



ASAR Australasian Severe
Asthma Registry

ANNUAL REPORT 2020

PUBLIC



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



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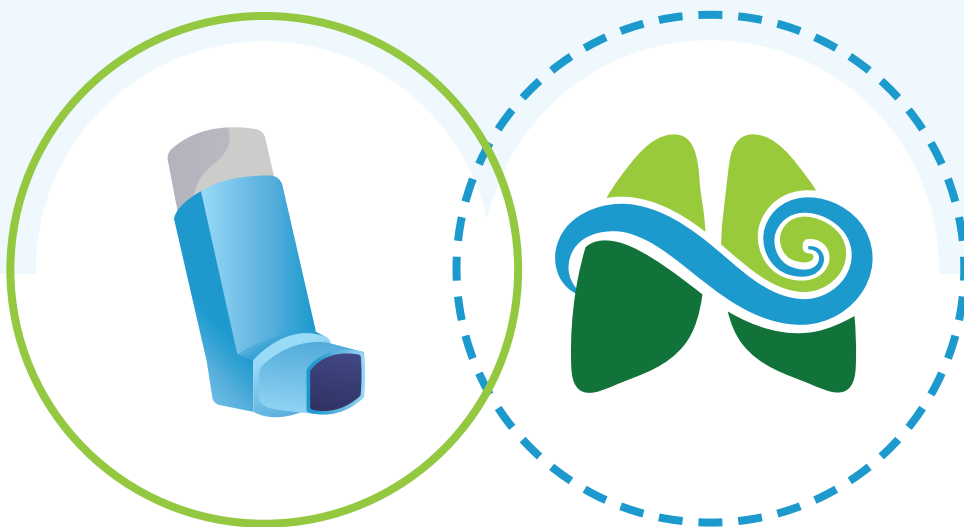


SUMMARY

Severe asthma is a public health concern in the Australasian region. The medical complexity and heterogeneity of severe asthma poses unique challenges for the clinical management of patients in healthcare settings. Furthermore, it is highly prevalent in Australia and New Zealand. Consequently, it is responsible for deleterious illness outcomes, economic burden, and burden of disease. Little is known about the longitudinal clinical outcomes and the impact of severe asthma on the Australasian cohort.

The Australasian Severe Asthma Registry (ASAR) is a collaborative clinical quality registry established to address the lack of knowledge for the severe asthma cohort in the Australasian region. After transitioning from the Severe Asthma Web-based Database (SAWD), the ASAR is now a longitudinal clinical quality registry (CQR) following patients for 10 years. Despite the COVID-19 pandemic, 2020 was a successful year for the ASAR, with many exciting milestones being achieved, including the inaugural ASAR biennial research summit and the ASAR REDCap database rollout. On 31st December 2021, the ASAR had a total of 831 registered, eligible patients who had completed the baseline visit.

The purpose of this report is to share an overview of the ASAR. This includes the key achievements of the ASAR in 2020, in addition to a snapshot of the registry population. The future directions of the ASAR, its importance and its contribution to the understanding of the clinical management and quality of life for the Australasian and international severe asthma cohort is also discussed.



This report was developed by the TSANZ-ASAR Operations Team:
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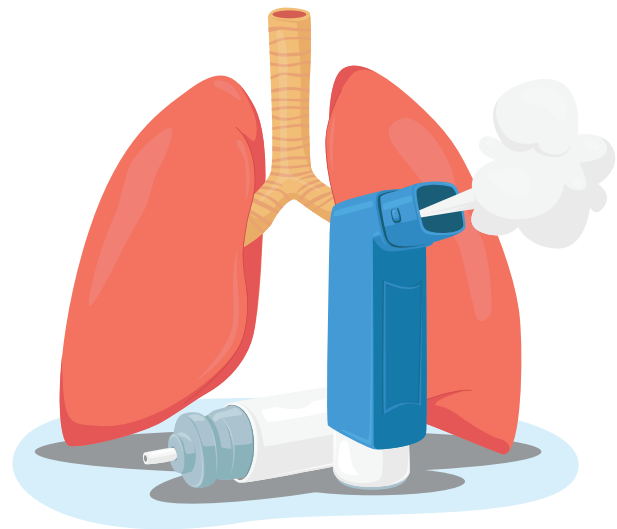


BACKGROUND

Medically complex and heterogenous in its presentation, severe asthma is highly prevalent in Australia and New Zealand. Severe asthma is defined as asthma that requires treatment with high dose inhaled corticosteroids plus a second controller and/or systemic corticosteroids to prevent the disease from becoming "uncontrolled" or, asthma that remains "uncontrolled" despite this therapy (Chung et al., 2014). There is significant heterogeneity in the phenotypic characteristics of severe asthma resulting in substantial complexity in the clinical management of people with severe asthma (Albers et al., 2018).

In Australia, approximately one in nine (11%), or 2.7 million Australians have a diagnosis of asthma (Australian Institute of Health and Welfare, 2020) and in New Zealand, it is one in eight (12%), or 452,000 New Zealanders (Ministry of Health, 2017).

International datasets estimate that of these, 3-10% (Chung et al., 2014, Hekking et al., 2015) will have a severe, uncontrolled form of the disease. This equates to 81,000-270,000 people in Australia and 13,560-45,200 New Zealanders suffering with an uncontrolled severe form of asthma.

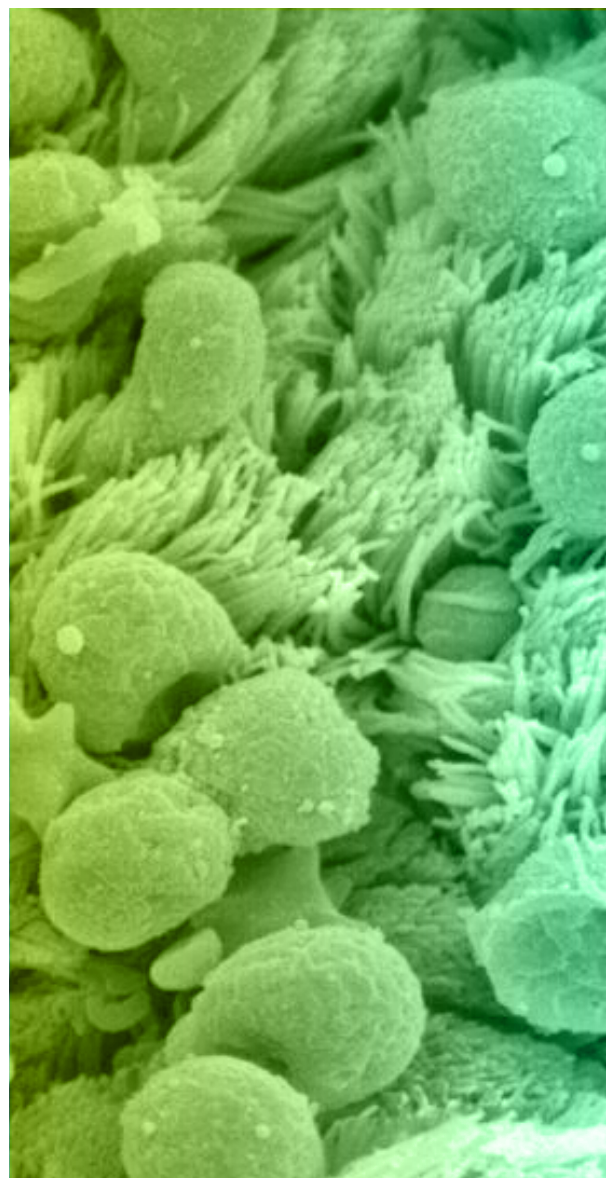


Pivotal randomised-controlled trials (RCTs) have demonstrated the efficacy of emerging and available biologic treatments. While promising in the treatment of severe asthma, these treatments are inherently expensive and require effective targeting to eligible patients who meet the criteria through adequate phenotyping (Grainge et al., 2016). With only 10% of patients meeting the specific eligibility criteria for clinical trial entry, questions about the generalisability of the RCT outcomes are raised. To achieve a more comprehensive, real-world understanding of the efficacy of these treatments for severe asthma, investigation and evaluation of clinical practice evidence is warranted (Albers et al., 2018).

The high prevalence and clinical complexity of severe asthma translates to significant burden of disease, healthcare costs and deaths in our region (Australian Bureau of Statistics, 2019). In New Zealand, asthma was estimated to cost \$1.018 billion in 2018, with \$198.3 million in direct costs, and \$828.2 million in indirect costs from workdays lost, disability affected life years, and mortality (Telfar Barnard and Zhang, 2018). The estimated cost of asthma to the Australian health system in 2015 was \$1.2 billion. Severe asthma, while representing only 3-10% of the asthma population, consumes up to 50% of asthma-related healthcare expenditure (O'Neill et al., 2015). Further associated economic costs (including productivity loss and associated financial costs e.g., travel and government programs) totalled \$3.3 billion (Asthma Australia and National Asthma Council Australia, 2015). The overall burden of disease which accounts for suffering and premature death experienced by people with asthma in Australia in 2015 was estimated at \$24.7 billion. These numbers reflect the significant long-term impact of severe asthma on daily living and quality of life.

The burden of disease of asthma is disproportionately high in our region and is indicative of the far-reaching consequences for individuals with asthma. Adverse physical effects of oral corticosteroid toxicity are well known and include hypertension, decreased bone density with resultant increased risk of fractures, cataract, gastrointestinal conditions, and metabolic issues (Rice et al., 2017). People with severe asthma are more likely to experience greater impairment at work and outside the workplace than people who have non-severe asthma (Hiles et al., 2018). Furthermore, they are two to three times more likely to experience symptoms of anxiety and depression than those with mild or non-steroid dependent asthma (Amelink et al., 2014). Understanding the complexity and impact of severe asthma from a real-life, local perspective is imperative to manage the significant burden of severe asthma.

The Australasian Severe Asthma Network (ASAN) demonstrated the importance of effective collaborative networks and population databases in the SAWD. Severe asthma registries are valuable evidence platforms used to systematically obtain and report outcomes. They provide the basis for understanding population status, treatment options and to promote evidence-based clinical guidelines. The now established ASAR is a prospective, clinical quality registry of people with severe asthma in Australia and New Zealand and will be utilised to monitor clinical outcomes and quality of life for the severe asthma cohort in Australia and New Zealand.



Scanning electron image of the bronchial epithelium



REGISTRY GOVERNANCE

Governance for the ASAR is provided by the Thoracic Society of Australia and New Zealand (TSANZ). In 2020, the TSANZ-ASAN ASAR Management Committee (Table 1) was refreshed for greater geographical and discipline representation, and we welcomed members from Western Australia and New Zealand. The ASAR Management Committee meets bi-monthly and ad hoc. This committee provides strategic and financial oversight, in addition to managing ongoing academic aspects and interests of the ASAR.

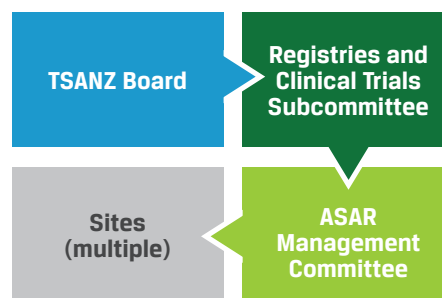


Table 1. TSANZ-ASAN ASAR Management Committee

| Name | Position | Institution, State |
|--------------------------------|---|--|
| Professor Peter Gibson (Chair) | Senior Staff Specialist | Hunter Medical Research Institute/ John Hunter Hospital, NSW |
| Professor Matthew Peters | Respiratory and Sleep Medicine Physician, Head Respiratory Medicine | Concord Repatriation General Hospital, NSW |
| Professor John Upham | Senior Respiratory Physician | Princess Alexandra Hospital, QLD |
| Professor Philip Bardin | Respiratory and Sleep Physician | Monash University and Medical Centre, VIC |
| Dr Gregory Katsoulotos | Consultant Physician and Senior Lecturer | St George & Sutherland Clinical School, UNSW Sydney, NSW |
| Dr Li Ping Chung | Respiratory Physician | Fiona Stanley Hospital, WA |
| Dr James Fingleton | Respiratory Physician, Director of Asthma and COPD Programmes | Medical Research Institute of New Zealand, New Zealand |
| Dr Elaine Yap | Respiratory Physician | Middlemore Hospital, New Zealand |
| Dr Erin Harvey | Australasian Severe Asthma Network Project Manager | Hunter Medical Research Institute, NSW |
| Ms Ceri Banks | Clinical Research Nurse Consultant (Respiratory) | Frankston Hospital, Peninsula Health, VIC |

The TSANZ-ASAN Operations Team (Table 2) continues to be responsible for coordinating the daily processes of the ASAR, including liaising with key internal and external stakeholders, site communication, data analyses and dissemination of information.

Table 2. TSANZ-ASAN Operations Team

| Name | Position |
|-------------------|--|
| Dr Hayley See | Research and Policy Manager and Conjoint Lecturer, University of Newcastle |
| Dr Ezinne Igwe | ASAR Clinical Research Analyst |
| Ms Laura Mitchell | ASAR Clinical Registry Officer |



KEY ACHIEVEMENTS 2020

Our sincere appreciation to our ASAR colleagues for your contribution and effort in what was a tumultuous and challenging year amid the global COVID-19 pandemic. Your commitment to the project contributed to 2020 being a year of growth and success for the ASAR.



ASAR REDCap Database Roll-Out

In 2020, one of the most important achievements was the roll-out of the ASAR REDCap database which continues to be hosted at HMRI. Going live in April 2020, this was the culmination of a substantial rebuild, and data preservation process to integrate the previously collected SAWD data. The data integration to the ASAR REDCap system was a multifaceted process which involved:

- shutting down SAWD and revoking access from all sites for the SAWD platform;
- downloading and cleaning the SAWD data;
- streamlining the variables to establish the ASAR variable list and data dictionary to reduce duplicity;
- the TSANZ clinical analyst matching each SAWD variable to the updated ASAR variable and data dictionary; and
- uploading the data into the ASAR REDCap database.

Ongoing site-feedback is implemented into the platform in real-time. The ASAR database now functions as the primary registry platform for severe asthma within Australia and New Zealand. The use of the ASAR dataset in this way has significantly reduced data collection and entry burden for sites and capitalises on the already collected data.

Inaugural ASAR Biennial Research Summit

On the 3rd December 2020, the TSANZ's ASAR Operations Team and the ASAR Management Committee hosted the inaugural ASAR Biennial Research Summit. After initially being postponed due to COVID-19 restrictions, the summit was held as a two-hour webinar and brought together practitioners, researchers, TSANZ members, international collaborators and ASAR sponsors in the virtual space.

The objectives of the ASAR Biennial Research Summit were three-fold:

1. Provide an overview and update of the successful transition from SAWD to the Australasian Severe Asthma Registry – a clinical quality registry;
2. Detail the ASAR methods, site experience, preliminary results, and future directions; and
3. Provide a forum to discuss the ASAR with current and prospective stakeholders.

The summit, a welcome opportunity to collaborate, was well attended and received fantastic feedback. The comprehensive programme provided the audience with an in-depth overview of the ASAR. The site experience of the ASAR research-in-action, presented by Ms Ceri Banks was the highlight of the summit. Overall, the 2020 ASAR Biennial Research Summit was a decisive success! For the post-summit report, click here: [[2020 \(thoracic.org.au\)](https://2020.thoracic.org.au)]

International Collaboration

The first ASAR data transfer to the International Severe Asthma Registry (ISAR) was completed in 2020! The ISAR is a global research initiative collecting anonymous longitudinal real-life data for the severe asthma cohort with collaborators from over 29 countries. The anonymous ASAR data is now being utilised in several ethically approved research analyses. This is a significant achievement for the ASAN and TSANZ. A collaboration of this nature demonstrates the importance of the ASAR in its contribution to the understanding of severe asthma on the global scale.

The Australian Register of Clinical Registries (ARCR)

After establishing the ASAR as a CQR, the TSANZ applied for ASAR to be registered on the Australian Commission on Safety and Quality in Healthcare's (ACSQHC) Australian Register of Clinical Registries (ARCR). The purpose of the ARCR is to foster collaboration and awareness of CQR activity among key stakeholders. CQRs monitor the quality of health care, within specific clinical domains, by routinely collecting, analysing, and reporting health-related information, for a self-improving health system. The ASAR meets the ACSQHC's detailed security, technical and operating standards and was successfully listed on the ARCR: [Australian Register of Clinical Registries | Australian Commission on Safety and Quality in Health Care](#) This listing generates visibility of the ASAR and promotes interactions with other Australian CQRs.



ETHICS AND SITE GOVERNANCE

Ethics Approvals

Australia

The ASAR is approved by the Hunter New England (HNE) Human Research Ethics Committee (HREC) in Australia with National Mutual Acceptance (NMA) for sites within Australia ongoing. In December 2020, the annual ethics report was submitted to HNE HREC.

New Zealand

In New Zealand, the key ethics goal was to gain approval for the study based on the current ASAR protocol, which included opt-out consent. The TSANZ-ASAR operations team consulted with key stakeholders in New Zealand to determine the most appropriate approach. A comprehensive ethics amendment was submitted to the Health and Disability Ethics Committees (HDECs) in New Zealand. This amendment received provisional approval in December 2020.

Site Governance

The key focus of the TSANZ operations team for sites within Australia for 2020 was to gain site-specific approvals through local research governance offices (RGOs). The NMA streamlines Human Research Ethics Approval across state jurisdictions within Australia as evident with ASAR, however, sites must also comply with local governance requirements. The TSANZ ASAR operations team has worked extensively with site coordinators to support the local governance process. Excitingly, an additional 10 sites received approval in 2020! Gaining additional local governance (Aust) and locality approval (NZ) will remain a key focus in 2021.



2020 New Enrolments

Between 1st January 2020 and 31st December 2020, 92 new patients were enrolled in ASAR. Of these 92 new patients, 87 have been classified as severe asthma patients, three are non-severe asthma patients, and two are unclassified patients with asthma. In 2020, there were 237 new data points entered into the ASAR database (Table 3). These data points are summarised below according to visits completed.

Table 3. New ASAR patient enrolment and visits in 2020

| Visit | Visit 1 Baseline | Visit 2 (1-year) | Visit 3 (2-year) | Visit 4 (3-year) | Visit 5 (4-year) | Visit 6 (5-year) | Visit 7 (6-year) | Visit 8 (7-year) |
|-----------------|---------------------|---------------------|---------------------|---------------------|---------------------|---------------------|---------------------|---------------------|
| Patient numbers | 92 | 11 | 5 | 51 | 24 | 15 | 31 | 2 |

ASAR Population at Baseline

On the 31st December 2020, the number of confirmed eligible ASAR participants was 831. This comprises participants enrolled through the SAWD and participants who have been enrolled into the ASAR since the successful transition in 2019. Table 4 shows the number of participants who have had completed baseline visits since commencing the systematic surveillance of the Australasian severe asthma cohort in 2013.

Table 4. Patient enrolment at baseline by year

| Visit | Year | | | | | | | | Total |
|----------|------|------|------|------|------|------|------|------|------------|
| | 2013 | 2014 | 2015 | 2016 | 2017 | 2018 | 2019 | 2020 | |
| Baseline | 20 | 206 | 164 | 201 | 111 | 17 | 20 | 92 | 831 |

In the ASAR cohort, there are 691 patients with severe asthma and 131 with non-severe controlled asthma. This classification is based on the definition of severe asthma used in ASAR (Figure 1). Of the sample population, 492 patients (60%) are classified as having uncontrolled asthma according to GINA categorisation. Of these, 92% (n=451) are confirmed severe asthma patients. The sample population is 60% (n=502) female with a mean age of 55 years. Of the registry population, 35% (n=287) are ex-smokers and 3% (n=25) reported to be current smokers. The severe asthma group has a significantly higher baseline mean Body Mass Index (BMI) of 30.84 ± 7.80 compared to the non-severe group with a mean BMI of 28.12 ± 5.82 .



FUTURE DIRECTIONS

The ASAR is a well-established registry platform with a rich dataset. Future directions are targeted to capitalise on the strong foundation through quality improvement, expansion, registry outputs and ongoing active collaborations.

A key focus of the ASAR is continuous quality improvement of the data capture and integrity of the registry. The TSANZ operations team will be implementing quarterly CQR reports in alignment with the requirements of the CQR framework. This involves systematically monitoring the quality of our health care data through routine collection, analysis, and reporting of health-related information to help identify outcome benchmarks, significant outcome variance, and inform improvements in healthcare quality. The report will present snap shots on data completeness overall and per site and will be helpful to monitor the clinical reporting at sites.

Expansion of the ASAR will include a range of different targets. Enrolment and recruitment will continue at existing approved sites, while the TSANZ operations team will work with ethics-approved Australian and New Zealand sites to gain local approvals. Local opportunities for expansion within the ASAR will be explored, such as, the feasibility of increasing sites and adding modules of interest, such as biologic treatment-specific arms. Global opportunities will also be sought and considered.

The ASAN and the TSANZ teams are actively identifying and defining research questions for ASAR outputs. These outputs will lean on the strengths of the registry through identifying novel questions that ASAR has the capacity to address. Findings from ASAR will help facilitate policies around severe asthma and subsequently, lung diseases. ASAR data is being utilised in the international analysis of severe asthma data by the ISAR. Publications and presentations resulting from this international collaboration will be shared by the TSANZ with ASAR collaborators and key stakeholders.

The ASAN and TSANZ work as a collective to further the ASAR. The already existing collaborations with site personnel, clinicians, researchers, and key stakeholders remain paramount. Information, updates and status will be shared through meetings, newsletters, CQR reports, presentations, and biennial summits. Opportunities to join authorship and output working groups will be communicated with the ASAR group. The ASAR is well positioned to maintain the international collaboration with ISAR, as well as fostering collaborations locally and with other international groups.

By following severe asthma patients as well as sub-populations within this group, ASAR will be well placed to be the first point of contact for all severe asthma research questions in Australia and New Zealand. This will help improve patient care and provide evidence on policies around severe asthma management.



CONCLUSION

Despite a global pandemic and the many challenges this presented, 2020 was a successful year for the ASAR. The registry experienced substantial growth with site approvals and ongoing enrolments. The ASAR contributed its first data as a global contributor to the understanding of severe asthma through the ISAR collaboration. The TSANZ and ASAN were proactive and responsive to the needs presented throughout the year. After what was a difficult year, the ASAR Biennial Summit ended the year on a positive, collegial note sharing the achievements of the ASAR and welcoming opportunities for future collaborations and ideas.

With ongoing support from researchers, patient populations and external stakeholders, the ASAR will continue its important contribution to the understanding of severe asthma and its treatment in real-world settings. It will allow us to characterise severe asthma in Australia and New Zealand and the impact of asthma and its treatments on the quality of life and clinical outcomes of the cohort. The ASAR is a robust registry with the potential for research outcomes to be used to improve patient care and management of severe asthma.

Table 5. SAWD and ASAR reports, presentations, and publications to date.

| Type | Details | Date |
|---------------------------------|--|--------------------------|
| BIENNIAL RESEARCH SUMMIT | ASAR Biennial Research Summit | 3rd December 2020 |
| Annual Report | ASAR Annual Report 2019 (circulated to PIs, Sponsors). Public edition circulated to all TSANZ members and appropriate consumer groups. | June 2020 |
| PUBLICATION | Eileen, W., Wechsler, M. E., Tran, T. N., Heaney, L. G., Jones, R. C., Menzies-Gow, A. N., ... & Cho, Y. S. (2019). Characterization of severe asthma worldwide: data from the International Severe Asthma Registry (ISAR). <i>Chest</i>. 157(4), 790-804. doi: 10.1016/j.chest.2019.10.053 | Nov 2019 |
| PUBLICATION | Denton, E. et al. (2019). Severe Asthma Global Evaluation (SAGE): An electronic platform for severe asthma. <i>The Journal of Allergy and Clinical Immunology: In Practice</i>. 2019;7(5), 1440-1449. doi: 10.1016/j.jaip.2019.02.042 | May 2019 |
| Poster | Price, D. B. et al. (2019). International Severe Asthma Registry (ISAR): The Story so Far. In <i>C44. Asthma Epidemiology</i> (pp. A4900-A4900). American Thoracic Society. | May 2019 |
| Poster | Price, D. B. et al. (2019). Cross-Country Comparison of Demographic and Clinical Characteristics of Patients Managed in Severe Asthma Services Across UK, USA, Australia, South Korea, and Italy. In <i>C44. Asthma Epidemiology</i> (pp. A4899-A4899). American Thoracic Society | May 2019 |
| PUBLICATION | Bulathsinhala, L. et al. Development of the International Severe Asthma Registry (ISAR): A modified Delphi study. <i>The Journal of Allergy and Clinical Immunology: In Practice</i>. 2019; 7(2), 578-588. doi: 10.1016/j.jaip.2018.08.016 | February 2019 |
| PUBLICATION | McDonald, V. et al. Treatable traits can be identified in a severe asthma registry and predict future exacerbations. <i>Respirology</i>. 2019; 24: 37- 47. doi: 10.1111/resp.13389 | September 2018 |
| Oral presentation | McDonald, V. et al., Treatable Traits in severe asthma. <i>Presented at the Newcastle Asthma Meeting (NAME), Newcastle</i> | 25th October 2018 |
| Poster | McDonald, V. et al., Identification of treatable traits in a severe asthma registry: prevalence and exacerbation predictors. <i>Presented at the ERS International Congress 2018, Paris</i> | 18th Sept 2018 |
| PUBLICATION | Hiles, S. et al., Working while unwell: Workplace impairment in people with severe asthma. <i>Clin Exp Allergy</i>. 2018; 48(6):650-662. | June 2018 |
| Oral presentation | McDonald, V et al., TSANZ Oral: Severe asthma treatable traits: prevalence and exacerbation prediction. <i>Respirology</i> (2018) 23 (Issue S1). <i>Presented at the TSANZ ASM, Adelaide</i> | 27th March 2018 |
| Oral presentation | Hiles, S et al., TSANZ Oral: Working while unwell: Workplace impairment in people with severe asthma. <i>Respirology</i> 2018; 23 (Issue S1). <i>Presented at the TSANZ ASM, Adelaide</i> | 27th March 2018 |
| Oral Presentation | Hiles, S. et al. The Impact of Severe Asthma – Workplace productivity in the Severe Asthma Web-based Database. <i>Presented at the Newcastle Asthma Meeting (NAME), Newcastle</i> | 27th Oct 2017 |
| PUBLICATION | Wang, G. et al. Severe and uncontrolled asthma in China: A cross-sectional survey from the Australasian Severe Asthma Network. <i>J Thorac Dis</i>. 2017; 9(5):1333-1344. doi: 10.21037/jtd.2017.04.74 | May 2017 |
| Report | SAWD data report, Q4 2016 | 19th Dec 2016 |
| Poster | Harvey, E et al., ASAN group, TSANZ Asthma & Allergy SIG 2 Poster Presentations: Severe asthma is associated with work productivity loss, activity impairment and reduced quality of life. <i>Respirology</i> (2016);21(issue S2):108-15 <i>Presented at the TSANZ ASM, Perth</i> | April 2016 |
| Poster | Harvey, E. et al., ASAN group, TSANZ Asthma & Allergy SIG 2 Poster Presentations: Characterisation of severe asthma phenotypes via a severe asthma registry: The Severe Asthma Web-based Database. <i>Respirology</i> 2016;21(issue S2):108-15. <i>Presented at the TSANZ ASM, Perth</i> | April 2016 |
| Report | SAWD data report, Q3 2015 (circulated to PIs and sponsors) | 1st Oct 2015 |
| Report | SAWD enrolment report, Q1 2015 (circulated to PIs and sponsors) | 29th April 2015 |
| Report | SAWD data report, Q4 2014 - preliminary baseline data (circulated to PIs and sponsors) | 5th March 2015 |

ACKNOWLEDGEMENTS

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ASAR

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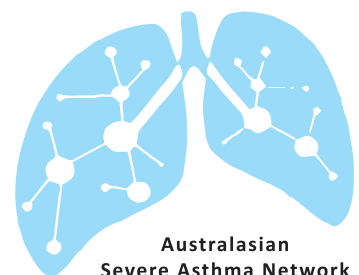
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