

PURPOSE AND SCOPE

Our Endorsement and Partnership Policy is an important tool for helping the Australian Clinical Trials Alliance ("ACTA") to guide decisions and outline the procedures for ACTA members or other external organisations who wish to partner with ACTA and/or have their research or project endorsed by ACTA.

This policy provides a framework for ACTA to evaluate research, projects and partnerships that align with our mission and contribute to the advancement of knowledge in Clinical Trial Networks (CTN), Coordinating Centres (CC) and Clinical Quality Registries (CQR).

INTRODUCTION

ACTA is the national peak body supporting and representing networks of clinician-researchers conducting investigator-initiated clinical trials, maintaining clinical quality registries, and operating clinical trial coordinating centres within the Australian healthcare system.

ACTA promotes effective and cost-effective healthcare through clinical trial networks and clinical quality registries that generate evidence to support decisions made by health practitioners, policymakers, and consumers.

ACTA connects clinical researchers with governments, policy makers, and consumers on issues that impact the conduct of investigator-initiated clinical trials and clinical quality registries across the Australian health care system.

ACTA's activities help expand the capacity, efficiency and effectiveness of clinical trial networks, clinical coordinating centres and clinical quality registries.

OBJECTIVES

ACTA is committed to the highest standards of integrity and conduct, and as a trusted advisor ACTA believes it has an important role in endorsing and partnering with organisations for the betterment of the Australian health care sector. The following are examples of activities that could be considered for endorsement or partnership (noting this is not an exhaustive list):

- Competitive grant application for endorsement.
- Joint submission to government as a partnership.

ELIGIBILTY CRITERIA

To be considered for research/project endorsement or partnership, proposals must meet the following criteria:

1. Alignment with ACTA's Mission

The research, project or partnership should align with the mission and goals of ACTA, promoting innovation, sustainability, collaboration and positive impact in CTNs, CCs, and CQRs. Endorsements or partnerships will be considered if the requests come from ACTA members.

ACTA will consider endorsing or partnering with the following, if the endorsement or partnership is in the best interests of ACTA members:

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- Commonwealth health jurisdictions.
- State health jurisdictions.
- Federal/state government agencies (such as, but not limited to, the Inter-Governmental Policy Reform Group (IGPRG) and the Australian Commission on Safety and Quality in Health Care (ACSQHC)).
- Royal Australian Colleges.

ACTA will consider non-Australian based requests if they are in the best interests of ACTA and its members.

2. Scientific Rigour

The research, project or partner should adhere to the highest standards of scientific rigour and integrity. Research/projects should be well-designed, methodologically sound, and contribute meaningfully to the existing body of knowledge.

3. Ethical Considerations

The research, project or partner must comply with ethical guidelines and standards. Any potential conflicts of interest or ethical concerns should be thoroughly evaluated and noted prior to submission.

4. Potential Impact

The research, project or partnership should have the potential for significant impact within the sector, contributing to advancements, solutions, or improvements that align with ACTA's mission and goals.

Any endorsements and/or partnerships should assist in raising the profile of the sector, while also improving health outcomes for consumers/patients and ultimately improving Australia's healthcare system.

5. Benefits of Endorsement or Partnership

The research, project or partnership should benefit both ACTA and the requesting party.

ENDORSEMENT PROCESS

1. Submission / Expression of Interest

Researchers, institutions or organisations seeking endorsement of their research or project must submit a proposal to ACTA (acta@acta.au). The proposal should include details on research/project objectives, methodology, ethical considerations, potential impact to ACTA, timelines and any other relevant details.

The requesting party must address each of the eligibility criteria listed above by completing the Eligibility Criteria Form (Schedule 2). Failure to complete this form may significantly delay the review process.

The preferred timeframe for the ACTA Board to review requests for endorsement is a minimum of two weeks.

ACTA Board Directors may be approached for advice on submissions; however, proposals should be submitted as stated above.

2. Evaluation

Requests for endorsement will initially be reviewed by ACTA's operational team to ensure a submission meets expected parameters in alignment with this Policy.

Once reviewed, the submission will be forwarded to the ACTA Board for review and decision.

Directors will evaluate the proposal based on the eligibility criteria outlined above.

ACTA reserves the right to request additional information or clarification during the evaluation process.

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3. Decision

A decision on endorsement will be determined by a majority of votes of the Board Directors. The Board's final outcome will be communicated in writing to the original requester.

PARTNERSHIP PROCESS

1. Submission / Expression of Interest

Institutions or organisations seeking to establish a partnership with ACTA should submit an expression of interest, outlining the objectives, scope and potential benefits of the collaboration. The proposal should clearly outline ACTA's role in the proposed partnership.

Expressions of interest should be sent to ACTA (acta@acta.au).

The preferred timeframe for the ACTA Board to review requests for partnership is a minimum of two weeks.

ACTA Board Directors may be approached for advice on submissions; however, proposals should be submitted as stated above.

2. Evaluation

ACTA will undertake a thorough evaluation and due diligence process to assess the compatibility of goals, values and expectations of the potential partner to ensure they are in alignment with ACTA's mission and goals.

Directors will evaluate the proposal based on the eligibility criteria outlined above.

ACTA reserves the right to request additional information or clarification during the evaluation process.

3. Decision / Partnership Agreement

A decision on partnership will be determined by a majority of votes of the Board Directors. The Board's final outcome will be communicated in writing to original requester.

Upon successful evaluation and due diligence review, a formal partnership agreement will be drafted, specifying the terms, responsibilities and expectations of both parties.

COMMUNICATION AND PROMOTION

1. Endorsements

Research and projects, that have been approved for endorsement by ACTA's Board may be acknowledged and communicated via ACTA's various promotional platforms, including its website, social media, newsletters, electronic direct mail marketing (eDMs), and/or publications.

2. Partnerships

Upon execution of any Partnership Agreement, the partnership may be formally announced through joint media releases, or per the terms of the Partnership Agreement. This may include communication and promotion of the partnership via ACTA's various promotional platforms, including its website, social media, newsletters, eDMs, and /or publications.

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MONITORING AND REVIEW

1. Periodic Review

Endorsed research/projects, and Partnership Agreements should be subject to periodic reviews to assess the progress, adherence to agreed terms and ongoing alignment with ACTA's mission and goals.

Endorsed projects and active partnerships will be reviewed at ACTA Board meetings, when required. A list of endorsed projects and partnerships will be maintained by ACTA and presented to the Board as a standing agenda item.

2. Variation to Terms (including Termination)

ACTA reserves the right to vary the terms or terminate endorsements and partnerships if there is a deviation from the agreed terms by the other party. In addition, variation or termination should occur if ethical concerns arise or if the research/project no longer aligns with ACTA's mission or goals.

By endorsing research/projects and establishing partnerships, ACTA aims to further promote, advocate for, support and represent networks of clinician-researchers conducting clinical trials, maintaining clinical quality registries, operating clinical trial coordinating centres and consumers within the Australian healthcare system.

This policy will be periodically reviewed and updated to ensure its continued effectiveness while meeting the mission and goals of ACTA.

3. Risk Management

ACTA will review and manage any potential risks regularly that may arise from this Policy, in alignment with ACTA's risk management process.

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SCHEDULE 1: CONTACT DETAILS FOR SUBMISSIONS

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$\Lambda CT\Lambda$	Cantral	Contact	
ALIA	Central	COHIACI	

Dino Cercarelli (Chief Operating Officer)

acta@acta.au

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SCHEDULE 2: ELIGIBILITY CRITERIA FORM PROJECT NAME: PRINCIPAL INVESTIGATOR: ACTA MEMBER ORGANISATION: DATE OF REQUEST: DATE ENDORSEMENT IS REQUIRED: [Please provide a short paragraph on each of the five eligibility criteria below] 1. ALIGNMENT WITH ACTA'S MISSION 2. SCIENTIFIC RIGOUR 3. ETHICAL CONSIDERATIONS 4. POTENTIAL IMPACT 5. BENEFITS OR ENDORSEMENT OR PARTNERSHIP

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