cancer voices sa
RAISING A VOICE FOR THOSE AFFECTED BY CANCER

nRAH Clinical Trials - an urgent issue for discussion

Clinical Trials are a key component of best practice, evidence based clinical care with access to latest treatment options. This is particularly important for patients with cancer, hence Cancer Voices South Australia, representing people affected by cancer, are **extremely concerned to learn that clinical trial activity at the nRAH is not a core commitment from government**.

We believe optimal provision of clinical trials at nRAH is an issue that **must** be rapidly resolved, and opportunities exist for turning this into **a solution even better than merely replicating what we had before**. **We could have a dedicated clinical trials centre to accompany the state of the art hospital**.

This solution could best be realized by urgent discussions between stakeholders:

- Clinical researchers
- consumers
- clinical trial and support staff
- SAHMRI, University and other clinical trial related organisations
- nRAH and SA Health

The current situation re clinical trials at nRAH:

Clinical trials have been overlooked in the nRAH space allocation and planning as outlined in the report by M James[1] that clearly indicates a shortfall of at least 300 current trials which cannot be accommodated.

The time is now critical to remedy and resolve this oversight because:

[1] Report on the RAH Research Relocation Project. Stage: Documentation of space requirements. 7May2016

- there are optimal resolution opportunities, but only for a limited period

- a large number of patients (estimated as ~1,000-2,000) are currently on trials and with transition to nRAH this will need to continue seamlessly to avoid serious consequences in terms of
    - ongoing patient care, for patients currently enrolled on trials
    - legal contractual obligation 'breach of agreement' for CALHN with each clinical trial sponsor (estimated at 300+ trials) for which legal costs and consequences could be invoked
- there is risk to the South Australian and nRAH reputation - to reveal we didn't factor in the significance of catering to facilitate the latest world class treatments that include clinical trial research activity, in stark comparison with similar medical facilities (see Appendix 1 Royal Melbourne Hospital, Victorian Collaborative Cancer Centre), – even more so given SA is 'touting' the nRAH facility as world class,
- this would also pose a risk to retention of our elite health and research workforce and in turn to key elements of the SA tertiary level economy
- new trial contracts are/ risk being lost while there is uncertainty about the facilities at nRAH.

South Australia appears to be heading in the opposite direction to the progressive, collaborative approach being taken elsewhere, with the transition to the nRAH losing capability and collaboration between health services and research. See Appendix 2 Benefits of Clinical Trials, and Appendix 3 What can governments do to support clinical trials?

Surely South Australia has the opportunity for nRAH to leverage on the West End clinical and health research precinct to create and capitalise on leading clinical treatment and research collaborations?

Possible Solutions:

1 - A dedicated clinical trial hub integrated within nRAH is the model based on best practice and excellence adopted everywhere else, interstate and overseas.

2 - At this stage, it is probable that the alternative best solution would best be realized by urgent discussions between stakeholders:

- clinical researchers
- consumers
- clinical trial and support staff
- SAHMRI, University and other clinical trial related organisations
- nRAH and SA Health

Only then can there be work on a solution accommodating the complexities of all trial activity which includes:

- Flexible clinic space to see trial patients whose visits are often lengthy and require complex documentation – currently this *cannot be done* anywhere in the nRAH due to the rigid rules on Blue Space, Outpatients, and Clinical space in the wings.
- Space for trial staff, confidential storage of site files, storage of trial lab kits, storage of trial specific equipment such as ECG machines, spirometers, etc which must be taken to the trial patient visits

- Space for lengthy discussions with potential trial patients about recruitment – these require many hours
- Space for visits from external monitors who oversee the conduct of all trials.

(We understand that a suitable area of nearby space is currently available.)

3 –Given the requirements above, it is likely that space within the nRAH AND space as close as possible to the nRAH will have to be considered together.

Current unknowns and further questions:

- What is the timeframe to find a solution?.
  Note: a solution must be found before the nRAH can open. If not, some trial patient medications could not continue no matter where they were in their course of treatment. That determines the timeframe.
- Who needs to be involved in finding the best solution with the constraints we now have?
  We believe the Health Minister needs to commit to resolve this.
- What space could be made available at/around nRAH to accommodate all current clinical trials?.
- What are the opportunities for turning this into a solution even better than merely replicating what we had before?
  Could the Dept of Health turn this around entirely to achieve a dedicated clinical trials centre to accompany the state of the art hospital?

We outline the risks if this is not rapidly resolved, and opportunities:

RISKS

- to patient outcomes.
- increased cost of running clinical trials in SA. Transition of patient care by the shift to nRAH must occur seamlessly and without major disruption in terms of increased FTE requirements from inefficiencies created by dispersed locations for staff base and trial activities.
- loss of clinical trial contracts and activity due to uncertainty or inefficiency of clinical trial operations at nRAH Note that each trial contract is signed be CALHN and has the undertaking that the institution will provide adequate facilities.

OPPORTUNITIES

Create a collaborative, coordinated precinct at nRAH that supports clinical research and interacts with the surrounding health and research facilities.

This could:
- increase clinical trial activity and hence create access to the newest treatments at no cost to the SA taxpayer
- enhance the profile, research capability, competitiveness and success of SA health research funding applications… which would bring more investment into SA (see Appendix 4 Examples of advances from clinical trials)
- this in turn would create new job opportunities to boost the SA economy, and avoid these opportunities going to innovative centres interstate.

From the perspective of cancer patients and people affected by cancer in South Australia:

- it is vital to **retain** access to latest treatment options, which is usually via clinical trials. This is particularly vital when no further standard treatment options exist, as is often the case for patients with advanced cancer or those with rare cancers.
- the move to nRAH MUST NOT result in a LOSS of clinical trial function and capability in SA that is currently available at the old RAH.
- the move to the nRAH MUST NOT create disruption in the care of patients moving onto or needing to exit from treatment trials, ie from disruption due to the physical dislocation of clinical trial facilities at nRAH
- Clinical trials provide access to the latest treatments at no cost to SA Health or to the patients.
- Our best and brightest clinicians are usually the ones participating as investigators in clinical trials, and this helps retain the highest quality clinical workforce in our public hospitals and in this state.
- Clinical trials provide a collaborative framework that directly connects our clinicians with the latest innovative technologies, allowing them to make informed decisions on treatment pathways.
- The leverage and boost to the SA economy from investing in clinical trials activity is realised through the access to potentially high cost new treatments for no cost, improved health outcomes of patients, best clinical staff recruitment and retention, skilled workforce of clinical trials staff employed, money coming into the state from trial sponsors, new knowledge generated by participation in trials and the networking and collaboration creating new opportunities and knowledge exchange.

NB We do not want the only option to be access to interstate or overseas clinical trials, which means it is only accessible for those wealthy enough to afford to fund this for themselves.

Julie Marker, Chair, on behalf of Cancer Voices SA Executive Team
Cancer Voices SA
Raising a voice for people affected by cancer.

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Appendix 1 Opportunities for best practice: Australian examples of clinical excellence

Around the world, state-of-the-art health centres of excellence are integrating clinical care with research and education. Examples include

The Royal Melbourne Hospital:

- we foster research that enhances patient care, challenges clinical practice and promotes innovative health service delivery.
- is investing in expanding our clinical trials capacity and is strengthening partnerships with sponsors, contract research organisations and collaborators.

https://www.thermh.org.au/research/collaborations-partners

The newly opened Victorian Collaborative Cancer Centre:

- The role of the VCCC is to improve the collaboration between partner organisations and to develop a strategic program of work that integrates research, education and clinical care to substantially improve outcomes for patients with cancer.
- Through our work, the VCCC aims to provide three key benefits to the community:
    - Improve survival of cancer patients and their experience.
    - Create a world-class Centre of Excellence in cancer.
    - Increase the funding and support for cancer research.

https://www.victorianccc.org.au/assets/Uploads/2015-VCCC-Annual-Report-Web-Version.pdf

These examples in practice are backed up by recommendations from the peak cancer organisations, Clinical Oncological Society of Australia (COSA) and Cancer Council Australia in 2010:

- **Australia must increase its clinical trial capacity to ensure that Australians continue to have access to world class evidence-based health care**.
- key factors include **a strong institutional culture within hospitals which recognizes properly conducted clinical research as an important standard of care**; the availability a strong independent clinical trials research sector …; and of the availability of a skilled clinical trials workforce
- **To encourage a pro-research culture in hospitals, clinical research should be included in hospital performance indicators and accreditation processes**.
- Government can support clinical trials by: providing dedicated clinical research funding; **improving support for clinical research within public hospitals**; streamlining ethics and governance review processes for clinical trials;

Enhancing Australia's position as a preferred destination for clinical trials
https://www.cosa.org.au/media/1082/cosa_submission_cca_-aust-preferred-destination-for-ct_feb2010.pdf

Appendix 2 Benefits of Clinical Trials

The capacity to conduct clinical trials in Australia offers a range of national benefits.
The average dollar invested in Australian health R&D returns $2.17 in health benefits. In addition, economic and employment benefits arise from the financial investment required to conduct clinical trials. These benefits include spin-off developments in complementary sectors such as biotechnology which then further enhance the prospect of conducting additional trials within the country.
There are also major benefits in the form of development, maintenance and retention of world-standard local expertise in scientific and medical research and clinical care.
Most important are the benefits to patients which include:
• Early access to new therapies for patients participating in trials
• Improved outcomes for patients participating in clinical trials, even for those not given the treatment under investigation
• Improved quality of care leading to improved outcomes for all patients, even those not participating in a trial, as a result of clinicians involved in trials transferring the more rigorous care protocols required for trials into routine care.
• Faster uptake of proven new therapies due to the development of a pool of local clinician expertise arising from participation in trials.

For these reasons, it is essential that Australia maintains and increases its clinical trial capacity.

Enhancing Australia's position as a preferred destination for clinical trials
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Appendix 3 What can government do to support clinical trials?

• Improve support for clinical research within public hospitals
Fifty-six percent of clinical trials are based in public hospitals. However, there is a need for state and territory departments of health to encourage a stronger institutional culture within public hospitals in support of research and innovation that recognizes well conducted clinical research as an important standard of care.
Public hospitals benefit from trials being conducted within their institution because they can provide subsidized care and free drugs to patients as well as the prestige of being part of innovative research..

Public hospitals should support clinical trials by
• Adopting a pro-research culture that recognizes properly conducted clinical research as an important standard of care.
• Providing appropriate infrastructure support.
• Providing protected time for research and related activities, such as participation in grant review panels, by funding pharmacy and clinical research fellowships and backfill for clinician researchers that are independent of fluctuating trial income. This would also ensure a clear career path that will retain high quality staff.
• • Not charging for services associated with conducting trials, such as fees for ethics and governance approval.
A pro-research culture could be encouraged by including specific clinical research indicators (eg number of trials supported, funding provided, timeliness of research review processes etc) as a necessary part of hospital accreditation requirements and performance indicators.

The need for research to be valued and enabled as a normal part of providing health services was identified by the National Health and Hospitals Reform Commission in its final report on the Australian health system.

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Appendix 4 Examples of advances from clinical trials.

Clinical trials have moved drug treatments from non-specific 'shotgun' approaches to highly targeted pharmaceuticals. This has occurred in a spectacular way in cancer treatments where the older drugs are 'poisons' and the modern drugs, developed by clinical trials, are targeted to specific mutations in the person's tumour. If the patient's tumour has the mutation, they will receive the targeted drug. If the mutation isn't present, there is no advantage to use of the drug in that patient.

For example, the monoclonal antibody, trastuzumab, targets a growth signalling cell receptor which is overexpressed in 15-30% of breast cancers. The receptor is called HER-2 and trastuzumab can suppress tumour growth. By using the drug only in women with HER-2 positive tumours, the effectiveness is enhanced.

Likewise, the cystic fibrosis (CF) drug, ivacaftor, improves the activity of a mutant protein that is responsible for the clinical problems in cystic fibrosis (CF). However, it works only on one of the mutations that can occur in the protein and therefore it is used in only the 4% of patients who have this mutation.