Dear STInG members,

Welcome to our annual STInG newsletter! We are excited to share a snapshot of what we've been up to in 2025 and to let you know some of the initiatives we are planning for 2026. One of the major highlights of 2025 was our three-part webinar series on Data and Safety Monitoring Boards (DSMBs), which attracted more than 250 participants from across Australia. We were thrilled to see such enthusiasm for ACTA STInG activities and hope our 2026 program will generate just as much interest.

As always, we are looking forward to catching up with many of you at the ACTA Clinical Trials and Registries Symposium, being held in Melbourne from 17–19 November. As part of the symposium, we will host our annual STInG members' meeting at 7.15am on Tuesday 18 November at the Crown Promenade, with the option to join online. Each year we have a special discussion topic at this meeting. This year we will focus on how generative Artificial Intelligence (AI) can support the day-to-day work of clinical trials biostatisticians — a topic we're sure will spark plenty of interest and is one that we plan on revisiting regularly in ACTA STInG as generative AI continues on its rapid development.

Late last year STInG extended its remit to include registry statisticians, broadening our community to support this major area of research and statistical practice. As such, STInG continues to expand and now has 225 members from over 95 institutions across Australia — welcome to all new members.

In this newsletter, you will find updates on our Trial of the Year – Excellence in Statistics Award, our DSMB mentoring scheme, STInG-Chat, and a range of resources designed to support you in your work as a clinical trials statistician.

We hope you enjoy reading these updates and that you will join us — whether in person or online — for our members' meeting. As always, please reach out with your thoughts, feedback, or ideas for future STInG initiatives.

Best wishes, Kate and Andrew Co-chairs, ACTA STInG





STInG Newsletter - October 2025



ACTA Statistics in Trials Interest Group (STInG) is a group of statisticians, data analysts and clinicians with an interest in statistics in clinical trials and/or registries.

ACTA STING Excellence in Trial Statistics Award



The achievements of Australia's clinical trials sector took centre stage at the 2025 ACTA Trial of the Year (TOTY) Awards ceremony, commemorated on International Clinical Trials Day, 20th of May 2025 in Sydney. These awards celebrate excellence in clinical research, recognising outstanding trials that push the boundaries of scientific inquiry. The awards included the **ACTA STING Excellence in Trial Statistics Award** which highlights the quality of statistical design, trial methodology, statistical rigour, and interpretation of results. It is a fantastic way for trial statisticians to receive recognition for their hard work and critical input, and we highly encourage you to consider applying for this award in 2026.

This year, we were pleased to announce that **Kate Francis**, Lead Statistician from the Interdisciplinary Maternal Perinatal Australasian Collaborative Trials Network was awarded winner of the ACTA STING Excellence in Trial Statistics Award for the **PLUSS trial**.

The PLUSS trial was a multicentre, double-blind, randomised controlled trial of 1,000 infants investigating whether the administration of intra-tracheal Budesonide during the initial treatment of respiratory distress syndrome in extremely preterm infants increased survival without bronchopulmonary dysplasia at 36 weeks postmenstrual age. The trial included transparent

reporting of outcomes that were pre-specified in their publicly available, and peer reviewed statistical analysis plan. Read all about the trial <u>here</u>. Congratulations Kate!



From left to right: Prof Steve Wesselingh, Kate Francis, Prof Chris Reid

Prof **Laurent Billot** from The George Institute for Global Health was recognised as runner-up for their exceptional work on **BLING III** - A phase III randomised controlled trial of continuous beta-lactam infusion compared with intermittent beta-lactam dosing in critically ill patients. Read all about the trial here.

Data and Safety Monitoring Board (DSMB) mentoring program



The STInG **Data and Safety Monitoring Board (DSMB)** mentoring program was launched in 2021 to facilitate and support training for statisticians in the role of a DSMB statistician. Moreover, this is an important initiative for the Australian clinical trials community to have an expanded pool of statisticians able to participate in DSMBs; a critical aspect of clinical trial conduct. The mentoring program pairs statisticians (mentees) looking to develop their skills with mentors who have substantial DSMB experience with the aim of the mentee being able to take on a DSMB role following completion of the program, and ultimately become a mentor themselves. So far, 14 mentoring pairs have taken part in the program with most still ongoing. We are pleased to have received almost 30 applications following our call for mentees and mentors mid this year.

To find out more about the DSMB mentoring program, or for general resources, follow this <u>link</u>, or email us: <u>dsmb.program@acta.au</u>.

A HUGE thank you to the coordinators of the DSMB program- Anneke Grobler and Sabine Braat. This fantastic initiative couldn't run without your leadership, support, and dedication.



2025 STInG Webinars

<u>6 March 2025</u>: Developing a best practice guide for registry-based trials, presented by *Dr Swarna Vishwanath*

Registry-based trials (RBTs) leverage existing clinical registries to offer faster, cost-effective alternatives, enhancing Australia's research capacity. However, RBTs face methodological and operational challenges. This presentation provided a detailed look at a project focused on creating a best practice guide to support the planning, execution, and documentation of RBTs. Watch Here: ACTA Webinar – Developing a Best Practice Guide for Registry Based Trials – ACTA – Australian Clinical Trials Alliance

<u>21 May 2025</u>: Data Integrity Tool for assessing the integrity of randomised trials, presented by *Sol Libesman and Kylie Hunter*

This webinar covered:

- An introduction to the integrity crisis in medical research and actions to address this
- The importance of individual participant data to identify integrity issues
- The Individual Participant Data (IPD) Integrity Tool: What it is. How and when it can be used
- Future directions, questions, and comments

Watch Here: Data Integrity Tool for assessing the integrity of randomised trials

<u>September-October 2025</u>: Three-part webinar series on Data and Safety Monitoring Boards (DSMBs):

With a steady increase in the number of clinical trials comes an increasing demand for clinicians and statisticians who can serve on DSMBs. STInG recently hosted a 3-part webinar series to provide training on the complexities of serving on a DSMB:.

1) <u>9 September 2025</u>: Interim Data Sharing by Data Safety Monitoring Board: What to share, with whom, and why, presented by *Lehana Thabane*

Watch Here: Interim Data Sharing by Data Safety Monitoring Board: What to share, with whom, and why - Part 1

2) <u>7 October 2025</u>: The challenges of stopping trials for benefit: Lessons learnt from the immediate Kangaroo Mother Care (iKMC) trial, presented by *Lehana Thabane*

Watch Here: The challenges of stopping trials for benefit: Lessons learnt from the (iKMC) trial - YouTube

3) <u>14 October 2025</u>: Adaptive Allies: The Evolving Roles of DSMBs and Investigators in Bayesian Platform Trials, presented by *Tom Snelling & Julie Marsh*

Watch Here: Adaptive Allies: The Evolving Roles of DSMBs and Investigators in Bayesian Platform
<u>Trials</u>

Remember: If you missed any webinars, or would like to watch them again, please access via the ACTA webpage (under: Resources > STING / DSMB), or ACTA YouTube channel (Australian Clinical Trials Alliance - YouTube).

STInG-CHAT



STInG-Chat was established in 2023 to create a relaxed space for our STInG members to discuss statistical careers, ideas, and challenges. We share tips, tools, and workflows and aim to foster a sense of community.

These sessions see our hosts, Andrew Forbes and Kristy Robledo, interview clinical trial statisticians about various aspects of their work or career. This year, Andrew and Kristy discussed **What makes this trial great?** with the winners of the ACTA STInG Excellence in Trial Statistics Awards from 2024 and 2025- Francesca Orsini and Kate Francis (on the 1^{st of} October). We heard about their work carefully designing trials and their analytic approaches in close conjunction with their key subject-matter trialists, as well as their challenges and key decision-making that embodied what it took to win this prestigious award. Watch Here: <u>STInG Chat – What makes this trial great? – ACTA – Australian Clinical Trials Alliance</u>.

It was an engaging discussion and we plan to hold a similar session with 2026's STInG award winner. Next year, we also plan on having a session on 'soft skills' required for clinical trials statisticians - how to 'acquire' them and how to use them effectively.

We are always very keen to receive suggestions for future STInG-Chat sessions so if you have any ideas please do get in touch.

2025 Upcoming Events





The **ACTA 2025 Clinical Trials and Registries Symposium** is taking place from 17-19th of November at the Crown Promenade Hotel, Melbourne.

In accordance with this years' theme of '*Driving change*', ACTA is thrilled to come together once again with the Association of Regulatory and Clinical Scientists (ARCS) and the Australian Trials Methodology (AusTriM) Research Network to bring together like-minded industry leaders, establishing Clinical Trials Week as a key event on Australia's healthcare and research calendar.

The symposium is a fantastic opportunity to network with other STInG members as well as the broader ACTA community. It will also feature a platform trials workshop that will be relevant to many STInG members.

Register Here for ACTA: ACTA 2025

Register Here for ARCS: 2025 Clinical Summit



AusTriM Conference 2025

Following on from the ACTA symposium is the AusTriM conference, on the 20th of November, which showcases the latest statistical methodology developments in clinical trials in Australia and beyond.

This event is for:

- Clinical trialists working in, or interested in, new trial designs (such as adaptive, platform, cluster, or multi-stage designs) or analysis methods
- Biostatisticians
- Trial data managers and registry custodians
- Trial coordinators and research managers
- PhD candidates and Masters students in the field of clinical research and/or statistics
- Consumer advocates and consumers

Register Here for AusTriM: #atmc25

STInG Annual Members Meeting

Our annual STInG members meeting will be held on Tuesday 18th November, at 7:15-8am at the Crown Promenade Hotel, Melbourne during the ACTA Symposium. Please join us for this opportunity to meet and network with peers, while providing input on future STInG initiatives and direction. This year, we will focus the discussion on generative Artificial Intelligence in trials. We look forward to seeing you there!

Please note, while it would be great to meet you in person, if you cannot attend, the meeting will also be accessible virtually. If you have not received an invitation, please email us (acta@acta.au).

Looking to 2026

We have started planning the 2026 STInG activities calendar and are excited about what lies ahead.

Here's a sneak peek of what's to come:

- Target trial emulation for observational/registry data
- Registry statisticians Masterclass/Workshop- A tailored session exploring the performance of different statistical methods used in registries
- Confusions and controversies around pragmatic trials: Separating fiction from fact
- Perils and benefits of subgroup analyses

Keep an eye on your inbox and the ACTA Newsletter for updates and registration details.

If you have any suggested topics for STInG-Chat or Webinars that would be of interest, please email us: sting@acta.au.

STInG Membership

Late last year STInG extended its remit to include registry statisticians, broadening our community to support this major area of research and statistical practice. As such, STInG continues to expand and now has 225 members from over 95 institutions across Australia. STInG is led by an Executive Committee of 12 members, and we recently put a call out for new committee members to join the team. We would like to introduce **Andrew Martin, Liz Ryan, Mike Trott and Stuart Szwec** as our newest members and look forward to the ideas they will bring.

The core mission of STInG is to enable statisticians working in trials all across Australia to feel supported and heard. If you know of anyone who does not have this support and would like to become a member of STInG, please encourage them to complete this application form: <u>ACTA STInG membership application- New 2025 Survey.</u>

STInG Members Exclusive Directories

Did you know that members of STInG are able to access *member-only directories* via the ACTA website? These are available to support our members and encourage collaboration within our community.



1) The **Find a Statistician (FAS)** directory includes details of statisticians who may be available for support and collaboration on specific topics or research areas within trial design and analysis. We currently have 61 members listed on the FAS Directory. If you would like to be added, please follow this link: https://www.surveymonkey.com/r/Z7JW65B, indicate Yes to Question 11, and continue on to complete Page 2. Or, if you are a current member, please

check that your details are correct and up to date. If any changes are required, email sting@acta.au.

2) The Data and Safety Monitoring Board (DSMB) directory includes details and expertise of our members who may be available to sit on DSMBs for clinical trials. We currently have 44 members who have a wealth of expertise across many different trial designs, including adaptive trials.

Resources and Links



The **STInG Discussion Forum** is a valuable resource where you can post your questions and challenges, receive input from fellow statisticians, and enhance your networking and support. If you would like to post a discussion on our forum, please log-in via the Gaggle website and send your message: <u>Gaggle Mail | #1 Modern Listserv Replacement</u>

Platform trials: key features, when to use them and methodological challenges
Robert Mahar, Steve Webb, Ian Marschner, Andrew Forbes and Katherine Lee, <u>Medical Journal of Australia</u>, 2025 Jun 22;223(3):120–122.

A practical guide to simulation for an adaptive trial design with a single interim analysis Kaushala Jayawardana, Michael Dymock, Robert Mahar, Julie Marsh and Katherine Lee, *Trials*, 2025, 26, *Article number:* 400.

Staphylococcus aureus bacteraemia Network Adaptive Platform Trial (SNAP): For Investigators | SNAP Trial – Staphylococcus aureus Network Adaptive Platform Trial

As part of good clinical practice, every academic clinical trial should have a detailed statistical analysis plan (SAP) that is publicly available. <u>This page</u> provides guidance on how to develop a SAP, including a template, as well as examples of SAPs from previous winners of the ACTA STING Excellence in Trial Statistics Award.



Stay up to date with the latest news from ACTA by subscribing to the ACTA monthly newsletter here: Australian Clinical Trials Alliance