

The **ACTA Trial of the Year Award** was established in 2016 to recognise and celebrate the outstanding achievements of our Members who advance clinical practice and save or improve the lives of patients every year through investigator-driven clinical trials.

### Award Guidelines

Trials considered for the award will be collaboratively developed, multicentre, investigator-driven, randomised controlled trials that were designed to improve patient-centred outcomes or healthcare delivery.

The trial must have been designed and led by a network or investigator group that is a current Member of ACTA (Full or Associate Member) and the primary results\* of the trial must have been published in the 2019 calendar year (electronically or in print). Each trial may only be considered in one calendar year.

A peer-led panel of senior trialists and consumer representatives appointed by the ACTA Board will review all nominations and judge the trial that is the best demonstration of the following standards<sup>±</sup>:

- **It addressed a critical gap in the evidence or a significant innovation in healthcare delivery.**
- **The quality of the research design, conduct and analysis were outstanding.**
- **There is a high likelihood that findings from the trial will significantly impact clinical practice and policy and improve outcomes for patients or healthcare delivery.**

Any current ACTA Member (Full, Associate or Affiliate Member) can nominate a trial for consideration. Members may nominate more than one trial for consideration.

### ACTA STInG Excellence in Trial Statistics Award

Alongside the judging process for ACTA Trial of the Year, nominated trials can be reviewed by an expert panel of statisticians convened by the ACTA Statistics in Trials Interest Group (ACTA STInG).

This panel will consider the statistical methods summary provided on the trial nomination form, along with the trial's published statistical analysis plan and primary results paper to identify a trial for which:

- **The statistical aspects of trial design and planning (sample size, randomisation, analytical methods) were of high quality, appropriate for the research question(s), and documented in a publicly accessible statistical analysis plan following good statistical procedures/practice.**
- **The statistical analyses were executed as planned and, where not, deviations were transparent, of high quality, and executed well following good statistical procedures/practice.**
- **The reporting and interpretation of the statistical aspects of the trial were appropriate, transparent, and supported by results from pre-specified analyses and/or well-defended departures from planned procedures following good statistical procedures/practice.**

The **ACTA Trial of the Year Award** will be judged according to the criteria above, including whether the trial addressed a critical evidence gap and its likely impact on policy and practice. The **ACTA STInG Excellence in**

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\* Primary results refers to the first publication reporting the analysis of trial's primary endpoint as specified in the published protocol, statistical analysis plan or online trial registration profile.

<sup>±</sup> The ACTA Board will consider the recommendations of the judging panel in making its decision to announce the winning trial, named finalists and the recipient of the Excellence in Trial Statistics Award. The Board's decision will be final.

**Trial Statistics Award** will be judged separately on the statistical component alone. As such, it may be that the **ACTA Trial of the Year** wins both awards, or it may be one of the named finalists or a trial that otherwise does not make the finalists list for ACTA Trial of the Year wins the ACTA STInG **Excellence in Trial Statistics Award**.

### Announcement of winner(s)/finalist and requirements for investigators

The investigators of the winning trial(s) and finalists will be notified confidentially in the first week of May, with the awards to be announced publicly on 20 May 2020 in Sydney, during a ceremony that will also mark International Clinical Trials Day.

For the ACTA Trial of the Year Award either the Chief Investigator or a nominated senior member of the of the investigator group or network of the winning trial (and wherever possible, each of the named finalists) must be available to attend the ceremony in Sydney to receive the award and to participate in media activities in relation to the awards, including by helping to source trial participants or patients for interview.

For the ACTA STInG Excellence in Trial Statistics Award either the Chief Statistician or a nominated senior Statistician of the network or investigator group must be available to attend the award ceremony to accept the award.

### Prizes

The Chief Investigator of the trial named **ACTA Trial of the Year Award** will receive \$2500 to benefit the group and enhance the future of healthcare through the attendance of a clinical trial conference, registry symposium or training program for the group. ACTA will kindly seek a summary on how funds were invested back into trials or supported consumer engagement in clinical trials. In addition, the group will be awarded one complimentary registration and an invitation to give a presentation on key lessons learned from the trial at the ACTA 2020 Summit. Travel and registration costs to attend both the award ceremony and presentation at the ACTA Summit will also be supported for one representative.

The winning trial for the **ACTA STInG Excellence in Trial Statistics Award** will receive \$1000 to build capacity and capability within the sector through the attendance of a clinical trial conference, registry symposium or training program. ACTA will seek a summary on how funds were invested back into trials or supported early career biostatisticians.

### How to nominate a trial

Any current paid ACTA Member may nominate a trial for consideration by providing the following:

- **A completed nomination form signed by an ACTA member or Authorised Representative. This will include:**
  - **A brief peer summary (approx. one page) describing the trial and why it warrants recognition as ACTA Trial of the Year.**
  - **A brief lay summary (approx. half page) describing the trial and how the results are likely to impact patients and/or the delivery of healthcare. Lay summaries should be suitable for publication on the ACTA website and in the general media.**
- **A PDF copy of the published paper and supplementary materials. We encourage teams to submit material such as communication between the journal and the team and internal (more detailed) study reports.**

If applying for ACTA STInG Excellence in Trial Statistics Award, the following must also be provided:

# ACTA Trial of the Year Awards 2020

## Guidelines and Nomination Form

- A PDF copy of the protocol, statistical analysis plan, and supplementary material of the statistical analysis plan.
- A brief summary (approx. half to one page) describing the statistical design and analysis of this trial and why it warrants consideration for the Excellence in Trial Statistics Award.

Nomination forms can be downloaded from the ACTA website at:

<https://clinicaltrialsalliance.org.au/events-forums/clinical-trials-2020-national-tribute-and-award-ceremony/>

**Nominations will close at 5 pm AEDT, Friday 3 April 2020.** No further nominations will be accepted after the deadline.

Please submit the completed form, along with a PDF copy of the trial's primary results publication and supplementary materials, to:

Lisa Reid, Communications Manager  
[awards@clinicaltrialsalliance.org.au](mailto:awards@clinicaltrialsalliance.org.au)

The winner will be notified in the first week of May and announced publicly during the **ACTA Trial of the Year Awards Ceremony** on **Wednesday 20 May, 2020**.

Scientific Name of the Trial	
Short Name of the Trial	
Please confirm that the nominated trial is: (please tick)	<input type="checkbox"/> collaboratively developed <input type="checkbox"/> multicentre <input type="checkbox"/> investigator-driven <input type="checkbox"/> randomised controlled
Name of the ACTA member network or group that designed and led the trial	
Name of the coordinating centre that managed the trial's conduct	
Name of the Chief Investigator	
Email	
Phone	
Citation of the publication in which the primary results were reported	
Date published (electronic or in print)	
Where was the trial's statistical analysis plan published? (please provide a web address or citation where available)	
Did this trial receive funding from the NHMRC? If so, please provide the amount and the NHMRC Funding ID number.	
Did this trial involve any formal collaboration with a commercial entity? If so, please provide a brief summary of industry involvement.	

### Peer Summary

Please provide a brief summary (approx. one page) describing the trial and why it warrants recognition as Trial of the Year. In addition, please address each of the judging criteria:

- The trial addressed a critical gap in the evidence or a significant innovation in healthcare delivery.
- The quality of the research design, conduct and analysis were outstanding.
- There is a high likelihood that findings from the trial will significantly impact clinical practice and policy and improve outcomes for patients or healthcare delivery.

### Lay Summary

Please provide a brief lay summary (approx. half page) describing the trial and how the results are likely to impact patients and/or the delivery of healthcare. This should be suitable for publication on the ACTA website and in the general media.

A PDF copy of the published paper and supplementary materials is provided with this nomination form.

### ACTA STInG EXCELLENCE IN TRIAL STATISTICS AWARD 2020 NOMINATION FORM

If applying for the 2020 ACTA STInG Excellence in Trial Statistics Award, please also complete the below:

#### Statistical Methods Summary

Please provide a brief summary (approx. half to one page) describing the statistical design and analysis of this trial and why it warrants consideration for the ACTA STInG Excellence in Trial Statistics Award. In addition, please address each of the judging criteria:

- The statistical aspects of trial design and planning (sample size, randomisation, analytical methods) were of high quality, appropriate for the research question(s), and documented in a publicly accessible statistical analysis plan following good statistical procedures/practice.
- The statistical analyses were executed as planned and, where not, deviations were transparent, of high quality, and executed well following good statistical procedures/practice.
- The reporting and interpretation of the statistical aspects of the trial were appropriate, transparent, and supported by results from pre-specified analyses and/or well-defended departures from planned procedures following good statistical procedures/practice.

- A PDF copy of the protocol, statistical analysis plan, and supplementary material of the statistical analysis plan is provided with this nomination form.

#### DECLARATION FORM

I have read the award guidelines and believe this trial is eligible to be considered for (please tick):

- the ACTA 2020 Trial of the Year Award (compulsory)
- the ACTA STInG Excellence in Trial Statistics Award (optional)

Trial nominated by			
Email			
Phone			
Signature		Date	