



## Australian Clinical Trials Alliance

**Tender for:** Consumer Involvement and  
Engagement in Clinical Trials Toolkit:  
Online Platform (website)

**Tender No:** 002

Tenders must be received by 2pm on April 26th, 2019

Email to [acta@clinicaltrialsalliance.org.au](mailto:acta@clinicaltrialsalliance.org.au)

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## Part A: Information for Tenderer

### 1. Purpose of this Document

This document is a tender brief and has been prepared to provide information to assist prospective suppliers in the preparation and submission of proposals for the provision of Consumer Involvement and Engagement in Clinical Trials Toolkit (the Toolkit): Online Platform (website).

### 2. Project Overview

The Australian Clinical Trial Alliance (ACTA) is a not-for-profit organisation currently conducting a program of work funded by the Medical Research Future Fund to grow, strengthen and support Australia's investigator-led and registry data-informed clinical trials sector. We are striving for effective and cost-effective healthcare founded on evidence that empowers health practitioners, policy-makers, and consumers to make their best and most well-informed decisions.

ACTA is conducting a major project to develop an online Consumer Involvement and Engagement in Clinical Trials Toolkit (the Toolkit), which will be developed as an interactive website for use by researchers, research organisations and consumers. The Toolkit will draw on existing or adapted international resources and newly developed local resources to provide tools and guidance on consumer involvement and engagement (CI&E) in clinical trials in Australia. Consumer Involvement (CI) is defined as active partnerships with consumers and the community in aspects including the design and conduct of clinical and health service research, not simply as research participants, and Consumer Engagement (CE) as sharing information and knowledge about clinical trials with consumers and the community.

The project is a collaboration with and co-funded by CT:IQ, which is a consortium of stakeholders whose mission is to develop and implement recommendations that will improve the impact, quality and efficiency of clinical trials, leading to more rapid, lower cost and higher quality evaluation of healthcare interventions in Australia.

The project is advised by an external Reference Group on Strengthening Consumer Engagement in Developing, Conducting and Reporting Clinical Trials (hereafter Reference Group), comprising content experts, consumers and members of ACTA's Board.

#### 2.1 Key dates for this tender are indicated below. These dates are advised as a guide to projected timelines only. ACTA will attempt to maintain this schedule, but reserves the right to vary key dates:

Tenders advertised	05/04/19
Public information/briefing session	05/04/19 – 25/04/19
Closing date for submission of tenders	26/04/19
Short listing completed by	03/05/19
Presentations conducted by (preferred applicants only)	17/05/19
Contract awarded and all tenderers advised of tender outcome by	24/05/19
Commence contract	May 2019
Contract completion	October 2019

### 3. Project Objective

The project aims to create a centralised repository (online toolkit) of guidance and tools facilitating consumer involvement and engagement along the lifecycle of a clinical trial and support active and collaborative consumer partnerships with both researchers and research-focused organisations. An overarching aim of the Toolkit is to foster best practice across the research sector involved in clinical trials by providing a mechanism to share resources both locally and internationally.

### 4. Project Description and Conditions

#### 4.1 Scope

ACTA is seeking proposals from suitable suppliers to design and develop a Consumer Involvement and Engagement in Clinical Trials Toolkit (*Toolkit*) website, which will be developed as a streamlined website for use by researchers, research organisations and consumers in Australia. The toolkit will draw on existing or adapted international resources and newly developed local resources to provide tools and guidance on consumer involvement and engagement (CI&E) in clinical trials in Australia (ref to Attachment I toolkit project brief 2.5).

In terms of accessibility and navigational aspect of the proposed CI&E toolkit, please refer to the NIHR CT Toolkit (<http://www.ct-toolkit.ac.uk/>) from the UK and will have advantages over static guidance in that it will be a 'living repository' of information that can be amended and updated. The NIHR CT Toolkit provides practical advice to researchers and clinical trial units in designing and conducting publicly funded clinical trials in the UK, providing information on best practice through the use of an interactive route map. Each 'circle' on the Toolkit is a hyperlink to a landing page which provides a general introduction and signposts of other documents and tools. The CI&E toolkit will need to have 'access points or landing pages' which may contain text, documents and educational material (e.g. infographics and short videos). We envisage users of the CI&E toolkit will come to learn about consumer involvement and engagement activities and opportunities throughout the research continuum, and to quickly and easily find tools and guidance relevant to specific topics they are interested in exploring.

The toolkit website needs to exist as a standalone platform or suitable for integration into the ACTA website.

The successful tenderer is to deliver:

1. End-user research to understand personas, navigational pathways and access needs, for external content users (optional tender component).
2. Dedicated project manager to scope and deliver the project to completion.
3. User-interface designs for approval by project team
4. Front-end development. Using the approved user interface designs, translate them into the first part of the technical build. Deliver initial front-end build for approval by the project team.
5. Functional platform build. Using approved user-interface designs and front-end development, develop functional online website/toolkit. Deliver functional toolkit platform for user-testing and approval by the project team.
6. Training. Provide administrative and content editor training to up to 5 ACTA staff.
7. Hosting, Maintenance and Licensing. Services to support ongoing 12 monthly hosting, technical support and licensing of the approved online platform (optional tender component).

Note:

Technical requirements;

- The toolkit should be developed to be flexible in how it is hosted in relation to ACTA's website (e.g. integrated or stand-alone), and to be portable in the event that ACTA replaces its website or transfers ownership of the toolkit to another organisation.
- The toolkit should be easily edited by ACTA staff, collaborators and other web development providers engaged by ACTA, including editing text, adding and removing resources, modifying the topic structure, etc.
- The toolkit should meet current standards of accessibility in all aspects of its design.

#### 4.2 Background

4.2.1 Toolkit content is currently in development and is not part of this tender, please see project overview (refer to Attachment I)

#### 4.3 Project Governance

The project will have oversight primarily from ACTA and its expert Reference Group, and in addition the project working group. The project has a dedicated ACTA project manager, supported by an active project working group, who will work with all parties on a day-to-day basis to ensure co-ordination and delivery of work as per the project timeline. The successful supplier will work with the project group to co-design the online toolkit platform interface, informed by developed toolkit content and incorporating end-user's accessibility needs.

4.4 The supplier will report directly to the project manager via telephone, email, face-to-face meetings (project manager and working group) as required. In addition, a mid-term progress report/meeting as identified by ACTA will be required, under guidance of the project manager.

#### 4.5 Service Delivery Timeframes

Stages of implementation are envisaged to be (please outline during application);

May 2019 Start: on-board supplier and project overview

May - Aug 2019 design and build online platform

Aug - Sep 2019 user testing, training and support content upload

Oct 2019 Finish: deliver fully functional online platform

(Subject to satisfactory performance, the length of the contract may be extended by agreement between both parties).

#### 4.6 Record Management and Privacy

4.6.1 The successful tenderer will abide by all applicable laws.

4.6.2 The project is subject to a number of laws and policies including:

- (a) occupation health & safety;
- (b) confidentiality and use of information;
- (c) privacy ("the Laws").

The Contractor will:

- (i) demonstrate within its response an appropriate level of understanding of these Laws;
- (ii) demonstrate how it will operate the Project so as to comply with the Laws.

#### 4.7 Marketing

- 4.7.1 ACTA will have sole responsibility for all branding, marketing and other communications. This will include ownership of any trademarks, trade names, designs or other intellectual property. While ACTA will engage in a reasonable level of consultation with the successful tenderer in determining its marketing activities all marketing and branding decisions are entirely at the discretion of ACTA.
- 4.7.2 The successful tenderer will not have any contractual recourse to ACTA regarding performance on grounds related to ACTA's marketing activities or decisions.

#### 4.8 Intellectual property

- 4.8.1 ACTA will have ownership of intellectual property rights in any new or adapted materials and data generated or collected through the Project. Where pre-existing materials owned by the successful tenderer are contributed to the project, the successful tenderer will grant ACTA a permanent, perpetual, royalty-free, world-wide license to use those materials for any purpose. Where pre-existing materials created by a third party are used, the successful tenderer with ACTA will ensure that a permanent, perpetual, royalty-free, world-wide license to use those materials for any purpose is granted to ACTA prior to their use in the project.
- 4.8.2 The successful tenderer will use relevant existing ACTA databases (including dropbox) and, where additional information is required, will create databases as necessary for the Project.

#### 4.9 Professional Indemnity Insurance

ACTA requires that the successful tenderer will have in place professional indemnity insurance of at least \$10million per claim.

#### 4.10 Project Plan and Implementation

- 4.10.1 The successful supplier will work with the project manager to review the current overall project timeline and plan delivery of works as per this tender to align with critical milestones and deadlines.
- 4.10.2 Progress Reporting - The successful supplier will be required to provide Progress Reports to ACTA on a to be agreed basis between the contract execution date and completion that highlights not only progress to date but also outstanding issues. At least one face-to-face progress meeting will be required, beyond regular communication necessary to achieve project deliverables.

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**Part B: Tender Specifications**

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**5. Specification and Evaluation****5.1 Specification 1: The Tenderer**

The successful tenderer will require a background relevant to the project and demonstrated capacity to successfully undertake the project.

**5.1.1 Status of entity**

The tenderer must be a legal entity with which Australian Clinical Trials Alliance is able to contract.

The tender response must describe and provide evidence of the legal status of the tenderer, including their Australian Business Number (ABN).

**5.1.2 Understanding of requirements**

The tenderer must demonstrate an understanding of the requirements of the tender.

**5.1.3 Relevant experience**

The tender must describe the experience of the tenderer in relation to the provision of similar services.

References from or contact details of at least two clients for whom the tenderer previously has carried out similar projects must be provided.

Referees must not be members of the tender evaluation panel and should preferably be from outside ACTA.

**5.1.4 Financial, technical, planning and other resource capability**

The tender must provide sufficient supporting documentation to demonstrate to ACTA that it has the financial, technical, planning and other resource capability to successfully deliver the service.

**5.1.5 Staffing Policies and Practice**

The tender must describe staffing policies and practices of the tenderer that will be in operation for the period of the contract.

The tender must demonstrate a commitment to equal employment opportunity and maintenance of occupational health and safety.

The tenderer's employee policies and practices must demonstrate consistency with the Fair Work Act and National Employment Standards.

**5.1.6 Staff Competencies**

The tender must describe the minimum competencies of staff and policies to attain and maintain competency over the period of the contract.

**5.1.7 Project Management**

Tenderers must describe their record of managing projects on time and within budget while also delivering quality services and project outcomes.

**5.1.8 Electronic Communication**

Tenderers must describe their technical capacity for electronic communication and funds transfer and a commitment to establishing appropriate links to enable such communication with ACTA

## 5.2 Specification 2: Project Deliverables

- 5.2.1 The following specifications are indicative of the project components necessary to deliver the objectives. Successful suppliers may propose to deliver the project in other ways provided they achieve the objectives in a manner acceptable to ACTA.
- 5.2.2 The successful tenderer is required to deliver all approved components of the project. These components include but are not limited to the provision of:
- a. End-user research to understand personas, navigational pathways and access needs, for external content users (optional tender component).
  - b. Dedicated project manager to scope and deliver the project to completion.
  - c. User-interface designs for approval by project team
  - d. Front-end development. Using the approved user interface designs, translate them into the first part of the technical build. Deliver initial front-end build for approval by the project team.
  - e. Functional platform build. Using approved user-interface designs and front-end development, develop functional online website/toolkit. Deliver functional toolkit platform for user-testing and approval by the project team.
  - f. Training. Provide administrative and content editor training to up to 5 ACTA staff.
  - g. Hosting, Maintenance and Licensing. Services to support ongoing 12 monthly hosting, technical support and licensing of the approved online platform (optional tender component).

Note:

Technical requirements;

- The toolkit should be developed to be flexible in how it is hosted in relation to ACTA's website (e.g. integrated or stand-alone), and to be portable in the event that ACTA replaces its website or transfers ownership of the toolkit to another organisation.
- The toolkit should be easily edited by ACTA staff, collaborators and other web development providers engaged by ACTA, including editing text, adding and removing resources, modifying the topic structure, etc.
- The toolkit should meet current standards of accessibility in all aspects of its design.

## 5.3 Specification 3: Rates and Budget

All tenders must be GST inclusive. If the goods or services are GST exempt, reasons for this must be provided.

### 5.3.1 Assumptions and Conditions

Tenderers are to clearly document any assumptions or conditions on which their prices are conditional.

#### 5.4 Specification 4: Project Implementation

Tenderers are required to submit a project plan indicating how they propose to meet the project deadlines. The plan should also outline the level of involvement required of ACTA personnel.

##### 5.4.1 Project Management Methodology

Tenderers are to describe their project management methodology, including the key activities, outputs and controls.

##### 5.4.2 Project Personnel

Tenderers are to provide resumes of key project personnel.

### 6. Evaluation of Tenders

#### General

This section describes in general terms the evaluation criteria that will be used to assess Submissions. ACTA reserves the right to evaluate and accept or reject any of the submissions.

#### Specific Criteria

##### 6.1 Criteria Relating to Specification 1 and 2;

6.1.1 Criterion 1 The tenderer is able to appreciate the overall project objectives and propose delivery of an online platform (toolkit), hosting content which will meet owner and user needs.

This criterion is weighted Highly Important.

6.1.2 Criterion 2 The tenderer is able to provide costings proportionate for the delivery of the works in this tender, which align with overall project funding.

This criterion is weighted Highly Important.

6.1.3 Criterion 3 The tenderer has relevant and adequate experience in completing similar projects and has demonstrated the capacity to address each of the components of the project.

This criterion is weighted Highly Important.

6.1.4 Criterion 4 The tenderer has satisfactory financial, technical, planning and other resource capability to successfully complete the project.

This criterion is weighted Highly Important.

6.1.5 Criterion 5 The tenderer has provided a realistic and achievable plan to meet the project deadlines. The tenderer has a comprehensible, robust and effective project management approach.

This criterion is weighted Highly Important.

##### 6.2 Evaluation Process

Submissions will be evaluated against the indicated criteria. Following short-listing, one or more tenderers may be approached to make a presentation to the evaluation panel to provide clarification or further information.

All tenderers will be advised in writing of the final outcome of the tender, including the identity of the successful tenderer.

**Scoring**

Submissions will be scored against the following scale:

<b>Evaluation</b>	<b>Score</b>
Considerably exceeds all aspects of selection criteria	7
Exceeds all aspects of selection criteria	6
Exceeds most aspects of selection criteria	5
Exceeds some aspects of selection criteria	4
Meets all selection criteria	3
Fails some aspects of selection criteria	2
Fails most aspects of selection criteria	1
Fails all aspects of selection criteria	0

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**Part C: Conditions of Tender**

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**7. General Conditions**

**7.1** Organisations wishing to tender should submit their proposal in accordance with the ACTA's requirements as set out in this document. The conditions under which a response must be made are indicated in this section. Tenderers should familiarise themselves with this tender brief and ensure proposals conform. Tenderers are deemed to have:

- 7.1.1 examined the tender documents and other information made available by ACTA to the tenderers for the purpose of tendering;
- 7.1.2 examined all information relevant to risks, contingencies, and other circumstances having an effect in their tender and which is obtainable by making reasonable inquiries;
- 7.1.3 examined statutory requirements and satisfied themselves they are not participating in any anti-competitive, collusive, deceptive or misleading practices in structuring and submitting their tender;
- 7.1.4 satisfied themselves as to the correctness and sufficiency of their tenders and that their tendered prices are GST inclusive and cover the cost of complying with all conditions of tender and matters and things necessary for due and proper performance and completion of work described in the tender documents;

**7.2 Financial Assessments**

7.2.1 ACTA reserves the right to engage third parties to carry out assessments of tenderers' financial, technical, planning and other resource capability.

**7.3 Format of Response**

7.3.1 Electronic submission only (via email). A response schedule is at Part D of this document. Tenderers must address their responses to the specifications and will be assessed against the advertised evaluation criteria. The response schedule is structured to reflect the information requirements of this tender and tenderers are advised to use the response schedule in preparation of their submissions.

**7.4 Legal Entity**

7.4.1 Tenderers must provide proof of their legal status. A legal agreement/contract can only be entered into by Australian Clinical Trials Alliance with an agency or individual with legal status established under:

- Associations Incorporation Act.
- Corporations Law.
- Health Services Act.
- An Individual Act of Parliament.
- Natural Person (person at least 18 years of age, with mental capacity to understand the agreement, not under any order or bankrupt).
- Trustee Act.

7.4.2 ACTA prefers to deal with suppliers who have an Australian Business Number (ABN), unless there is clear evidence that the relevant supply is not assessable for income tax purposes (hobby or recreational interest).

**7.5 Consortia**

7.5.1 ACTA will contract with a single party that is capable of accepting the risks of delivery of the project.

## 7.6 Draft Agreement

7.6.1 The successful tenderer will be required to enter into an Agreement with ACTA. The Agreement is available on request. Any objections and suggested amendments to any terms and conditions of the Contract Documents should be set out in the Departures Schedule.

## 7.7 Statement of Departures

7.7.1 Tenderers are to indicate for each of the requirements in this section whether their response fully complies, partially complies or does not comply. Where a requirement is fully complied with, please provide details and evidence of how the response complies. Where a requirement is partially met indicate where the divergence is. Where you do not comply, please provide details of how you would propose to deliver the service and the rationale behind the proposal.

7.7.2 By submission of a tender in response to this document, tenderers are deemed to have accepted these Conditions of Tender.

## 7.8 ACTA Assignment of Interest

ACTA will be free to transfer to any entity its rights and obligations under the agreement. The Tenderer may also assign his interests in the Contract, subject to the prior written approval of ACTA.

## 8. Lodgement of Proposals

8.1 The proposal delivered via email and clearly endorsed:

Confidential

Tender Application - Consumer Involvement and Engagement in Clinical Trials Toolkit: Online Platform (website)

by email, addressed to: [acta@clinicaltrialsalliance.org.au](mailto:acta@clinicaltrialsalliance.org.au)

The closing time of 2:00pm is defined as 2:00pm Australian Eastern Daylight Time on 26<sup>th</sup> April 2019.

8.2 Proposals must be signed and dated by an authorised officer of the tenderer.

8.3 All proposals must be in the English language.

8.4 Proposals will be opened after 2:00pm on the closing date of tenders and notification of receipt will be forwarded to each tenderer.

## 9. Requests for Further Information

9.1 Clarification of Tender Specification and Requests for Additional Information

9.1.1 Requests for clarification of tender specifications and requests for additional information must be made in writing. Address such requests to: [acta@clinicaltrialsalliance.org.au](mailto:acta@clinicaltrialsalliance.org.au)

9.2 References

Tenderers must indicate at least two organisations which have been supplied with services similar to those requested in this project brief, and of whom officers considering proposals may make inquiries to assist in establishing the suitability of any item or service tendered.

## 10. Reservations

10.1 Withdrawal from Process

Australian Clinical Trials Alliance reserves the right to withdraw from the tender process described in this document for whatever reason, prior to the signing of any

Agreement/Contract with any party for the delivery of goods or services described in this document.

#### 10.2 Lowest Cost Proposal

The lowest cost proposal, or any proposal, will not necessarily be accepted.

#### 10.3 Negotiation

Australian Clinical Trials Alliance reserves the right to negotiate with short-listed tenderers after the nominated closing date for tender submission.

#### 10.4 Part Offers

Australian Clinical Trials Alliance reserves the right to accept tenders in relation to some and not all of the scope of activity described, or appoint one, more than one or no organisation on the basis of the tenders received.

### 11. Conflicts of Interest

#### 11.1 Declaration

Tenderers (including their officers, employees, contractors, partners and consultants) must declare to Australian Clinical Trials Alliance any matter or issue which is, may be perceived to be or may lead to, a conflict of interest regarding their proposal or participation in supply of the services described. Tenderers must describe a strategy so that any conflict of interest will be avoided.

### 12. Probity of Tender Procedures

#### 12.1 Notification of Probity Breach Required

Should any Tenderer consider that the tender process under this document has failed to accord it fair right to be considered as a successful bidder or that it has been prejudiced by any breach of these Conditions of Tender or other relevant principle affecting the Tenders or their evaluation, the Tenderer must provide immediate notice of the alleged failure or breach to the Contact Person. Notification must set out the issues in dispute, the impact upon the Tenderer's interests, any relevant background information and the outcome desired.

#### 12.2 Timeliness of Notification

Delay in notification of probity breach, or notification after the announcement of the successful Tender will preclude a Tenderer from relying upon or taking action based upon such breach.

#### 12.3 Resolution of Disputes

Dispute over the notification of breach will be resolved according to the Dispute Resolution section and clauses in the ACTA standard agreement, attached.

### 13. Disclosure

#### 13.1 Disclosure of tender and contract details

Subject to this clause and the Conditions of Contract, all documents provided by the Tenderer will be held in confidence so far as the law permits.

Notwithstanding any copyright or other intellectual property right that may subsist in the tender documents, the Tenderer, by submitting the tender, licenses Australian Clinical Trials Alliance to reproduce the whole or any portion of the tender documents for the purposes of tender evaluation.

In submitting its tender, the Tenderer accepts that the ACTA may publish (on the internet or otherwise) the name of the successful or recommended Tenderer(s), and the Contractor's name together with the provisions of the Contract generally.

**14. Lobbying of Tenders**

- 14.1** Any attempt by any tenderer (including their officers, employees, contractors, partners and consultants) to exert influence on the outcome of the assessment process by lobbying, directly or indirectly, ACTA staff, consultants or contractors, will be grounds for disqualification of the tender from further consideration.

**15. Pricing**

- 15.1** Tenders must contain a detailed cost summary as well as relevant stage and total project costing. The quotation must state the price for each unit of output.
- 15.2** Price variations over the period of the contract must be advised. Tenderers must state the factor and reasons for any variation.
- 15.3** All prices quoted must be represented in Australian dollars.

**16. Payments**

- 16.1** Tenderers must indicate whether they have the capacity to accept electronic funds transfer as a facility for contract payments.
- 16.2** A payment schedule will be negotiated with the successful tenderer in accordance with their bid.

**17. General Conditions of Response**

- 17.1** Tenders should be submitted using the Tender Response Schedule included within Part D of this document, or in the format indicated in the Tender Response Schedule.
- 17.2** All parts of the Tender Response Schedule should be completed and submitted before the nominated closing date for submissions.
- 17.3** Any additional supporting information should be attached to the completed Tender Response Schedule and clearly referenced.
- 17.4** The Tender Response Schedule must be signed by an authorised officer of the tenderer.

Part D: Tender Response Schedule

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**Tender Response Schedule**

**For**

**CONFIDENTIAL**

**Consumer Involvement and Engagement in Clinical Trials Toolkit: Online Platform (website)**

Note: These response schedules are available in electronic format [in Word for Windows format] on request from Australian Clinical Trials Alliance care of:

Nicola Straiton

Email: [acta@clinicaltrialsalliance.org.au](mailto:acta@clinicaltrialsalliance.org.au)

Alternatively, the entire document, including these response schedules may be downloaded from website link at:

<http://www.australiandclinicaltrialsalliance.org.au>

**Tender Response Schedule—Part 1  
Tenderer Details**

**Tendering Organisation**

Entity Name											
Entity Status											
ACN number											
Registration for GST	Yes:					No:					
Australian Business Number (ABN)											
Place of Incorporation											
Postal Address											
Principal office in Australia											
Contact Person											
Position/Title											
Telephone No						Facsimile No					
E-mail address											

**Sub-Contractor #1**

Name											
Address											
Tasks/aspects/scope of project to be undertaken											

**Sub-Contractor #2**

Name											
Address											
Tasks/aspects/scope of project to be undertaken											

[Repeat as Required]

**Tender Response Schedule—Part 2  
Supporting Information**

Tenderers are required to describe the nature and extent of any relevant experience.

Tenderers are required to disclose sufficient information to ensure that they have adequate experience and financial, technical and other resources capability to successfully undertake the proposal. Provide details (Title, year, etc.) of relevant supporting documents and attach copies to your submission.

**Profile of Tenderer**

Range of services currently delivered	
Years of operation in this capacity	

**Financial/Planning/Technical Capability**

Will you provide valid tax invoices?	Yes:		No:		
Proof of insurance cover					
Business Plan (if available)					
Summary of entity’s achievements					
Technical capability (if applicable)					

**Qualifications and Experience of Key Project Staff**

Name	
Title/Office Held	
Qualifications	
Previous Experience	
Role/functions to be performed	

Name	
Title/Office Held	
Qualifications	
Previous Experience	
Role/functions to be performed	

Name	
Title/Office Held	
Qualifications	
Previous Experience	
Role/functions to be performed	

[Repeat as Required]

**Infrastructure/Equipment Capability**

Address of project delivery venue	
Ownership of project delivery venue	
Description of project delivery venue	
Current use of project delivery venue	
Equipment to be used to support project	

**Tender Response Schedule—Part 3  
References**

**Referee #1**

Company Name	
Postal Address	
Street Address	
Contact Person	
Position/Title	
Telephone No	
Facsimile No	
Nature of work performed	

**Referee #2**

Company Name	
Postal Address	
Street Address	
Contact Person	
Position/Title	
Telephone No	
Facsimile No	
Nature of work performed	

**Tender Response Schedule—Part 4****Proposal****1 Overview (guide for applicants)**

Provide details of the project and its structure, to describe how the project/service will be implemented, managed and monitored. The extent to which a practical, workable and sector sensitive approach is developed is a key consideration. Describe how you intend to provide the deliverables for each job/project and your understanding of the nature of each deliverable.

Consider the following aspects of the project in preparing and documenting response to this part:

- methodology: provide a detailed and considered discussion of the proposed methodology and how it addresses the key needs of the tender as described in this tender brief;
- broad approach to the project;
- components, sub components and major tasks;
- timetable indicating sequence and duration of each task, prepared in accordance with the key dates nominated in this brief;
- key project review points;
- deliverables and outcomes for each phase of the project;
- how any standards specified in this tender brief will be satisfied;
- tenderer inputs;
- ACTA resource/input required;
- other stakeholder input or partnering relationships required and how they will be established and managed;

The Selection Criteria that will be relevant to the evaluation of this part of your response relate primarily to Specification 2 (Project Deliverables). These criteria are detailed in section 5.2 of this document.

**2 Price/Cost of Proposal**

**Price Validity**

Prices quoted remain valid from the date of submission until:	
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**Summary of Costs**

The tenderer is required to identify a project costing summary detailing the costs attributed to the project elements identified below.

<b>{Project}</b>	
Project Delivery	
Other	
<b>TOTAL</b>	\$

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**Tender Response Schedule - Part 5**  
**Acceptance of Terms & Conditions**

An authorised officer of the tenderer must signify acceptance of the terms and conditions under which the tender is advertised. Signature as indicated in this part, and submission of a tender in response to the tender brief, signifies acceptance of all terms and conditions unless specifically indicated in this section by the tenderer.

Tenderers must indicate their understanding and acceptance of each part of this tender document, by signing or initialling in the table below. Where any part of this tender is not understood or accepted, tenderers must attach a tabulated Statement of Departures with explanation of why that part is not accepted.

**Acceptance of Conditions**

<b>Part</b>	<b>Acceptance (initial)</b>	<b>Non-Acceptance (initial, and attach tabulated Statement of Departures)</b>
Part A: General Information for Tenderers		
Part B: Tender Specifications		
Part C: Conditions of Tender		

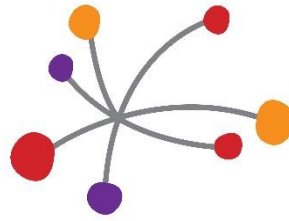
**Endorsement**

Signature of Authorised Officer for Tenderer	
Name of Authorised Officer	
Title/Office Held	
Date	

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**Attachment I**

**Supplementary Tender Information: Consumer Involvement & Engagement  
Toolkit Project v2.5 as per section 4.2.**



CT:IQ  
Clinical Trials:  
Thinking Smarter

## Attachment I

Supplementary Tender  
Information:  
Consumer Involvement &  
Engagement Toolkit Project

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## Executive Summary

ACTA (Australian Clinical Trials Alliance) is not-for-profit organisation currently conducting a program of work under the Medical Research Future Fund to grow, strengthen and support Australia's investigator-led and registry data-informed clinical trials sector. ACTA are striving for effective and cost-effective healthcare founded on evidence that empowers health practitioners, policy-makers, and consumers\* to make their best and most well-informed decisions.

ACTA in collaboration with Clinical Trials: Thinking Smarter (CT:IQ) are conducting a major project to build an online Consumer Involvement and Engagement in Clinical Trials Toolkit (the Toolkit), which will be developed as an interactive website for use by researchers, research organisations and consumers. The project is a co-funded by CT:IQ, which is a consortium of stakeholders whose mission is to develop and implement recommendations that will improve the impact, quality and efficiency of clinical trials, leading to more rapid, lower cost and higher quality evaluation of healthcare interventions in Australia.

The toolkit will draw on existing or adapted international resources and newly developed local resources to provide tools and guidance on consumer involvement and engagement (CI&E) in clinical trials in Australia. For this project, consumer involvement (CI) is defined as active partnership - involving consumers and the community in clinical and health service research, not simply as research participants and engagement (CE) as sharing information and knowledge about clinical trials with consumers and the community.

The project aims to create a centralised repository (toolkit) of guidance and tools, facilitating consumer involvement and engagement along the lifecycle of a clinical trial and support active and collaborative consumer partnerships with both researchers and research-focused organisations.

With overarching toolkit goal, for now and the future, to ensure emerging guidance and tools can be considered and incorporated into the model, and to foster best practice across the research sector by providing a mechanism to share resources both locally and internationally.

## Background

To facilitate ACTA's program of work, several national reference groups were formed late 2017, with the aim to bring together ACTA members, key experts, stakeholders and consumers working in and around the discrete program areas. The concept for the toolkit project was initially generated by ACTA Reference Group E '*Strengthening Consumer Engagement in Developing, Conducting and Reporting Clinical Trials*', which since inception has been keen to understand consumer involvement within the sector\*\*, from an organisational as well as trial and sector-wide perspective. Activities to inform this work to date have included:

- An internal scoping review of international best practice on consumer involvement in research. The purpose of this review was to highlight the spectrum of activities that have added value in their countries of origin in order to support the development of the most appropriate models for consumer involvement in clinical trials for Australia.
- National consultations on consumer involvement in clinical trial activities, within the investigator-led research environment. ACTA undertook consultations with a substantial cross-section of the sector (researchers and research organisations) as well as consumers during April-October 2018. Preliminary findings identifying a number of opportunities that could enhance the capacity of the sector to involve consumers and/or strengthen the many existing partnerships.

As a result, this proposal to provide guidance using an interactive toolkit model to enhance consumer involvement and engagement for researchers, research organisations and consumers was developed.

CT:IQ share in the vision to strengthen consumer involvement in clinical trials. CI&E is critical to fostering consumer access to innovative therapeutic solutions and delivering better health outcomes for patients, participants and the community. As such CT:IQ members, one of which includes ACTA, were invited to pitch projects during a CT:IQ stakeholder meeting late 2018 for consideration of further seed funding to enhance development and delivery. The CT:IQ Steering Committee and Executive Committee both recognised the

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\* defined as patients and potential patients, carers, and people who use health care services.

\*\* defined as clinical trials networks, clinical quality registries and the co-ordinating centres and registries that support them.

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importance and significance of the CI&E Toolkit Project and alignment with CT:IQs overarching objectives. For which CT:IQ is now excited to be collaborating with ACTA to deliver on the CI&E toolkit projects in 2019.

## **Objectives**

The proposed toolkit has two main objectives; firstly, to provide tools and guidance to enhance both consumer involvement (CI) and consumer engagement (CE) within clinical trial activities. Secondly during the national sector consultation, it was highlighted that supporting the role of consumers within the clinical trials environment may require increased clinical trial awareness amongst the broader Australian population. As a result, this project aims scope and understand this further, and in the initial stage of development will seek opportunities to increase the knowledge and capacity of the wider community.

## **CI&E Toolkit Activity**

It is envisaged that the Toolkit will contain guidance in relation to forming and maintain partnerships with consumers, rationale and approaches to involving and engaging consumers and provide useful tools to involve consumers in the more discrete activities along the clinical trial lifecycle. This lends itself to being portrayed visually, to allow ease of navigation for the sector and consumers alike. The proposed CI&E toolkit will be an online interactive platform, and in concept based on the National Institute for Health Research (NIHR) Clinical Trial Toolkit from the UK (<http://www.ct-toolkit.ac.uk/>) having significant advantages over static guidance documents, in that it will be a 'living repository' of information that can be amended and updated.

The first phase of the project will work to address the findings of the national consultations, indicating how to enhance and grow consumer involvement in clinical trials activities, training and guidance materials would be useful for both early and advanced researchers and how research organisations can involve consumers across the research continuum. An established working group will review and ratify existing, adapted and newly developed guidance and tools which point to best practice approaches, with examples of content including rationale and value of CI&E, planning and methods of CI (e.g. conduct and management, priority setting) and communication of clinical trial results amongst other components.

The second phase of the project will review content and build on foundation tools and CI&E guidance, ensuring the toolkit meets the basic needs of the users (researchers and research organisations) and in addition to develop (identify, adapt or generate) consumer-facing tools and guidance to support involvement and engagement in clinical trial activities. The latter stage of this phase will aim to provide access to key guidance useful to consumers currently working in partnership with (or keen to work with) researchers on individual research projects or useful to broader clinical research community. The opportunity to increase clinical trial awareness, in relation to the role and value of clinical trials, will be also be explored as an educational component of the toolkit and options to highlight this effectively developed during this phase.

The deliverable at the end of the toolkit will be an online platform, providing guidance and tools to encourage and facilitate consumer involvement and engagement within clinical trial activities.

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### **Phase One Content**

The development and delivery of the guidance content related to phase one is currently in progress and under review with the project working group, with core content centred around (but not limited to) the following guidance and tools;

<b>Example: Phase One Content (under development)</b>
What is CI&E?
Why Involve consumers?
Why Engage Consumers?
Principles
Diverse and Inclusive
Identifying Aims and Objectives
Priority Setting
Design and Grant Application
Conduct and Management
Dissemination and Implementation
Who to Involve?
Involvement methods
Recruiting
Consumer Training
Feedback

### **Phase Two Content**

Under Tender 2019.

#### **Delivery Timeframe**

The project is initially scoped for delivery of the online toolkit by end of 2019.