in Australia.

Trial approval for other Phase 1 studies continues to be achieved within four to five week and Australia remains as having one of the fastest clinical trial approval systems in the world. Australia’s robust regulatory framework falls under the Clinical Trial Notification (CTN) system. The Human Research Ethics Committee is the main reviewer and approver under this system.

Conducting Phase 1 trials with Nucleus is also cost effective. With the AUD/ USD currency pair falling over 10% since January 2020, and more significant reductions in the Australian dollar in the past few weeks, currency exchange rates are offer significant savings.

As of 23rd March 2020, USD \$1.0 is buying AUD \$1.73

In addition, clients may be eligible for R&D Tax incentives which provides a further 43.5% cost saving.



KEY TAKEAWAYS

- + **Nucleus is Australia’s largest Phase 1 Clinical Trials provider**
- + **R&D tax incentives can provide a cash refund of up to 43.5%**
- + **Pricing in AUD offers significant savings against the USD**

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NUCLEUS NETWORK IS
CO-LOCATED WITHIN TWO OF
THE SOUTHERN HEMISPHERE'S
MOST RENOWNED MAJOR
TEACHING HOSPITALS.

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3 WORLD-CLASS MEDICAL PRECINCTS

According to Gerry McDougall, PwC US' Health Sciences Leader and renowned for his experience in health precincts, Australia has the ideal environment – physically, culturally and technologically – for it to become the leader in bio-tech clusters, health service delivery and research capabilities which could change the world.²

"The forward thinking of convergences across the entire healthcare ecosystem and strategically focusing on health and healthcare as major economic drivers from an holistic perspective is very exciting."³

According to McDougall, Australia also has a compelling case for creating a world-class clinical trials sector because of existing infrastructure.

"What you have in Australia that truly sets you apart is not about the health sector or precincts themselves—it is having the environment and culture that can not only retain your brightest minds, but attract the world's best thinkers."⁴

Nucleus is co-located within two of the southern hemisphere's most renowned major teaching hospitals: the Alfred Hospital in Melbourne and the Royal Brisbane and Women's Hospital in Brisbane.

In Melbourne, Nucleus is part of the Alfred Research Alliance. With more than 8000 health professionals, researchers, students and support staff, the Alfred Research Alliance is an innovative, multi-layered collaborative community which brings together some of the world's leading experts in almost every field of biomedical, translational, clinical

and public health research, and in education and healthcare.

In Brisbane, the Nucleus clinic resides within the QIMR Berghofer precinct at the Royal Brisbane and Women's Hospital, Brisbane, Australia. QIMR Berghofer is one of Australia's most successful medical research institutes focused on improving health by developing new diagnostics, better treatments and prevention strategies, specifically in the areas of cancer, infectious diseases, mental health and complex disorders.

Working in close collaboration with clinicians and other research institutes, QIMR Berghofer is home to more than 600 scientists, students and support staff.

Across Melbourne and Brisbane, the Nucleus precinct location affords the unique ability to access:

- 1 **hospital emergency services**
- 2 **hospital leading clinicians**
- 3 **hospital patients**
- 4 **complex pharmacodynamic assessments.**



KEY TAKEAWAYS

- + **Australia is renowned globally for the quality of its medical research**
- + **Australia is an emerging world-leader in health precincts and bio-tech clusters**
- + **Nucleus Melbourne clinic is co-located within the Alfred Hospital Alliance precinct**
- + **Nucleus Brisbane clinic is co-located within the QIMR Berghofer Royal Brisbane Hospital precinct**



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STRATEGICALLY DESIGNED
FOOTPRINT OF THE **NUCLEUS
NETWORK** FACILITIES ENABLES
DEDICATED ISOLATION WARDS,
SCREENING AREAS, ADMISSION
AREAS, CONSULTING ROOMS
AND BATHROOM AMENITIES.

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4 SOCIAL DISTANCING MEASURES

Social distancing is a central aspect of plans by Governments, and advice by the World Health Organization (WHO), to limit the spread of the Coronavirus.

According to New Scientist, there is evidence from outbreak simulations, and from previous outbreaks, including the 1918 flu pandemic and the 2014 Ebola outbreak, that social distancing can effectively limit the spread of infections. Coronavirus belongs to a family of viruses that are predominantly transmitted by droplets emitted from the mouths and noses of infected people when they cough or sneeze, which can land on surfaces and people's hands.⁵

Social distancing in a confined clinical environment can have its own challenges.

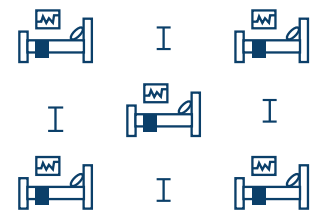
With almost 2000 sq meters of dedicated clinical space at the Melbourne facility, and over 2000 sq meters at the Brisbane facility, the recent Australian Government mandates of 4 sq meter per person does not impact Nucleus ability to schedule trials.

Implementing a belts and braces approach, Nucleus has instituted an occupancy approach of 'every second bed'. With the largest share of Phase 1 beds in Australia, Nucleus is able to conduct – without interruption – clinical trials, utilizing every second bed in its Melbourne and Brisbane clinics. A supportive large dedicated outpatient area means scheduled screening and follow-up visits continue with minimal impact.

The strategically designed footprint of the Nucleus facilities enables dedicated isolation wards, screening areas, admission areas, consulting rooms and bathroom amenities.

According to Nucleus Chief Operating Officer Charlotte Hall, "this approach has been highly successful in providing our participants and staff added peace of mind and safety measures within our clinics. We've taken the best practice advice from the WHO and effectively doubled the distance between accommodation of our trial participants."

As health authorities grapple with increasing number of confirmed cases, and a strain on healthcare facilities, the Nucleus approach of 'every second bed' is setting new benchmarks in safety and risk mitigation.



KEY TAKEAWAYS

- + WHO advocates social distancing as a key initiative in preventing virus spread
- + Typical clinical trial facilities face challenges in adequate distancing measures
- + Nucleus has implemented 'every second bed approach'

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AT NUCLEUS NETWORK,
NEW LEAD GENERATION
THROUGH ADVERTISING
CAMPAIGNS TARGETING
MULTIPLE DEMOGRAPHICS
IS AN ONGOING DAILY
ACTIVITY.

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5 ROBUST PARTICIPANT PIPELINE

A diverse group of clinical trial participants can provide findings that are more generalizable to the entire population and also identify groups where treatment may not be effective. Both of these are important considerations when it comes to creating interventions that produce the greatest benefit for the most people.⁶

Diversity, which includes everything from race, ethnicity, and age to gender and disease stage, is essential to the clinical trial industry to improve the safety and efficacy of treatments for everyone. By designing studies that are sensitive to the cultural and social norms of diverse populations, traditionally underrepresented groups can be better engaged in clinical research.⁷

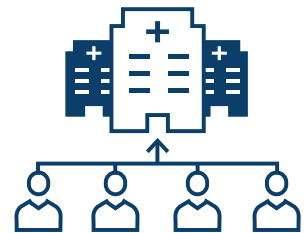
Access to demographically diverse participant groups is a distinct advantage for clients looking to access best-in-class data from Phase 1 trials. The Nucleus locations of Melbourne and Brisbane and represent a combined total population of approx. 7.5 million. These cities include diverse population groups with Melbourne ranked as one of the most diverse cities in the world. Melbourne has the 10th largest immigrant population among world metropolitan areas, and ranked fourth globally for residents born overseas.

A robust and 'loyal' database of eligible participants is vital for targeted recruitment communications tactics. At Nucleus, positive clinical trial experiences have transformed repeat participants into community educators and advocates to family, friends and the

broader community. Outside of targeted advertising campaigns, these first-hand referrals are proven to be one of the most effective forms of new lead generation and eligible study conversion. This currently represents over one quarter of our pipeline.

At Nucleus, new lead generation through advertising campaign targeting multiple demographics is an ongoing daily activity. This helps to source trial-specific candidates whilst augmenting our overall participant database pool.

Nucleus has witnessed an above-average increase in participant enquiries in the first quarter of 2020, coinciding with increased media exposure relating to COVID-19. This phenomenon is attributable to the slow-down in many industries and the casualization of workforces. As a result of this, Nucleus trend analysis predicts the pipeline of diverse participant groups to continue increasing above average trend lines for the remainder of 2020.



KEY TAKEAWAYS

- + Good participant recruitment underpins effective studies and good data
- + Access to diverse participant groups is attractive to clients
- + Nucleus locations are recognized for diverse population groups
- + Participant pipeline for 2020 trending above average



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NUCLEUS NETWORK HAS
EXPANDED ON ITS BEST PRACTICE
RECRUITMENT FRAMEWORK
THAT ADDRESSES EACH TOUCH
POINT OF THE PARTICIPANT
RECRUITMENT... DURING THE
COVID-19 PANDEMIC

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6 RIGOROUS PARTICIPANT SCREENING

The ever-changing landscape associated with COVID-19 is presenting challenges to all businesses. None more so than participant recruitment for clinical trials.

Measures to mitigate the spread of COVID-19 within participant cohorts must be assessed at every touchpoint of the participant journey.

From outbound campaigns, lead generation content and online forms, through to phone screening and on-site Medical assessments; screening must be regular, rigorous and well documented.

Nucleus has expanded on its best practice recruitment framework that addresses each touch point of the participant recruitment and onboarding process in recruiting during the Covid19 pandemic. This process extends to all inpatient and outpatient studies.

The following questions have been added to our regular phone screen criteria:

- *Have you traveled overseas in the last 2 weeks? If answered yes, participant is not booked in for a screening until the 15th day onward.*
- *Have you had any contact with a confirmed Coronavirus / COVID -19 patient? If answered yes, participant is not booked in and further questions on their contact is requested. Participants must be symptom free for 14 days post contact of a confirmed case of COVID-19 before being allowed to participate in screening for any study.*

- *Do you have any cold or flu symptoms? If answered yes, participant is not booked in and they are advised to get back in touch once the symptoms have passed.*
- *A comprehensive information pack is provided in the confirmation email to participants, outlining how we are handling COVID-19 within the clinic.*

Participants are also required to read and sign the Nucleus travel questionnaire as part of the clinical pre-screening. This on-site clinical pre-screening includes a series of comprehensive questions for both inpatient and outpatient participants. Crucially, this is conducted in the reception area away from all active clinical spaces.

Upon arrival at reception, hand sanitizing measures are requested of all participants, staff and suppliers. Effective control measures are implemented (see section 8) for participants with any questionable health profiles.

External participant visitors have also been banned from entering all Nucleus clinical facilities for the foreseeable future.



KEY TAKEAWAYS

- + Participant recruitment protocols critical
- + Every participant touch point must be considered
- + Nucleus protocols for participant recruitment include several preventative measures

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WITHIN BOTH THE **NUCLEUS NETWORK** MELBOURNE AND BRISBANE CLINICS, DEDICATED TEAMS OF CLINICAL STAFF HAVE BEEN ASSIGNED TO WORK ONLY IN FUNCTIONAL DESIGNATED AREAS.

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7 DEDICATED TRIAL TEAMS

Cross-pollination of medical officers, clinical staff and teams within a clinical trials environment is common practice. However, in the current climate of mitigating the spread of infection, the establishment of dedicated trial teams is a savvy, practical and common-sense approach.

With a clinical workforce exceeding 250 staff, Nucleus has implemented a unique team structure that allows for dedicated clinical staff to be assigned to specific functions.

Within both the Nucleus Melbourne and Brisbane clinics, dedicated teams of clinical staff have been assigned to work only in functional designated areas.

There are dedicated clinical teams focused on all screening / outpatient visits only – they are not permitted to enter or access the clinical unit to work with confined participants. Complementary teams are assigned with the specific task of working in the clinical unit only – they are not permitted to enter dedicated screening areas.

Staff from different teams are also required not to co-mingle, ensuring there is no cross-pollination of team members. Virtual meetings and technology solutions are implemented to facilitate inter-team communications. However, where there is a valid study requirement for inter-team staff to co-mingle, full PPE safety measures are implemented.

Through this separation method, Nucleus reduces the risk of inhouse contamination across different operational areas of the clinic. This best-practice approach also allows for the efficient isolation of a specific team in the event of contagion, whilst ensuring business continuity for all in-patient and out-patient studies.



KEY TAKEAWAYS

- + Establishment of dedicated teams as a risk mitigation strategy
- + Large clinical workforce
- + No cross-pollination of teams across different functional areas at Nucleus
- + Contingency for rapid isolation of a team without impact on overall business and studies



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MEASURES IMPLEMENTED
BY **NUCLEUS NETWORK**
GO ABOVE AND BEYOND
RECOMMENDED CLINICAL
PRACTICES AND PROVIDE
A GOLD STANDARD IN
INFECTION CONTROL.

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8 GOLD STANDARD INFECTION CONTROL

Healthcare-acquired infections are one of the most common complications of health care. They are a significant patient safety issue, and can also be an Occupational Health and Safety issue. A well-functioning Infection Prevention and Control program helps minimize these risks for patients, residents, visitors and staff.⁸

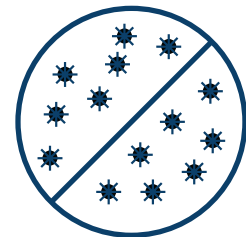
Transmission-based precautions (TBPs) are used in addition to standard precautions when standard precautions alone may be insufficient to prevent transmission of infection. TBPs are used for patients known or suspected to be infected or colonized with epidemiologically important or highly transmissible pathogens that can transmit or cause infection.⁹

The type of TBPs applied is based upon the mode of transmission of the pathogen. For diseases that have multiple routes of transmission, more than one TBP category is applied. Droplet transmission – such as that profiled in COVID-19 – is identified as a route of transmission.

In addition to the standard infection control practiced in its two clinics, Nucleus has implemented TBPs in response to the increased risk associated with COVID-19. These TBPs include:

- *Regular hand sanitizing using alcohol-based handrub with 70% alcohol*
- *'Every second bed' approach as outlined in section 4 'social distancing'*
- *Minimum of 1.5m spacing in waiting, dining and recreational areas*
- *N95 masks worn by medical officers and nursing staff during all possible COVID-19 participant interactions.*
- *Gloves, gowns, goggles and personal protective equipment (PPE) worn by medical officers, nursing and clinical staff during all participant interactions*
- *Our cleaning is completed with the same products as used by the Hospitals.*
- *Infection prevention and control procedures in line with WHO and best practice guidelines.*

These measures implemented by Nucleus go above and beyond recommended clinical practices and provide a gold standard in infection control.



KEY TAKEAWAYS

- + **Infections in clinical settings are an OHS and patient safety issue**
- + **TBPs provide a higher level of infection control**
- + **Nucleus has implemented TBPs at its clinics**
- + **Minimum of 1.5m spacing through all Nucleus facilities**

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THE NUCLEUS NETWORK
CRITICAL RESPONSE TEAM HAS
DEEP SPECIALIST SKILL SETS, ALL
WORKING TOWARDS ENSURING
THE SAFETY AND WELLBEING OF
EMPLOYEES, ALONGSIDE COMMUNITY
AND COMMERCIAL CONSIDERATIONS.

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9 CROSS-FUNCTIONAL RESPONSE TEAM

In responding to the COVID-19 crisis, Nucleus have assembled a cross-functional Crisis Response Team that are responsible for setting the overall organizational tone of the COVID-19 response, acting as a single source of truth, in real time, for all information and actions related to the outbreak and response.

It is headed by the CEO and includes a medical expert, an operations leader, head of finance, and a customer representative. The team has deep specialist skill sets, all working towards ensuring the safety and wellbeing of employees, alongside community and commercial considerations.

The Nucleus Crisis Response Team

CHIEF EXECUTIVE OFFICER

CHIEF OPERATING OFFICER

CHIEF FINANCE OFFICER

CHIEF MEDICAL OFFICER

**VP MARKETING AND
BUSINESS DEVELOPMENT**

The Crisis Response Team has proactively prepared a response pack of internal intelligence relating to clinical operations, financial modeling, customer engagement, corporate operations, staff welfare, corporate affairs, media statements, participant recruitment and establishment of a client enquiry hotline and FAQ document.

On a daily basis this team reviews every active clinical trial, as well as clinical trials being planned for ethics, and assesses the current landscape as it relates to the safety of employees and participants. In a situation where the safety of employees or participants requires further discussion a minimum of two members of the Crisis Response Team will liaise directly with the client.

In addition, the teams responsibilities can be summarized as follows:

- *acting as the single source of truth for issue resolution*
- *ensuring that sufficient resources are deployed where and when needed*
- *coordinating the portfolio of remedial actions across the work streams of all teams, based on scenarios and triggers*
- *aligning team leaders on scenarios, with the help of roundtables and other exercises as needed.¹⁰*



KEY TAKEAWAYS

- + **Best practice response to a crisis requires a cross-functional team**
- + **Speed over elegance is the recommended approach**
- + **Nucleus has a cross-functional team of subject matter experts**
- + **Nucleus has measures, processes and procedures in place to respond to evolving situation systematically**



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LONG-STANDING RELATIONSHIPS
HAVE ALLOWED **NUCLEUS**
NETWORK TO SOURCE CLINICAL
SUPPLIES WITH CONFIDENCE.

”

10 SUPPLY CHAIN SURETY

COVID-19 has placed the global supply chains for both pharma and medtech products under pressure.

Organizations have scrambled in an attempt to stabilize supply chains by using safety stocks, alternative sources, and working with suppliers to solve bottlenecks. However, the fast-moving nature of COVID-19, and the closure of Chinese suppliers, has left many organizations – including clinical trial providers – with only short term supplies.

Nucleus has preferred providers for all clinical supplies. These long-standing relationships have allowed Nucleus to source clinical supplies with confidence.

While many pharma and medtech supply chains have been able to largely meet demand to date from existing inventory, Nucleus has activated analytics and scenario modeling to fully understand demand and supply chains. This has also assisted to identify the top products facing potential supply issues, with a perspective on the next few months, taking into account potential more-aggressive infection scenarios.

Accordingly, Nucleus has implemented an allocation process for affected products and is actively managing the distribution of constrained products.

Nucleus has also taken additional steps to bolster supply chains and operations to withstand the impact of future public health crises. This involves multiple steps, including further diversifying (and building further redundancy and resilience into) international supply chains, employing ongoing contingency planning as the new normal, strategically holding inventory to recognize the supply chain risks identified in this global crisis, and developing a manufacturing network strategy to enable longer-term resiliency.



KEY TAKEAWAYS

- + **Nucleus has long-standing supply chain relationships**
- + **Nucleus is actively managing the distribution of constrained products**
- + **Nucleus has taken steps to bolster supply chains for business continuity**

CONCLUSION

The coronavirus pandemic is testing the leaders of companies and organizations in every sector around the world. Its consequences could last for longer and present greater difficulties than anyone anticipates.

But for biotech innovators, pharmaceutical companies and clinical research organizations, this is not the time for hesitation. These organizations are on the frontline of vaccine development and improving the health of communities around the globe with a number of vital drug discoveries.

The Nucleus roadmap outlined in this document is your foundation for trial realization and advancement, all within one of the most renowned countries for medical and clinical research excellence.

In summary, the key value proposition underpinning your success for conducting Phase 1 trials with Nucleus in Australia in a time of uncertainty, include:

Speed: Nucleus is Australia's largest Phase 1 clinical trials provider. With approx. 70% of all available beds for such trials, a workforce of over 400 specialists, and two clinics in the capital cities of Melbourne and Brisbane, Nucleus is uniquely positioned to provide specialized Phase 1 clinical trial services.

Clients benefit from Australia's simplified and efficient regulatory process with trial approval for Phase 1 studies achieved within four to five weeks. COVID-19 studies can expect much faster approvals.

Quality: All data produced through Nucleus clinics is FDA and EMA ready. As well as adhering to ICH preclinical

toxicology and safety pharmacology guidelines, Nucleus has been audited by the FDA, inspected by the EMA and has previously held ANVISA certification.

Depth of medical expertise with five Principal Investigators and both Nucleus sites are located within two of Australia's leading health, scientific and medical precincts.

Cost: We can offer our sponsors a dual site strategy to conduct their clinical trial under one HREC application and approval, at a reduced start-up cost. Clients may be eligible for R&D Tax incentives which provides up to 43.5% saving in costs.

With the AUD/USD currency pair falling over 10% since January 2020, and more significant reductions in the Australian dollar in the past few weeks, currency exchange rates are offer significant savings. As at 23rd of March 2020, USD \$1.0 is buying AUD \$1.73.

Participants: The Nucleus locations of Melbourne and Brisbane represent a combined total population of approx. 7.5 million. These cities include diverse population groups with Melbourne ranked as one of the most diverse cities in the world.

Nucleus has witnessed an above-average increase in participant enquiries in the first quarter of 2020, coinciding with increased media exposure relating to COVID-19. From outbound campaigns, lead generation content and online forms, through to phone screening and on-site Medical assessments, the Nucleus participant screening methodology is consistent, rigorous and well documented. ➡

CONCLUSION CONT.

Transmission-Based Precautions

(TPGs): Nucleus has implemented the highest level of TPGs within its operations including the creation of dedicated teams of clinical staff. These staff are assigned to work only in functional designated areas and there is no cross-pollination of these teams.

Nucleus has instituted an occupancy approach of 'every second bed'. With the largest share of Phase 1 beds in Australia, Nucleus can conduct – without interruption – clinical trials, utilizing every second bed.

The strategically designed footprint of the Nucleus facilities enables dedicated screening areas, outpatient areas, isolation wards, consultations rooms and bathroom amenities.

Organizational resilience: Led by the CEO, Nucleus has assembled a cross-functional Crisis Response Team. This team has deep specialist skill sets, all working towards ensuring the safety and wellbeing of employees, participants, the community and commercial considerations.

This team meets daily to review every active clinical trial, as well as clinical trials being planned for ethics, and assesses the current landscape as it relates to the safety of employees and participants.

To ensure business continuity, Nucleus has a robust supply chain in place with preferred providers for all clinical supplies. These long-standing relationships have allowed Nucleus to source clinical supplies with confidence.

While many pharma and medtech supply chains have been able to largely meet demand to date from existing inventory, Nucleus has activated analytics and scenario modeling to fully understand demand and supply chains. This has also assisted to identify the top products facing potential supply issues, with a perspective on the next few months, taking into account potential more-aggressive infection scenarios.

Accordingly, this paper is provided as a roadmap to the successful delivery of Phase 1 clinical trials at Nucleus in Australia. This approach has established processes, behaviors and values that will accelerate our clients' clinical trials requirements during the crisis and support their aspirations for medical innovation.

Nucleus is your partner in unlocking the next generation of therapeutics.

For all general enquires regarding our approach to trials during the COVID-19 pandemic, please contact us directly via the following channels:



Email our dedicated response team:
covid19@nucleusnetwork.com.au



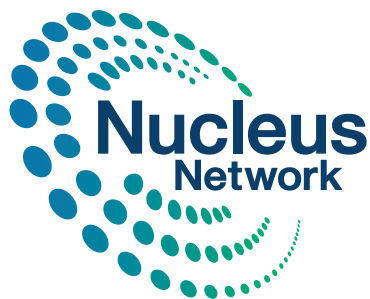
Complete an enquiry form on our website:
<https://nucleusnetwork.com.au/news/covid-19/>



Reach out via our LinkedIn page:
www.linkedin.com/nucleus-network

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