



ASAR Australasian Severe
Asthma Registry

ANNUAL REPORT 2021

PUBLIC



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SUMMARY

Australia and New Zealand have some of the highest rates of severe asthma in the world. Severe asthma – heterogenous and medically complex – presents unique challenges for the clinical management of patients in healthcare settings. Consequently, it is responsible for substantial adverse illness outcomes, economic burden, and burden of disease. Little is known about the longitudinal clinical outcomes and the impact of severe asthma in the Australasian context.

The Australasian Severe Asthma Registry (ASAR) is a collaborative clinical quality registry (CQR) 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 CQR following patients for 10 years. The ASAR currently has 937 participants and includes longitudinal follow-up to year eight.

The ongoing COVID-19 pandemic presented an array of challenges for the ASAR, participating sites, site personnel and participants. Despite this, 2021 was a successful year with ongoing recruitment and follow-up and exciting milestones achieved.

The purpose of this ASAR Annual Report Public Version is to share key achievements of the ASAR in 2021 and a snapshot of the registry population. It highlights the importance of the ASAR in generating a greater understanding of the clinical presentation and management of severe asthma in the Australasian region, and our contribution to the global efforts. Importantly, it details the aims for 2022/23 and future directions for the ASAR.

This report was prepared by the TSANZ Registries Team:

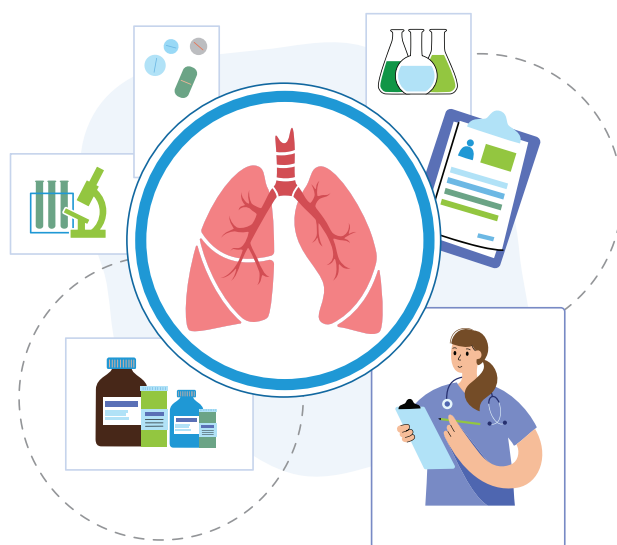
Laura Mitchell, Ezinne Igwe, Rebecca Hetherington, Bharvi Maneck and Hayley See

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Severe asthma is highly prevalent in Australia and New Zealand. International datasets estimate 3-10% of people diagnosed with asthma will have a severe, uncontrolled form of the disease – "severe asthma" (Chung et al., 2014, Hekking et al., 2015). Approximately one in nine (11%), or 2.7 million Australians have a diagnosis of asthma (Australian Institute of Health and Welfare, 2020). This equates to 81,000-270,000 people living with a severe asthma diagnosis. In New Zealand, one in eight (12%), or 452,000 people have asthma, and subsequently, 13,560-45,200 New Zealanders are expected to have an uncontrolled severe form of asthma (Ministry of Health, 2017).

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)



With significant heterogeneity in phenotypic characteristics, the clinical management of severe asthma is complex (Albers et al., 2018). Available and emerging monoclonal antibody treatments have demonstrated efficacy in randomised control trials (RCTs) and are promising in the treatment of severe asthma. Inherently expensive, they require effective targeting to eligible patients who meet the criteria through adequate phenotyping (Grainge et al., 2016). Questions are raised about the ability to generalise these outcomes with only 10% of patients meeting the specific eligibility criteria required for RCTs. As such, investigation and evaluation into the efficacy of these treatments is warranted in real-world clinical practice (Albers et al., 2018).

There is a disproportionately high burden of disease from severe asthma in our region. This is indicative of the wide-ranging consequences including psychosocial outcomes, impact on daily living and treatment side-effects. Within the workplace and social settings, people with severe asthma are more likely to experience greater impairment than people who have non-severe asthma. People with severe asthma are two to three times more likely to experience symptoms of anxiety and depression than their non-severe asthma counterparts (Amelink et al., 2014). Oral corticosteroid toxicity is known to have adverse physical effects including hypertension, decreased bone density with resultant increased risk of fractures, cataract, gastrointestinal conditions, and metabolic issues (Rice et al., 2017). Real-world, local evidence considering the complexity and impact of severe asthma is crucial to understanding, managing, and improving outcomes for the severe asthma population.

The complexity, adverse outcomes and high prevalence of asthma is associated with substantial costs, burden of disease, healthcare resources and death in our region (Australian Bureau of Statistics, 2019). In 2015, the estimated cost of asthma in Australia was \$28 billion or \$11,740 per person with asthma (Asthma Australia and National Asthma Council Australia, 2015). Of this, the overall burden of disease was estimated at \$24.7 billion and accounts for suffering, disability and premature death experienced by people with asthma. Asthma cost the Australian health system \$1.2 billion, and while severe asthma represents only 3-10% of the asthma population, it consumes up to 50% of asthma-related healthcare expenditure (O'Neill et al., 2015). In New Zealand, asthma was estimated to cost \$1.018 billion in 2018, with \$828.2 million in indirect costs from workdays lost, disability affected life years, and mortality and \$198.3 million in direct (healthcare) costs (Telfar Barnard and Zhang, 2018). These numbers provide a very stark reality of the impact of severe asthma on individuals, and the significant social, public health and economic implications.

Effective collaborative networks have demonstrated the importance of severe asthma registries. The ASAR, as a prospective, CQR of people with severe asthma in Australia and New Zealand is a valuable evidence platform which systematically obtains and reports outcomes. It is being utilised to monitor clinical outcomes and quality of life, in addition to promoting the understanding of local and global severe asthma population status, treatment options, and evidence-based clinical guidelines.



Cells lining the trachea, viewed with ZEISS ORION NanoFab microscope

Credit: Eva Mutunga and Kate Klein, University of the District of Columbia and National Institute of Standards and Technology



REGISTRY GOVERNANCE

Governance for the ASAR is provided by the Thoracic Society of Australia and New Zealand (TSANZ). The TSANZ ASAR Management Committee provides strategic guidance, in addition to managing ongoing academic aspects and interests of the ASAR (Table 1).

In 2021, the Committee met bi-monthly and was refreshed for greater geographical and discipline representation. We welcomed members from Western Australia and New Zealand.

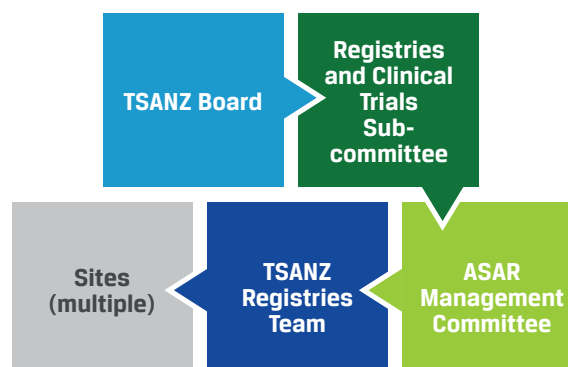


Table 1. TSANZ ASAR Management Committee

Name	Position	Affiliations
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

The TSANZ Registries Team (Table 2) is responsible for coordinating the daily processes of the ASAR, including liaising with key stakeholders, site communication, data analyses and dissemination of information.

Table 2. TSANZ Registries Team 2021

Name	Position
Dr Graham Hall	TSANZ CEO
Dr Hayley See	TSANZ Research and Policy Manager and Associate Adjunct, University of Newcastle
Dr Ezinne Igwe	TSANZ Clinical Research Analyst
Ms Laura Mitchell	TSANZ Senior Registries Officer



KEY ACHIEVEMENTS 2021

The year 2021 presented numerous challenges with the ongoing COVID-19 pandemic. Extended lockdowns, staffing redeployments and changes to clinical services and settings had notable impacts on severe asthma clinical management. Despite this, the ASAR continued to grow with new enrolments, follow-up visits and a focus on data quality.



New Zealand

In 2021, the Human Disability and Ethics Committee (HDEC) in New Zealand approved the ASAR! Excitingly, the use of opt-out consent was approved – a key achievement to promote recruitment. We welcome New Zealand to the ASAR and look forward to the addition of New Zealand-specific data to the registry.

Clinical Quality Reporting

The TSANZ Registries Team implemented quarterly CQR reports in alignment with the requirements of the CQR framework in 2021. The initial CQR reports have focussed on data quality and improvement. To date, these reports have presented snap shots on data completeness for the ASAR overall, and each site has been provided with a site-specific report. This has been helpful in identifying areas with lower levels of data completion, and the subsequent improvement in completion.

Dual and Triple Therapies Report

The ASAR Management Committee and the TSANZ Registries Team undertook an internal cross-sectional descriptive study of the ASAR baseline data. The study characterised patients receiving dual (ICS/LABA) or triple therapy (ICS/LABA + LAMA). Descriptive statistics on eosinophil levels and exacerbation history for a subset of these patients were also presented.

This study was disseminated to ASAR stakeholders as a report. It was well received and has contributed to discussions about future directions for the ASAR.

International Collaboration

The TSANZ and ASAR has continued its collaboration with the International Severe Asthma Registry (ISAR). The ISAR is a global research initiative collecting anonymous longitudinal real-life data for the severe asthma cohort with collaborators from over 29 countries. In 2021, the TSANZ formalised this collaboration with a new agreement. This is a significant achievement for the 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.

With the first anonymised data transfer in late 2020, ASAR data has been approved by the ASAR Management Committee for use in several of ISAR's ethically approved research analyses. The contribution to, and inclusion of the ASAR data in the ISAR dataset provides important geographical representation of the real-world experience from our region to the global understanding of severe asthma.



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.

New Zealand

The ASAR is approved by the Health and Disability Ethics Committees (HDECs) in New Zealand.

Site Governance

As of 31 December 2021, the ASAR was approved at 13 Australian and one New Zealand site. In 2021, one new site - Middlemore Hospital - was approved. Gaining additional local governance in Australia and locality approval in New Zealand will remain a key focus in 2022. Figure 1 demonstrates the locations of sites.



Figure 1. ASAR Sites in Australia and New Zealand

New Enrolments 2021

Between January 2021 and December 2021, 59 new patients were enrolled in ASAR. Of these 59 new patients, 48 have been classified as severe asthma patients and 11 are non-severe asthma patients.

In 2021, there were 257 new data points entered into the ASAR database (Table 4). These data points are summarised below according to visits completed.

Table 4. New ASAR patient enrolment and visits in 2021

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	59	78	16	13	34	29	16	12

Longitudinal Follow-Up

One of the key objectives of the ASAR is to generate longitudinal real-world outcome data in a well-characterised patient cohort in Australasia. The ASAR is seeing increasing numbers and now has participants in their eighth year (visit 9) of follow-up. Table 5 shows the number of participants who have completed baselines and follow-up visits in the ASAR.

Table 5. Total registry population visits completed.

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)	Visit 9 (8-year)
Patient numbers	937	782	685	195	138	105	68	16	2



ASAR Population at Baseline

This section provides an overview of the baseline characteristics of participants in the ASAR. Data was downloaded on 4 April to allow for sites to complete outstanding data entry.

As of 4 April 2022, the ASAR has a population of 937. In the ASAR cohort, there are 766 patients with severe asthma, 139 with non-severe controlled asthma and 32 with an unclassified asthma severity. This classification is based on the definition of severe asthma used in ASAR (Figure 2):

Severe Refractory Asthma: This group includes asthma for which control is not achieved despite the highest level of recommended treatment [refractory asthma and corticosteroid-resistant asthma], and asthma for which control can be maintained only with the highest level of recommended treatment.

The defining characteristics for the severe asthma cohort are as follows:

- 1) Confirmed asthma diagnosis;
- 2) Using maximum inhaled therapy [Inhaled high dose of corticosteroid and 2nd controller];
- 3) Uncontrolled asthma [currently, or on reduction in maximal therapy], which constitutes any ONE or more of:
 - a) Poor symptom control;
 - b) Frequent and/or very severe exacerbations;
 - c) Airflow obstruction;
- 4) Optimised management skills; and
- 5) Triggers and relevant co-morbidity have been assessed and managed.

Figure 2. ASAR definition of severe asthma.

The ASAR population is over 60% females with a mean age of 55 years. Over 60% of the population report to have never smoked, 34% are ex-smokers and 3% are reported as current smokers. The severe asthma has a significantly higher mean baseline Body Mass Index (BMI) and body surface area compared to the non-severe asthma group.

At baseline, the severe asthma group was more likely to have uncontrolled asthma than the non-severe asthma group. They were also more likely to have experienced asthma exacerbations in the 12 months preceding the baseline visit. A greater proportion of the severe asthma cohort were prescribed medications across several medication classes than the non-severe asthma group.





KEY PLANS FOR 2022/2023

The ASAR is now a well-established registry platform with a rich dataset. The ASAR Management Committee and TSANZ intend to capitalise on this strong foundation through quality improvement, expansion, registry outputs and ongoing active collaborations.

2022 ASAR Biennial Summit

The 2022 ASAR Biennial Research Summit will be hosted by the ASAR Management Committee and the TSANZ Registries Team on Friday 14th October 2022. This will be the first in-person Summit for the ASAR, and we are looking forward to (finally) meeting face-to-face!

The Summit is a fantastic opportunity for ASAR stakeholders and collaborators to come together to discuss ideas, future directions and to recognise the important contributions of collaborators to the success of the ASAR.

ASAR Expansion

The ASAR will focus on four important growth mechanisms: 1) ongoing recruitment and follow-up at approved sites; 2) gaining local governance approval at HREC/HDEC approved sites; 3) addition of new sites in Australia and New Zealand; and 4) exploring the feasibility of adding modules of interest, such as mAb-specific arms.

Clinical Quality Registry reports

A key focus for the ASAR will be continuous quality improvement of the data capture and integrity of the registry through CQR reports. These reports will continue to focus on the quality of the data in the ASAR and will be further utilised to identify outcome benchmarks, significant outcome variance and to inform improvements in healthcare quality.

Research Publications

The ASAR Management Committee has identified and formed working groups to address four priority research papers associated with the ASAR. These planned outputs will lean on the strengths of the registry through identifying novel questions that ASAR has the capacity to address.

International collaboration

The ASAR is continuing its collaboration with the International Severe Asthma Registry (ISAR). The ASAR is one of the largest contributors to the ISAR dataset and gives voice to the experience of severe asthma in our region. Importantly, this collaboration enhances the global understanding of severe asthma.



CONCLUSION

The continued growth of the ASAR in 2021, coupled with the focus on the quality of the data has positioned the registry to increase its impact. There is now a well-characterised cohort, with high levels of quality data in a core dataset. Importantly, there is a large baseline population (n=937) and increasing levels of longitudinal follow-up. The longitudinal follow-up is beginning to provide key insights to the experiences of people with severe asthma and non-severe asthma over time. The ability to compare outcomes for patients with severe asthma, and those with non-severe asthma is unique and highly advantageous to increasing the understanding of severe asthma in our region. The ASAR is a robust CQR with the potential for research outcomes to be used to improve patient care and management of severe asthma.

The ASAR Management Committee and the TSANZ extend our sincere appreciation to our colleagues at each site. We acknowledge the challenges of the last few years, and we are looking forward to growing the registry with you.

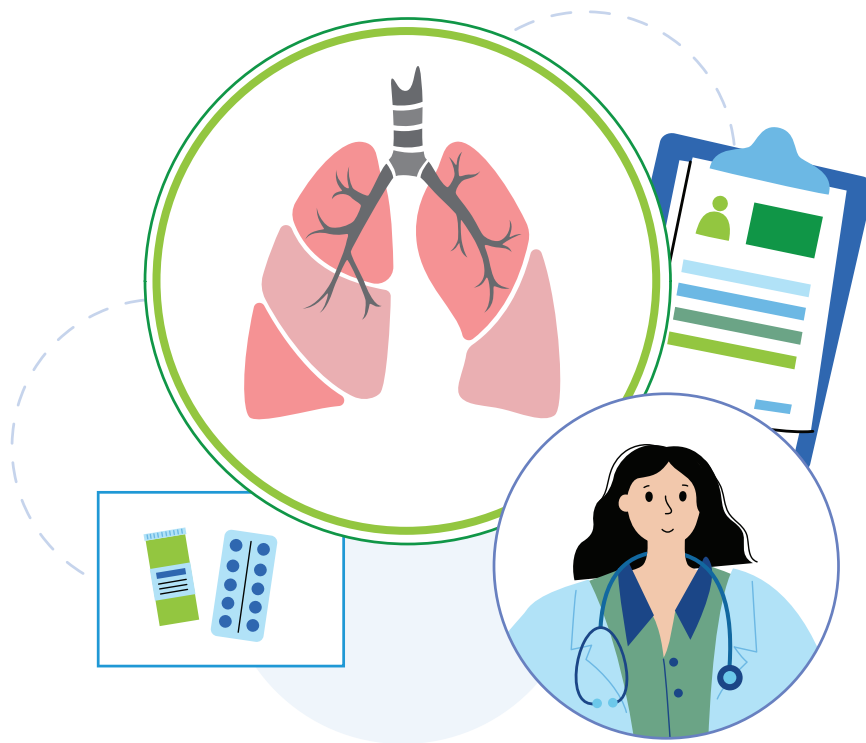


Table 6. SAWD and ASAR reports, presentations, and publications to date.

Type	Details	Date
Report	Clinical Quality Report (circulated to ASAR PIs and site personnel)	December 2021
Report	ASAR – Dual and Triple Therapies Report. Circulated to internal ASAR sponsors and sites.	November 2021
Report	Clinical Quality Report (circulated to ASAR PIs and site personnel)	September 2021
Annual Report	ASAR Annual Report 2020 (circulated to site personnel, PIs, Sponsors). Public edition circulated to all TSANZ members and appropriate consumer groups.	August 2021
Report	ASAR Biennial Research Summit: Virtual Research Day Report. Circulated to Summit delegates, ASAR Sponsors and supporters, TSANZ members, and ASAR site personnel.	February 2021
BIENNIAL RESEARCH SUMMIT	ASAR Biennial Research Summit	3 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>	25 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>	18 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>	27 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>	27 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>	27 Oct 2017

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Type	Details	Date
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	19 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)	1 Oct 2015
Report	SAWD enrolment report, Q1 2015 (circulated to PIs and sponsors)	29 April 2015
Report	SAWD data report, Q4 2014 - preliminary baseline data (circulated to PIs and sponsors)	5 March 2015

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AstraZeneca 

GSK

sanofi

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ASAR

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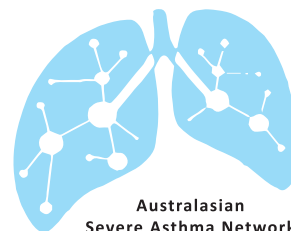
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