

The **ACTA Consumer Involvement Award** has been established 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 consumer involvement in investigator-driven clinical trials.

*Consumer Involvement is defined as an active partnership involving consumers (patients, carers or members of the public who use health services) in clinical research, above and beyond participation in trials.*

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### 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). Recruitment for the trial must be complete (as per the enrolment target) 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 panel of senior trialists and consumer representatives appointed by the ACTA Board will review all nominations and judge according to the following criteria<sup>±</sup>:

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

The **ACTA Consumer Involvement Award** will be judged separately to the **ACTA Trial of the Year** and **ACTA STInG Excellence in Trial Statistics Awards** and it is not compulsory that a trial be considered for all three awards.

### *Announcement of winner and requirement for nominees*

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 at the **National Tribute and Awards Ceremony**, which align with the week of International Clinical Trials Day, held annually on 20 May.

The Chief Investigator or a nominated senior member of the investigator group or network of the winning trial and preferably 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.

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<sup>±</sup> 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. The Board's decision will be final.

### **Prizes**

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, the winning group will be awarded one complimentary registration and an invitation to give a presentation at the ACTA 2021 Summit on key lessons learned from involving consumers in the winning trial. Travel and registration costs to attend both the awards ceremony and presentation at the ACTA Summit will also be supported for one consumer.

### **How to nominate a trial**

Any current and financial ACTA Member may nominate a trial for the **ACTA Consumer Involvement Award** by providing the following:

- **A completed nomination form signed by an ACTA Member or Authorised Representative; this will include:**
  - A brief summary (approx. half-page) describing the trial and the reasons and method for involving consumers.
  - A brief summary (approx. half-page) describing the trial and how the results are likely to impact patients and/or the delivery of healthcare.
- **Up to one PDF attachment (optional), providing evidence in support of the achievements described.**

Word versions of the nomination forms can be downloaded from the ACTA website at:

<https://clinicaltrialsalliance.org.au/events-forums/clinical-trials-2021-national-tribute-and-award-ceremony/>

**Nominations will close at midnight, Sunday 14 March 2021.** No further nominations will be accepted after the deadline.

Please submit the completed form to: [awards@clinicaltrialsalliance.org.au](mailto:awards@clinicaltrialsalliance.org.au)

The winner will be notified in the first week of May and announced publicly at the **National Tribute and Awards Ceremony**.

Scientific Name of the Trial	
Short Name (or acronym) of the Trial	
Name of the ACTA Member network or group that designed and leads the trial	
Name of the coordinating centre that manages the trial's conduct (if relevant)	
Name of the Chief Investigator	
Email	
Phone	
Did this trial receive funding from the NHMRC? If so, please provide the amount and the NHMRC Funding ID number.	
Did this trial receive funding from the Commonwealth, other than the NHMRC? If so, please provide the amount and identifier (where appropriate).	
Did this trial involve any formal collaboration with a commercial entity? If so, please provide a brief summary of industry involvement.	
Trial Identifier (if available)	
Disease(s) or therapeutic area being targeted	
How many consumers were involved in this trial	
Study Sample Size (planned)	
<b>Please confirm that the nominated trial meets the following eligibility criteria: (please tick)</b>	<input type="checkbox"/> collaboratively developed <input type="checkbox"/> multicentre <input type="checkbox"/> investigator-driven <input type="checkbox"/> randomised controlled <input type="checkbox"/> trial recruitment is complete (as per the enrolment target)

### 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.

*(for reference only: please complete the word version of the nomination form)*

### 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:

- A PDF copy** of evidence of the impact the patient-centric activity had on the trial is provided with this nomination form, if available, is provided with this nomination form. Documentation in support of the achievements described, may include but are not limited to the published paper or trial protocol.

### DECLARATION FORM

Trial Nominated by (if different to Chief Investigator)	
Email	
Mobile number	

I have read the award guidelines and believe this trial is eligible to be considered for **the ACTA 2021 Consumer Involvement Award**.

Signature:

Date:

Signature of Chief Investigator:

Date:

**Nominations will close at midnight, Sunday 14 March 2021.** No further nominations will be accepted after the deadline. Please return your completed form to [awards@clinicaltrialsalliance.org.au](mailto:awards@clinicaltrialsalliance.org.au)