The Thoracic Society of Australia & New Zealand
LEADERS IN LUNG HEALTH

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Health and Medical Research team at the
Australian Commission
on Safety and Quality in Health Care
Via email: HMR@safetyandquality.gov.au

Dear Health and Medical Research Team,

Re: National One Stop Shop Survey

On behalf of the Thoracic Society of Australia and New Zealand (TSANZ), we submit the following in place of the survey.

The Thoracic Society of Australia and New Zealand (TSANZ) is a health promotion charity whose mission is to lead, support and enable all health workers and researchers who aim to prevent, cure, and relieve disability caused by lung disease. TSANZ is the only Peak Body in Australia that represents all health professionals working in all fields of respiratory health.

The TSANZ has a membership base of over 1800 individual members from a wide range of health and research disciplines. The TSANZ is a leading provider of evidence-based guidelines for the treatment of respiratory disease in Australia and New Zealand and undertakes a large amount of professional education and training. The TSANZ is also responsible for significant research administration and coordinates the Australasian Severe Asthma Registry (ASAR) – a clinical quality registry.

As the leaders in lung health, we promote the:

- highest quality and standards of patient care
- development and application of knowledge about respiratory health and disease
- highest quality air standards including a tobacco smoke free society and effective regulation of novel nicotine delivery systems
- collaboration between all national organisations whose objects are to improve the wellbeing of individuals with lung disease and to promote better lung health for the community
- professional and collegiate needs of the Membership

As the peak member body for respiratory health in Australia, the importance of this consultation process and the aim for a National One Stop Shop is recognised by the TSANZ. As such, the TSANZ has widely disseminated to the TSANZ membership through newsletters and through targeted communications to working groups and committees. The TSANZ are grateful for the opportunity to contribute to the National One Stop Shop consultations.

In addition to being a professional body, the TSANZ governs the *Australasian Severe Asthma Registry (ASAR)* – a clinical quality registry (CQR). In 2019, the Australasian Severe Asthma Network (ASAN) collaborated with the TSANZ to upgrade and transition its severe asthma research register into a CQR.

The ASAR now has National Mutual Acceptance (NMA) for sites within Australia. Currently, the ASAR has national coverage in New South Wales, Victoria, Queensland, South Australia, and Western Australia, in addition to ethics approval in New Zealand.

For the purposes of this letter, the discussion is from the perspective of the TSANZ Registries team, specifically, based on our experience with the systems we use regularly. We do not currently run clinical trials.

Addressing barriers

The TSANZ Registries team can relate to many of the challenges identified in the survey, most notably:

- Navigating the various approval processes and systems
- Knowing what approvals are required
- Duplicative manual data entry into multiple systems
- Comparative timeliness of research start-up
- Ethical review and approval processes and systems
- Local site research authorisation
- Costs of conducting research
- Access to research sites
- Research recruitment progress
- Quality of research administrative processes

One specific issue encountered by the ASAR in the ethics process was not knowing the jurisdiction-specific Western Australia Specific Module and the Victoria Specific Module were required for sites within WA, and VIC, respectively. This then required additional amendments and held up the local authorisation processes.

Navigating approval processes & systems and Site-Specific Authorisations

The TSANZ Registries team and the ASAR Lead HREC is based in NSW. As such, REGIS is the primary ethics application system used. The team also has experience with ERM, RGS and limited experience with GEMS. The ASAR has obtained site-specific authorisation in NSW, QLD, WA, SA, and VIC.

There are improvements that could be made to the system. One example of an aspect the TSANZ Registry team uses regularly and could be improved is the 'Forms'. Currently, the only way to view previously submitted forms and to identify what the form was is by downloading all the files. If there was the capability to add a reference title specific to the project to a line on the forms list, this would facilitate easy identification and negate the need to download each document. Please see below for an example: Reference title for the amendment - ASAR Progress and Extension 2021.

	Title	Status	Owner	Created date
⋮	039009 - Notification of an amendment to a research ...	Approved	[redacted]	20/08/2020 11:49:58 AM
⋮	036847 - Notification of an amendment to a research ...	Approved	[redacted]	27/07/2020 09:43:59 PM
⋮	027623 - Notification of an amendment to a research ...	Approved	[redacted]	05/03/2020 04:19:49 PM
⋮	076232 - Notification of an amendment to a resear...	Approved	[redacted]	08/12/2021 11:30:45 AM
	ASAR Progress and Extension 2021			

Further, it would be ideal if each form could be click on to review the form in full with the accompanying documents available for download, rather than having to download all. Currently, the approvals of amendments are provided in email form. It would be beneficial to also upload these into the relevant form as a complete form package.

System interactions: Workflow functionality

As identified in 'addressing barriers', previously, there are a number of challenges faced by researchers in gaining ethics approval and multi-centre approval. The TSANZ Registries team put forward the following suggestions for consideration for improving system interactions:

- When sites and Principal Investigators are nominated into the ethics application, automatic creation of a SSA application form for each site, Australia-wide.
- Create forms for Principal Investigators to complete their CVs and be able to update in real-time.
- When sites are loaded and include sites requiring specific modules, e.g. WA and VIC, that this is automatically prompted for the researcher to complete.
- Automatic replication of the study information into each SSA application form.
- Ability for sites to fill SSA-information concurrently such as personnel, contact details, etc so when ethics approval is received, the sites will only be required to upload the site-specific documentation e.g. adding site logo to PICF.
- Automatic renewal notices for ethics extension.

Systems interactions: Filtering functionality

The TSANZ Registries team currently share information with sites, Principal Investigators, Sponsors, patient/consumer advocacy groups, potential sponsors, the TSANZ membership body, pharmaceutical companies, and an international collaborative body.

The TSANZ Registries team shares information under the following categories with stakeholders:

- Business needs – ASAR Annual Reports which are internally and externally disseminated
- Regulatory needs
- Approvals needs
- Medical and patient care needs
- Adverse event reporting
- HREC reporting

We share the information through various methods including:

- Email
- Online portal
- Written communication
- Internal systems
- Phone
- Video conference
- Face-to-face
- Seminars / conferences / workshops

National Clinical Trials (Health & Medical Research) Registry

While the TSANZ Registries team does not currently undertake clinical trials, we would support being able to access a registry of clinical trials. To utilise this registry effectively, it would be helpful if the

visible information for each trial included: title, population, study overview including brief methods, transparency of funding.

Information hub

The TSANZ Registries team would support an Information Hub that extends beyond clinical trials, including information on other research methods such as clinical quality registries. Specific information about the safe, efficient and effective conduct of research in addition to clinical trials would be useful. Information that could be included in this would be links to the Australian Commission on Safety and Quality in Health Care.

Further information that would be beneficial would include the state-based requirements for ethics approvals and variations in site-specific requirements for authorisations e.g. Victorian Specific Module, Western Australian Specific Module.

Research activity reporting

Measures that the TSANZ Registries team would consider to be most useful are:

- Overall study start-up timeline (regulatory timeline)
- HREC and local site authorisation approval timelines
- Site recruitment: actual and planned number of participants recruited
- Disease and population health information

An additional operational measure that would be important to receive would include site-specific reporting timelines.

It would be preferential to be able to access reports via various methods including:

- Email
- Online dashboard with the capability to download the file in Excel or CSV, or as a PDF, when appropriate.

Other functionality

Utilising the National One-Stop-Shop as a central repository of information for ethics and site-specific authorisations would be the most important piece of functionally. Automatically filling this information into forms would significantly reduce the burden on researchers and site personnel. For the research community to meet safety and regulatory obligations and requirements, the addition of in-built reminders to be sent would be helpful with a specific link to the required form.

We are excited by the prospect of the National One-Stop-Shop and look forward to seeing the next steps of this very important project.

Sincerely,

Dr Hayley See
TSANZ Research and Policy Manager