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

In 2023, ACTA is proud to be continuing to showcase the work and impact of Australian clinical trial teams. We look forward to receiving your nomination/s.

**THINGS TO KNOW**

* The nomination submission deadline is midnight, Tuesday 13 June 2023
* Please send your nomination/s to: awards@clinicaltrialsalliance.org.au
* For further information about the awards, please contact ACTA via: +61 3 8639 0770
or awards@clinicaltrialsalliance.org.au
* All winners will be notified by phone and/or email and announced publicly at the National Tribute and Awards Ceremony.
* The National Tribute and Awards Ceremony will be held at the International Trials Symposium on 28 November 2023 as part of the Gala Dinner

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| **ACTA TRIAL OF THE YEAR Award Guidelines** |

Trials considered for the ACTA Trial of the Year 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[[1]](#footnote-2) of the trial must have been published in the 2022 calendar year (electronically or in print).

A peer-led panelof senior trialists and consumer representatives appointed by the ACTA Boardwill review all nominations and judge the trial that is the best demonstration of the following standards[[2]](#footnote-3):

* **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; however, the trial must have been led by a network or investigator group that is a current Member of ACTA (Full or Associate Member). Multiple trials can be submitted using a separate nomination form for each trial. If suitable, trials can also be submitted in the ACTA Industry Partnership Award category (guidelines and application for this award are available on the [ACTA website](https://clinicaltrialsalliance.org.au/events-forums/clinical-trials-2022-national-tribute-and-award-ceremony/)).

A trial that has previously received the Award (or was runner-up) is not eligible to nominate a different aspect of the same overarching trial for this Award. This, for example, excludes nomination of a different domain of a previously awarded platform trial.

**prize for the ACTA TRIAL OF THE YEAR Award**

The Chief Investigator of the trial named **ACTA Trial of the Year Award** will receive $2,500 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, one nominated representative will be awarded a complimentary ticket to attend and accept the award at the *ACTA Trial of the Year Awards* in November and one complimentary registration and an invitation to give a presentation at the *2023 ACTA International Clinical Trials Symposium* in November on key lessons learned from the trial. Return economy airfares (excluding accommodation) will also be provided. The Trial of the Year Awards ceremony will be held during ACTA’s Symposium on 28 November 2023.

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| **ACTA STInG Excellence in Trial Award GUIDELINES *(Additional optional nomination)*** |

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) for the **ACTA STInG** **Excellence in Trial Statistics Award**.

This panel will consider the statistical methods summary provided within 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 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**.

 **prize for the ACTA STInG Excellence in Trial Statistics Award**

The winning trial group for the **ACTA STInG Excellence in Trial Statistics Award** will receive $1,000 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 further supported consumer engagement in clinical trials or supported early career biostatisticians.

In addition, the Chief Statistician or a nominated senior Statistician of the network or investigator group will be awarded one complimentary ticket to attend and accept the award at the *ACTA Trial of the Year Awards* in November and one complimentary registration and an invitation to give a presentation at the *2023 ACTA International Clinical Trials Symposium* in November on key lessons learned from the trial. Return economy airfares (excluding accommodation) will also be provided. The Trial of the Year Awards ceremony will be held during ACTA’s Symposium on 28 November 2023.

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| **ACTA CONSUMER INVOLVEMENT AWARD GUIDELINES *(Optional nomination)*** |

Trials considered for the **ACTA Consumer Involvement 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). **Recruitment for the trial must be complete** (as per the enrolment target)[[3]](#footnote-4) at the time of nomination, and the trial must not have been nominated for this award previously.

Applicants should demonstrate exceptional creative and collaborative initiatives that involved consumers, incorporating the needs and values of patients and the public into trial protocol development (including priority setting) and design.

A peer-led panelof senior trialists and consumer representatives appointed by the ACTA Boardwill review all nominations and judge according to the following criteria[[4]](#footnote-5):

* **Consumers were significantly involved in protocol development or design activities**
* **Consumer involvement provided valuable and exceptional guidance to the proposed conduct of the trial.**

**PRIZE FOR THE ACTA CONSUMER INVOLVEMENT AWARD**

The winning trial for the **ACTA Consumer Involvement Award** will receive $1,000 to benefit the CTN and enhance the future of consumer involvement in healthcare through the attendance of a clinical trial conference, registry symposium or training program for the group. ACTA will seek a summary on how funds were invested back into trials or further support consumer engagement in clinical trials.

In addition, one nominated representative will be awarded a complimentary ticket to attend and accept the award at the *ACTA Trial of the Year Awards* in November and one complimentary registration and an invitation to give a presentation at the *2023 ACTA International Clinical Trials Symposium* in November on key lessons learned from the trial. Return economy airfares (excluding accommodation) will also be provided. The Trial of the Year Awards ceremony will be held during ACTA’s Symposium on 28 November 2023.

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| **ACTA HEAT Excellence in Trial-BASED HEALTH ECONOMICS Award GUIDELINES** |

The nominated analyses will be reviewed by an expert panel of health economists convened by the ACTA Health Economics Alongside Trials Interest Group (ACTA HEAT) for the **ACTA HEAT** **Excellence in Trial-Based Health Economics Award**.

This panel will consider the health economics methods summary provided within the trial nomination form, along with the trial’s health economics analysis plan; health economics results paper and/or primary results paper to identify a trial for which:

* **The health economics aspects of trial design and planning (e.g. collection and valuation of healthcare use data, patient-reported outcomes) were of high quality, and appropriate for the research question(s).**
* **The health economics analyses were executed as planned (e.g. as stated in the Health Economics Analysis Plan (HEAP) and, where not, deviations were transparent, of high quality, and well executed following best practices.**
* **The reporting and interpretation of the health economic analyses and sensitivity analyses were appropriate, transparent, and supported by results**
* **The health economics analyses make a significant contribution to trials methodology, or health and social policy, or health impact.**

The **ACTA HEAT** **Excellence in Trial-Based Health Economics Award** will be judged on the criteria above. It may be that the **ACTA Trial of the Year** award also wins the ACTA HEAT award, 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 HEAT** **Excellence in Trial-Based Health Economics Award**.

**prize for the ACTA HEAT Excellence in Trial BASED HEALTH ECONOMICS Award GUIDELINES Award**

The winning individual or group for the **ACTA HEAT Excellence in Trial-Based Health Economics Award** will receive $1,000 to build capacity and capability within the sector through the attendance at a clinical trials conference, registry symposium or health economics training program. **ACTA will seek a summary on how funds were invested** back into trials or methodological research.

**requirements OF AWARD WINNERS**

For the **ACTA Trial of the Year Award** and the **ACTA Consumer Involvement Award**, either the Chief Investigator or a nominated senior member of the investigator group or network of the winning trial (and wherever possible, each of the named finalists and a nominated consumer involved in the trial) must be available to attend the ceremony 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.

For the **ACTA HEAT Excellence in Trial-Based Health Economics Award**, either the lead Health Economist or a nominated senior member of the trials network or coordinating centre must be available to attend the award ceremony to accept the award.

**HOW TO NOMINATE A TRIAL**

Any current and financial Full, Associate or Affiliate ACTA Member may nominate a trial for consideration by providing the following:

* **A completed nomination form signed by an ACTA Member or authorised representative from an ACTA Member.** This will include:
	+ A brief peer summary (approx. one page) describing the trial and why it warrants recognition
	+ A brief easy English summary (approx. half page) describing the trial and how the results are likely to impact patients and/or the delivery of healthcare. Easy English 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.**

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

* **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**
* **A PDF copy of the protocol, statistical analysis plan, and supplementary material of the statistical analysis plan of the primary results paper.**

If applying for ACTA Consumer Involvement Award, the following must be provided:

* **A brief summary on the level of consumer involvement**
* **A brief summary of consumer involvement value**
* **A PDF copy of evidence of the impact the patient-centric activity had on the trial. Documentation may include but are not limited to the published paper or trial protocol.**

If applying for ACTA Heat Excellence in Trial Based Health Economics Award

* **A completed nomination form signed by an ACTA Member, HEAT SIG member or authorised representative from an ACTA Member. This will include:**
	+ **A brief peer summary (approx. one page) describing the health economic analysis and why it warrants recognition**
* **A brief easy English summary (approx. half page) describing the health economic analysis and how the results are likely to impact patients and/or the delivery of healthcare. Easy English 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.**

The nomination form for all awards is included below. Please ensure you complete all relevant sections of the form before submission.

**Nominations will close at midnight, 13 June 2023.** No further nominations will be accepted after the deadline.

Please **submit the completed form in Word format**, along with a PDF copy of the trial’s primary results publication and supplementary materials, to: **awards@clinicaltrialsalliance.org.au****.**
All winners will be notified at least six weeks prior to ACTA’s **National Tribute and Awards Ceremony – Trial of the Year Awards**. Information about this event is available on the [ACTA website](https://clinicaltrialsalliance.org.au/events-forums/clinical-trials-2022-national-tribute-and-award-ceremony/).

**NOMINATION FORM**

**SECTION 1 OF 6**

**This section must be completed for all award nominations**

|  |  |
| --- | --- |
| **Scientific name of the trial** | Click or tap here to enter text. |
| **Short name of the trial** | Click or tap here to enter text. |
| **Please confirm that the nominated trial meets the following eligibility criteria *(please tick all that apply)*** | [ ]  collaboratively developed[ ]  multicentre[ ]  investigator-driven[ ]  randomised controlled*ACTA Consumer Involvement Award only:*[ ]  trial recruitment is complete (as per enrolment target)  |
| **Name of the ACTA Member network or group that designed and led the trial** | Click or tap here to enter text. |
| **Name of the coordinating centre that managed the trial’s conduct** | Click or tap here to enter text. |
| **Name of the Chief Investigator** | Click or tap here to enter text. |
| **Email** | Click or tap here to enter text. |
| **Phone** | Click or tap here to enter text. |
| **Citation of the publication in which the primary results were reported (include weblink if available) *– NOT APPLICABLE for the Consumer Involvement Award[[5]](#footnote-6)***  | Click or tap here to enter text. |
| **Date trial results published (electronic or print)*****– NOT APPLICABLE for the Consumer Involvement Award*** | Click or tap here to enter text. |
| **Is there a statistical plan published? If so, please provide the web address**  | Click or tap here to enter text. |
| **Did this trial receive funding from the NHMRC? If so, please provide the amount and the NHMRC Funding ID number.** | Click or tap here to enter text. |
| **Did this trial receive funding from the Commonwealth, other than the NHMRC? If so, please provide the amount and identifier (where appropriate).** | Click or tap here to enter text. |
| **Did this trial involve any formal collaboration with a commercial entity? If so, please provide a brief summary of industry involvement. *(You may also like to consider submitting a nomination for the*** [***ACTA Industry Partnership Award***](https://clinicaltrialsalliance.org.au/events-forums/clinical-trials-2022-national-tribute-and-award-ceremony/)***)***  | Click or tap here to enter text. |

**SECTION 2 OF 6**

**This section must be completed for all award nominations**

**DECLARATION**

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

[ ]  **ACTA Trial of the Year Award** ONLY

[ ]  **ACTA Trial of the Year Award** AND **ACTA STInG Excellence in Trial Statistics Award**

[ ]  **HEAT Excellence in Trial Based Health Economics Award**

[ ]  **ACTA Consumer Involvement Award** ONLY

[ ]  **ALL AWARDS**

|  |  |
| --- | --- |
| **Trial nominated by** | Click or tap here to enter text. |
| **Email** | Click or tap here to enter text. |
| **Phone** | Click or tap here to enter text. |
| **Signature** | Click or tap here to enter text. | **Date** | Click or tap here to enter text. |

**Nominations will close at midnight, 13 June 2023.** No further nominations will be accepted after the deadline. Please return your completed form to awards@clinicaltrialsalliance.org.au.

**SECTION 3 OF 6**

**If you are nominating a trial for the ACTA Consumer Involvement Award only, please skip this section and go to section 5.
Please complete this section for all other award nominations**

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| **Peer summary****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.
 |
| Click or tap here to enter text. |
| **Easy English summary** |
| Please provide a brief easy English 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. |
| Click or tap here to enter text. |

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

**SECTION 4 OF 6**

**Please complete this section if you would like the nominated trial**

**to be considered for the 2023 ACTA STInG Excellence in Trial Statistics Award.**

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| **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 below. This summary comprises an important part of the assessment for the Award:* 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.
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| Click or tap here to enter text. |

[ ]  **A** **PDF copy** of the protocol, statistical analysis plan, and supplementary material of the statistical analysis plan of the primary results paper is provided with this nomination form.

**SECTION 5 OF 6**

**Please complete this section if you would like the nominated trial**

**to be considered for the 2023 ACTA Consumer Involvement Award.**

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| **Trial recruitment enrolment target** |
| **S**Click or tap here to enter text. **on the Level of Consumer Involvement (max 600 words)** |
| **Brief summary on the level of consumer involvement (max 600 words)** |
| Describe the initiatives undertaken to incorporate consumers’ perspectives into the trial. Describe how consumer(s) were involved in any of the following activities. Activities designed to support any phase of the clinical trial journey may be submitted, including but not limited to:* Identification of a research gap.
* Protocol concept: including consumer insights on the burden of disease and collaboration in developing research questions with the study team or investigator e.g., what we want to know from the research and development of competitive grant funding application (if applicable).
* Protocol development: including elements of inclusion/exclusion criteria, study procedures, development of the patient information & consent form(s), initiatives to enhance patient convenience and study compliance, endpoint data collection.
* Patient-centric recruitment or retention plans; including social media strategies.
* Engagement of relevant charities or patient groups. Initiatives to enhance patient convenience and study compliance.
 |
| Click or tap here to enter text. |
| **Brief summary on consumer involvement value (max 600 words)** |
| Describe the value to the study of consumer involvement in this clinical trial’s activities? e.g., experiential knowledge, often subjective or qualitative: |
| Click or tap here to enter text. |
| Describe the value to the study of consumer involvement in this clinical trial’s activities? e.g., experiential knowledge, often subjective or qualitative: |
| Click or tap here to enter text. |

[ ] **A PDF copy** of evidence of the impact the patient-centric activity had on the trial is provided with this nomination form, if available.

**SECTION 6 OF 6**

**Please complete this section if you would like the nominated trial**

**to be considered for the 2023 ACTA HEAT Excellence in Trial Based Health Economics Award**

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| **Brief peer summary describing the health economic analysis and why it warrants recognition** |
| **S**Click or tap here to enter text. **on the** **Level of Consumer Involvement (max 600 words)** |
|  **Brief English summary describing the health economic analysis and hot the results are likely to impact patients and/or the delivery of healthcare.**  |
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[ ]  **A PDF copy** of evidence of the impact the patient-centric activity had on the trial is provided with this nomination form, if available.

**YOU ARE NOW READY TO SUBMIT YOUR NOMINATION!**

**Nominations will close at midnight, 13 June 2023.**

No further nominations will be accepted after the deadline.

Please return your completed nomination to

awards@clinicaltrialsalliance.org.au

1. Primary results refer 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. [↑](#footnote-ref-2)
2. The ACTA Board will consider the recommendations of the judging panel/s in making decisions to announce the winning trials. ACTA Board’s decision will be final. [↑](#footnote-ref-3)
3. Non-finalised trials are eligible for the Consumer Involvement Award, only if the recruitment is complete. [↑](#footnote-ref-4)
4. The ACTA Board will consider the recommendations of the judging panel in making its decision to announce the recipient of the ACTA Consumer Involvement Award. ACTA Board’s decision will be final. [↑](#footnote-ref-5)
5. Trials nominated for the Consumer Involvement Award can still be in progress. [↑](#footnote-ref-6)