



**Australian
Clinical
Trials
Alliance**

**Approaches to
implementability,
implementation and
impact of clinical
trials: A survey of
Australian Clinical
Trials Networks and
Coordinating Centres**

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TABLE OF CONTENTS

Purpose of this document	3
Acknowledgements	3
Disclaimer	3
Executive Summary	4
Background	5
Methods	5
Results	6
Enhancing implementability through the planning and conduct of trials	6
Enhancing implementability through trial reporting	9
Policies and processes for considering implementability	10
Implementation of trial results into policy or practice	10
Measurement of implementation and impact	12
Identifying practical tools and guidance of assistance	13
Discussion	13
Summary of key findings	13
Strengths and limitations of the survey	14
Conclusions	14
Appendix: Survey Instrument	15

PURPOSE OF THIS DOCUMENT

This document represents a survey conducted with Australian Clinical Trial Networks (CTNs) and Coordinating Centres on their approaches to implementability, implementation and impact of clinical trials.

ACKNOWLEDGEMENTS

We acknowledge the contributions of survey participants. We also acknowledge members of ACTA's Impact and Implementation of CTN Trials Reference Group in the preparation, development and review of this document.

DISCLAIMER

The information in this document is for general guidance only. ACTA does not make any representations or warranties (expressed or implied) as to the accuracy, currency or authenticity of the information provided.

EXECUTIVE SUMMARY

The Australian Clinical Trials Alliance (ACTA) conducted a survey of Australian Clinical Trials Networks (CTNs) and Coordinating Centres. The objectives of the survey were to identify current practice relating to enhancing the capacity for trials to be implemented ('implementability'), and for results dissemination and implementation work to follow, along with surveying approaches to estimate the practice and/or policy impact of trials.

Seventeen (38%) of the 45 CTNs/Coordinating Centres approached responded to the online survey. Respondents worked in variety of clinical areas, and all generally conduct late phase clinical trials. Most therefore, intended to provide the information required to inform decisions about whether a candidate intervention should be adopted into practice or policy, should the results prove definitive.

The results of the survey indicate that many CTNs and Coordinating Centres undertake activities likely to enhance the implementability of their trials. These include comprehensive trial planning, consultation with clinical and consumer stakeholders, ensuring populations are applicable to the broader community, ensuring both interventions and comparators are grounded in current practice and feasible for implementation, and measuring fidelity within the trial. Activities least frequently undertaken included consultation with policy makers in planning the trial, ensuring the inclusion of participants in regional and remote areas, using core outcomes sets and routinely collected data, and measuring process indicators.

Most CTNs and Coordinating Centres reported overall commitments to timely, transparent and complete publishing of the trial's findings, although there was little consensus on a specific timeframe that would be feasible for all trials to meet, and it may be of interest to explore how this translates to timeframes in practice. CTNs and Coordinating Centres did not frequently have formal policies in place to encourage this or other aspects of implementability, and these issues were most often considered within the organisation through peer review and Scientific Advisory Committees.

There was little agreement on how a CTN or Coordinating Centre would identify whether the results of a trial warranted active implementation efforts. CTNs or Coordinating Centres were frequently involved in guideline development work, or facilitated the inclusion of trial results in evidence synthesis, but only a minority were actively involved in other implementation activities. This reinforces the understanding that implementation work is largely located outside the frame of organisations whose focus is conducting clinical trials, although only a small number of groups were able to name external organisations actively pursuing this work in relation to their trials.

Similarly, there was little active work to identify sources of data on either the implementation or the impact of trials, although some groups had examples that may be applicable across groups. A minority of groups had conducted active research themselves to obtain this information, and some barriers were identified to this area of work.

There is broad understanding and agreement among CTNs and Coordinating Centres around many areas of good practice that are likely to enhance the implementability of trials, although there remain opportunities to expand these activities and build them into routine practice, and an appetite among groups for further practical tools and guidance. Activities around assessing the appropriateness of implementation, and activities to measure implementation and impact are less widespread, representing further opportunities to assist CTNs and Coordinating Centres in thinking through and acting on these issues. Informed by an additional literature review of good practice, ACTA will proceed to develop such guidance and continue to work with members to enhance their work.

BACKGROUND

Clinical trialists conduct trials with the aim of influencing healthcare and health outcomes for the community. Similarly, funders of trials wish to ensure value for money when investing funds in trials, and increasingly call for trialists to demonstrate the impact (or potential impact) of their work.

The relationship between the conduct of a clinical trial and implementation in policy and practice is complex, even for late-phase trials testing interventions that are considered ready for implementation. Any single trial exists in the context of a broader body of evidence and the complex realities of health service delivery. There may be multiple stages of activity required before policy or clinical practice could be expected to change, and therefore implementation science is a sphere of enquiry in its own right.

Nevertheless, there is much that individual trialists and their organisations can do to enhance the capacity for trials to be implemented, and to envisage and measure impact in appropriate ways. Some are already actively involved in implementation work.

The Australian Clinical Trials Alliance (ACTA) is a peak body representing Clinical Trial Networks (CTNs) and Coordinating Centres in Australia. ACTA's members primarily support the conduct of investigator-initiated, multi-site clinical trials across a variety of clinical specialties. While most focus their activities in Australia, some operate routinely across Australia and New Zealand, and some also support the Australian sites of international, multi-site trials. ACTA is working to develop practical guidance to support CTNs and Coordinating Centres in a range of areas, including enhancing implementation and impact. To underpin the development of this guidance, several information-gathering projects have been conducted to map current good practice.

This report describes one element of this information-gathering: a survey of ACTA's member organisations on their current practice and views on implementability, implementation and impact. The objectives of this survey were to identify current practice relating to enhancing the capacity for trials to be implemented ('implementability'), dissemination and implementation work, and approaches to estimating or measuring the impact of trials among Australian CTNs and Coordinating Centres.

METHODS

A survey instrument (see Appendix 1) was developed based on preliminary work conducted by ACTA staff and an expert Reference Group, outlining major aspects of the planning, conduct and reporting of trials relevant to implementation, as well as post-trial implementation activities. The survey was piloted with three CTNs.

An invitation to participate in the survey was sent to all CTNs and Coordinating Centres who were current members of ACTA in October 2018, and for whom current contact details were available ($n = 45$), via an email to the named contact person provided to ACTA for membership purposes. The invitation included a link to a survey via SurveyMonkey, and a request to forward the survey for the attention of an appropriate senior scientific officer to complete on behalf of the CTN or Coordinating Centre. Participants were advised that responses would be kept confidential, and that all responses would be de-identified in reports of the survey results. Members were given two weeks to complete the survey and were sent one email reminder before the deadline. As the response rate was low, a second invitation to respond was sent to members who had not already done so, providing an additional period of ten days to submit a response.

Responses to all questions asked (with the exception of contact information) are summarised in the Results section. Where appropriate, responses are summarised as percentages of the number of respondents to the question. Questions around frequency of particular activities or practices by CTNs and Coordinating Centres were framed on a five-point scale: 'required by the CTN or Centre', 'often done', 'rarely done', 'considered but not done', and 'not considered'. Participants who did not respond to the survey were excluded from the analysis. Results are presented as reported by the participants, and no analyses to identify associations or subgroup effects were undertaken.

RESULTS

Seventeen responses were received, including the initial pilot responses and two response received during the second invitation period (38% response rate). The respondents were senior executive officers of the CTN or Coordinating Centre ($n = 9$, 53%), held senior scientific roles such as the Chair of the CTN or Chair of its Scientific Committee ($n = 6$, 35%), or were other senior researchers ($n = 2$, 12%).

Of the CTNs or Coordinating Centres who responded, 59% ($n = 10$) responded that they generally studied single interventions (e.g., a drug or device). The remainder ($n = 7$, 41%) studied a combination of single interventions and complex interventions (e.g., a bundle of care, strategy, process or behaviour change intervention).

All respondents confirmed that they generally conduct late phase trials, defined as clinical trials intended to estimate the effectiveness of a candidate intervention in comparison to alternative interventions or standard practice, and in large enough groups of people to provide precise and applicable estimates of the effects (both positive and negative) on health outcomes. Late phase trials are intended to provide the information required to inform decisions about whether the candidate intervention should be adopted into practice or policy, should the results prove definitive.

ENHANCING IMPLEMENTABILITY THROUGH THE PLANNING AND CONDUCT OF TRIALS

Twelve responses were received to questions around current practices in this section (see Figure 1) around issues relating to trial planning. Of those, all reported that a complete and comprehensive trial protocol, the explicit categorisation of trials as pilot/early/late phase, consultation with clinicians and health service providers, and the consideration (or undertaking) of systematic reviews or other synthesis, were either 'required' or 'often done'. Only three respondents reported that consultation with policy makers was either 'required' or 'often done' (25%), while five reported that it was 'rarely done' (42%), one that it was 'considered but not done' (8%), and three that it was 'not considered' (25%).

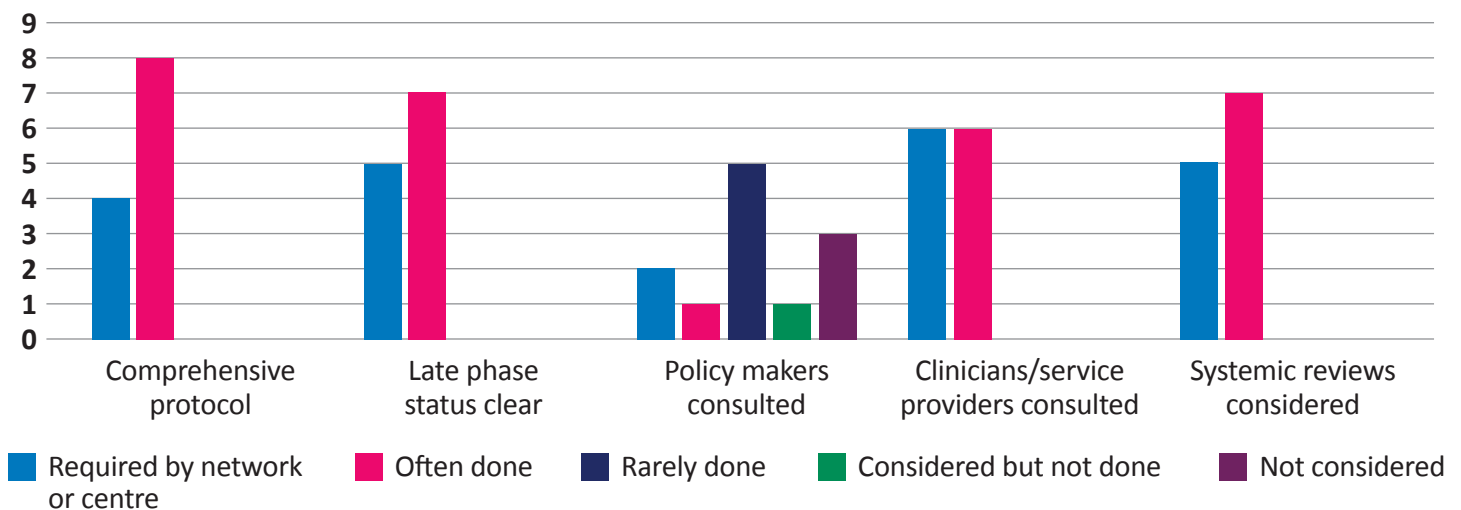


Figure 1: Issues relating to trial planning

With regards to the trial population (see Figure 2, overleaf) all twelve respondents reported that it was either 'required' or 'often done' that the participant population is representative of the community of interest (e.g., gender, ethnicity, age, socioeconomic), and that trial entry criteria reflect information that is readily available in actual clinical practice (e.g., diagnostic information). Eleven respondents (92%) reported that it was 'required' or 'often done' that the participant population is inclusive of people with comorbidities, with one reporting that it was 'rarely done'. Ten respondents (83%) reported that the possible effect modifiers to be analysed in the trial were planned (e.g., patients at different levels of risk) ('required' or 'often done'), allowing the participant population to include sufficient numbers to allow analysis of these effects. Two reported that this was 'rarely done'.

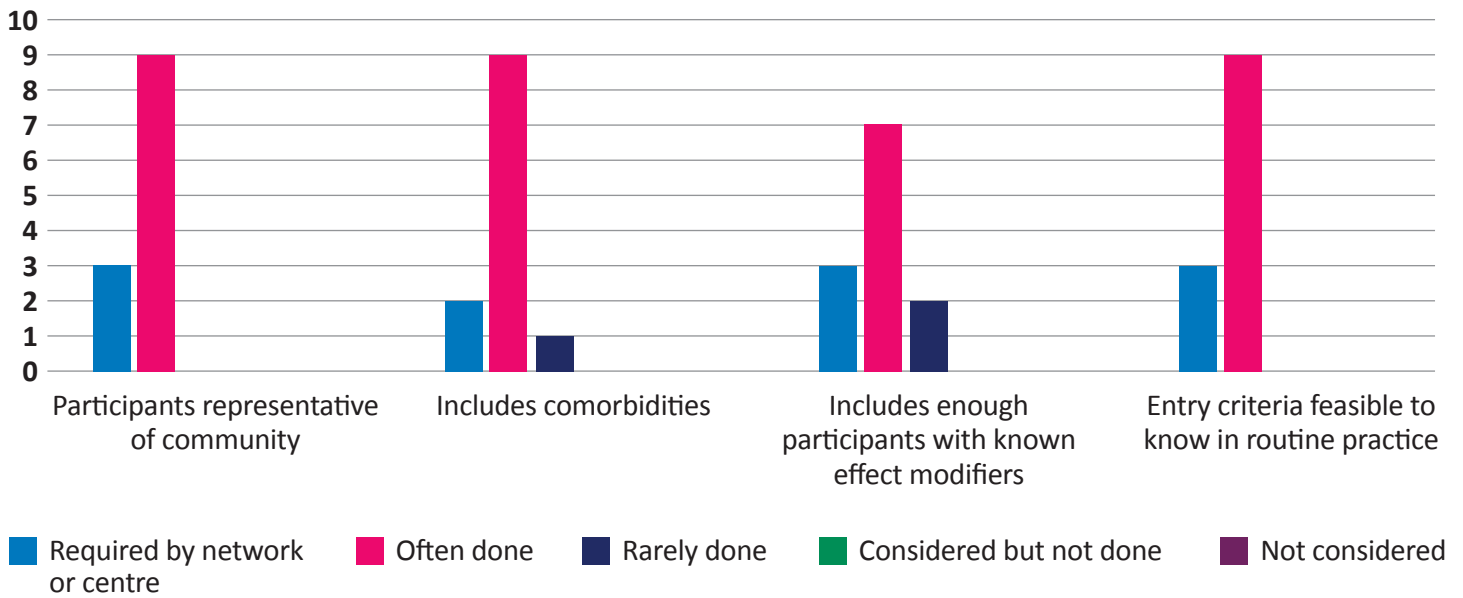


Figure 2: Issues relating to the trial population

In relation to the interventions and comparators selected for trials (see Figure 3), all respondents reported that it was either 'required' or 'often done' that the interventions are delivered in the same way that they would be delivered in actual practice (e.g., delivered by routine clinical staff), and that the comparator interventions reflect current practice.

Nine respondents (75%) reported that it was 'required' or 'often done' that evidence is obtained that comparator interventions reflect current practice using observational studies of actual practice, while two said this was 'rarely done', and one that it was 'not considered'. Seven reported that it was 'required' or 'often done' that evidence is obtained that comparator interventions reflect current practice using surveys of clinicians' beliefs about practice, while four said this was 'rarely done', and one that it was 'not considered'. Only six respondents (50%) reported that it was 'required' or 'often done' that the care settings in the trial include delivery for regional and remote populations, while five said this was 'rarely done', and one that it was 'considered but not done'.

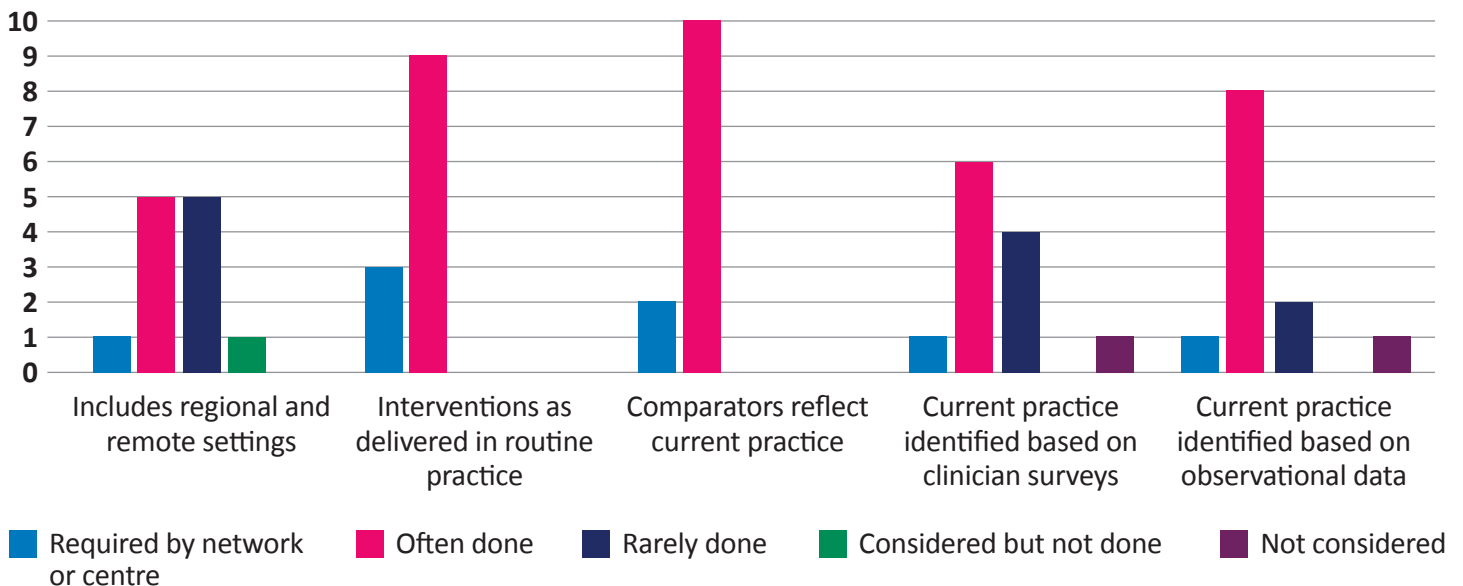


Figure 3: Issues relating to the trial interventions and comparisons

With regard to trial outcome measures (see Figure 4), all respondents reported that measurement of intervention fidelity (e.g, whether the interventions were delivered as per the trial protocol) was ‘required’ or ‘often done’. Eleven respondents (92%) reported that the measurement of outcome known to be sufficient to change practice or policy (based on previous trials or surveys of clinicians and policy makers) was ‘required’ or ‘often done’, with one respondent reporting that it was ‘rarely done’. Ten (83%) reported that consent for data re-use for future research was obtained from participants (‘required’ or ‘often done’), while two reported that it was ‘rarely done’. Nine respondents (75%) reported that economic evaluation was ‘required’ or ‘often done’, while three reported that it was ‘rarely done’.

Practice in relation to some aspects was less common. Seven respondents (58%) reported that measurement of process indicators (e.g, barriers or enablers that may explain why and how the intervention did or did not work (e.g., the RE-AIM framework), was ‘required’ or ‘often done’, while five reported that it was ‘rarely done’. Five respondents (42%) reported that the use of routinely collected outcome data (including clinical quality registries) was ‘required’ or ‘routinely done’, while six reported that it was ‘rarely done’, and one that it was ‘considered but not done’. Only three respondents (25%) reported the use of core outcome sets (e.g., COMET, ICHOM) were ‘required’ or ‘routinely done’, while six reported that it was ‘rarely done’, one that it was ‘considered but not done’, and two that it was ‘not considered’. An important consideration here is that it is unknown whether relevant core outcome sets exist that are relevant to the specific trials conducted by the respondents.

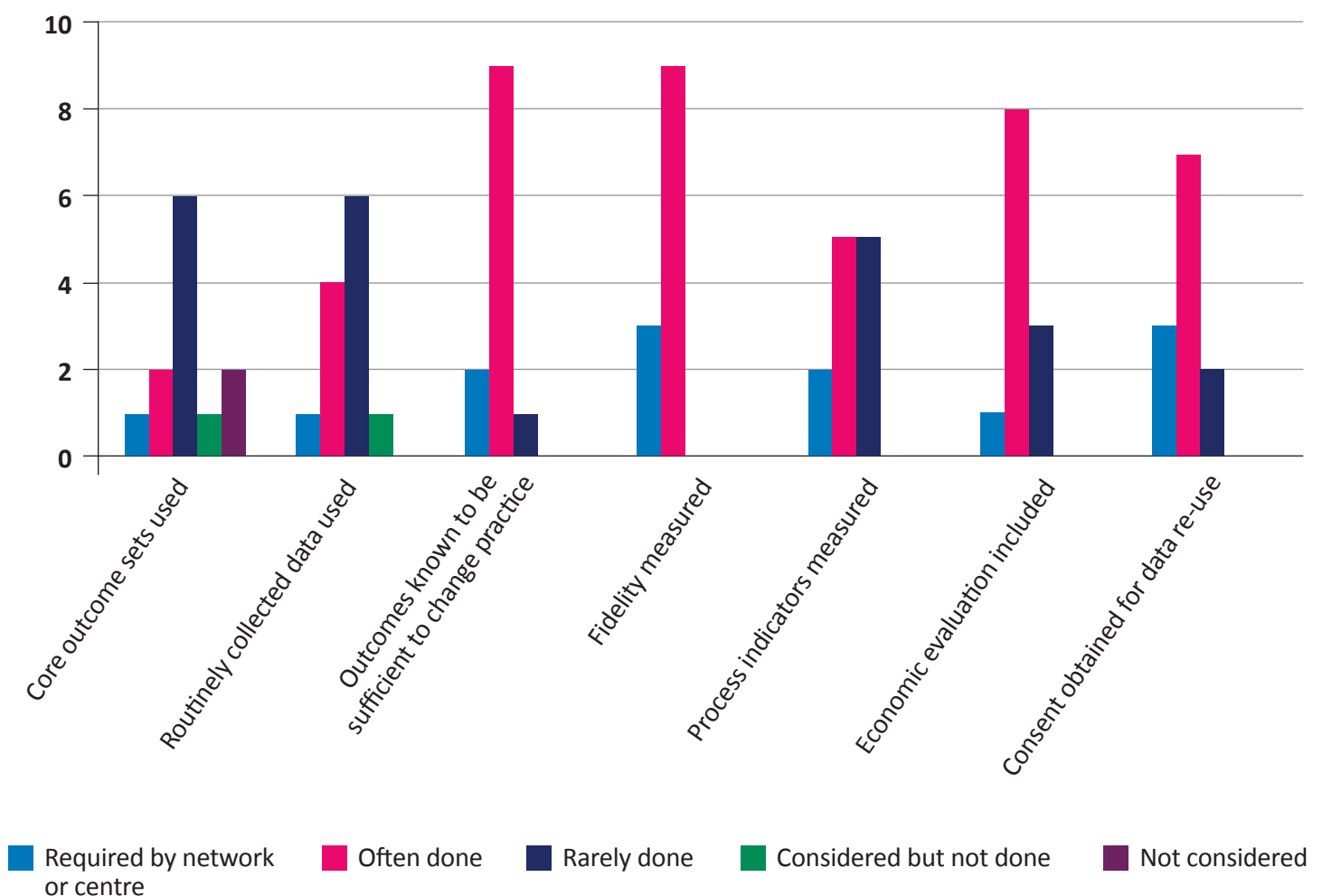


Figure 4: Issues relating to trial outcome selection and measurement

ENHANCING IMPLEMENTABILITY THROUGH TRIAL REPORTING

All respondents reported that several aspects of trial reporting (see Figure 5) were ‘required’ or ‘often done’, including that interests are transparently declared, that the trial protocol is published, that the trial is published regardless of its results, that the trial methodology is reported completely to enable assessment by others (e.g., using tools like CONSORT), and that information relevant to applicability is completely reported, including descriptions of the population and context of the trial. Eleven respondents (92%) reported that it was ‘required’ or ‘often done’ that the trial results are reported completely to minimise reporting biases (with one reporting that this was ‘not considered’), that trial interventions are reported in enough detail to enable replication in practice (e.g., using tools like TIDieR, TIDieR PHP, GREET, or other protocol documentation, with one reporting that this was ‘rarely done’), and that requests for further information are responded to after the trial is completed (with one reporting that this was ‘not considered’).

A less frequent practice was to write the trial report first using a template manuscript excluding the results, to ensure neutral language prior to analysis. Five respondents (42%) reported that this was ‘required’ or ‘often done’, four that it was ‘rarely done’, two that it was ‘considered but not done’, and one that it was ‘not considered’.

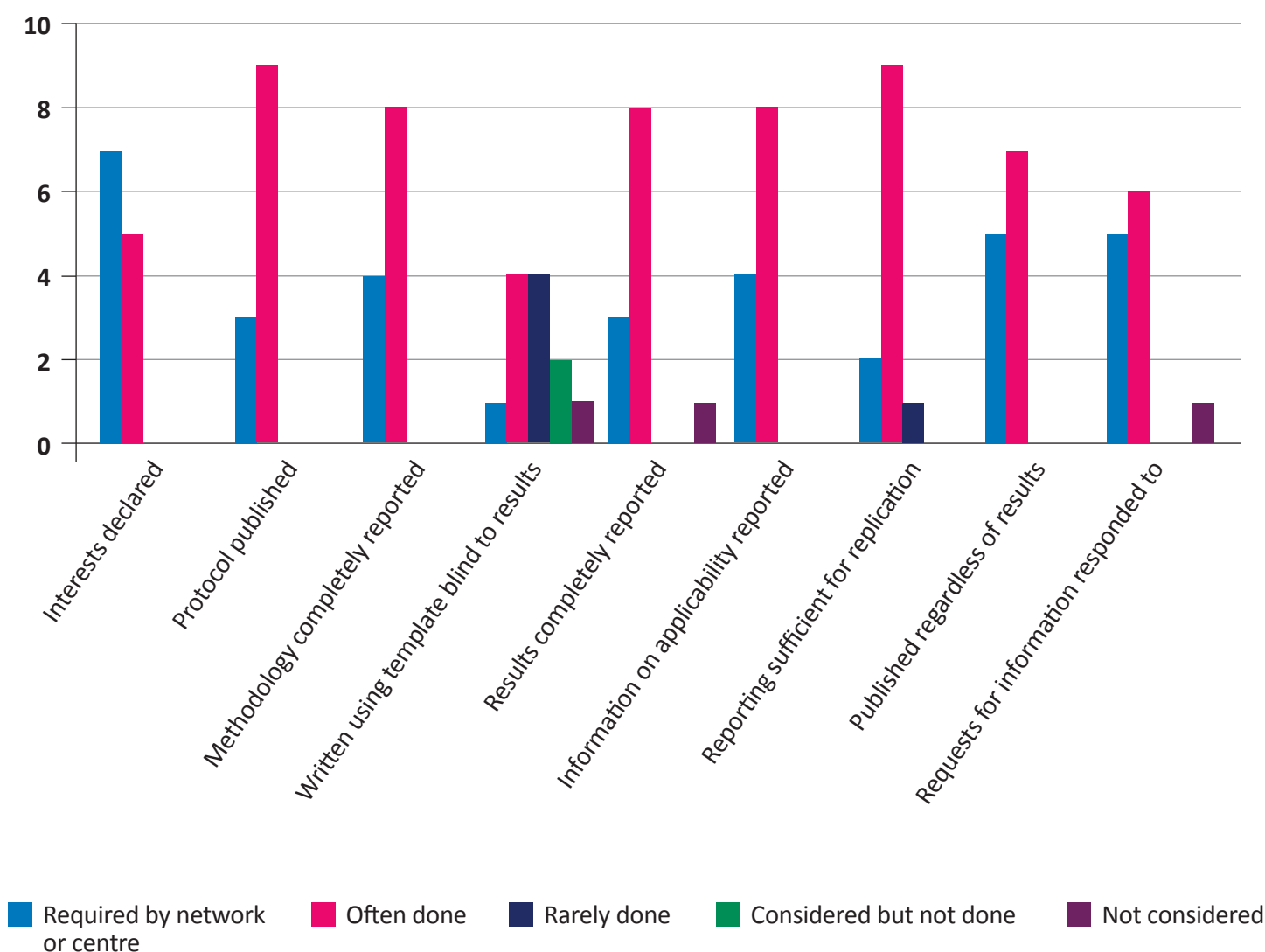


Figure 5: Issues relating to the reporting of trials

POLICIES AND PROCESSES FOR CONSIDERING IMPLEMENTABILITY

Respondents were asked whether the CTN or Coordinating Centre had any policies or guidelines about timeframes for reporting of trial results. Eleven respondents answered this question, of whom nine (82%) did not have a policy or guideline, although four of these noted that despite this, it was routine practice to report the results as soon as appropriate (e.g., within a year of completing data collection, cleaning and analysis, or as soon as appropriate for a given trial). Two respondents reported that there was a specific policy in place – one within six months, and the other again referring to appropriate timelines for specific trials.

Respondents were asked when and how issues around implementability were considered by the CTN or Coordinating Centre, and ten answered. All reported that these issues were considered by a scientific committee or similar. Eight (80%) reported that the issues were considered during peer review, and three (30%) reported that the issues were addressed in formal policy. No respondents reported that these issues were considered formally during assessment of proposals, or at symposia or scientific meetings.

IMPLEMENTATION OF TRIAL RESULTS INTO POLICY OR PRACTICE

Participants were asked whether the CTN or Coordinating Centre formally assesses whether the results of a trial warrant active implementation into policy or practice and what criteria were used, and ten responded (see Figure 6). Five respondents (50%) considered the likelihood that the proposed intervention would be acceptable and persuasive to clinicians and consumers. Four based their decisions on agreement that the trial had found a result large enough to be clinically meaningful. Three (30%) looked to identify a gap between the intervention supported by the trial and known current practice, or the feasibility of the intervention. One respondent each considered an assessment of the certainty of the body of evidence to which the trial contributes (e.g., through a systematic review and GRADE assessment, or an economic assessment of the costs and benefits or return on investment of the intervention). Four (40%) responded that they did not formally consider this question.

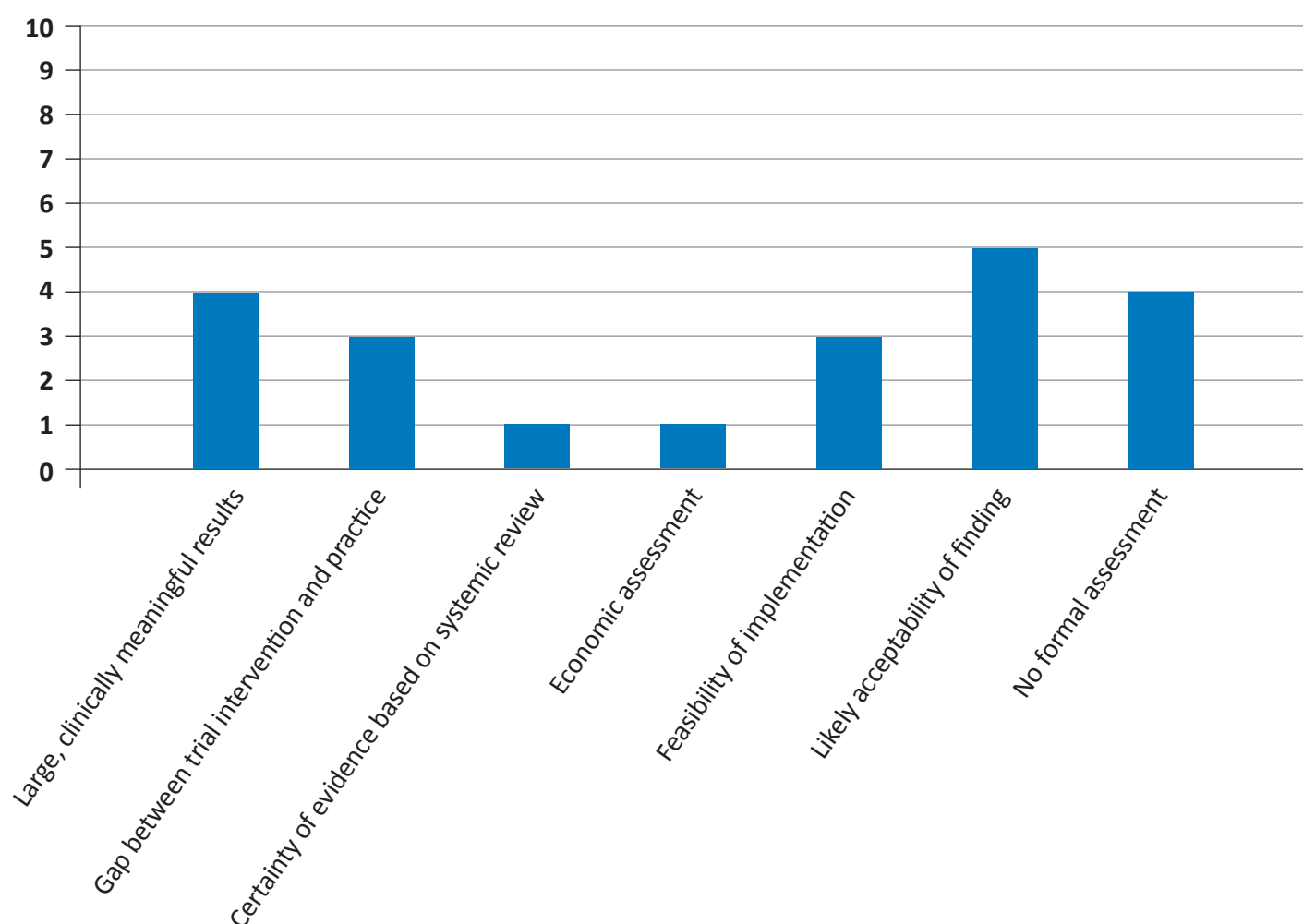


Figure 6: Assessment of whether trial results warrant active implementation into practice

Participants were asked whether they engaged in any specific implementation activities relating to the trials they endorse or conduct, and ten responded (see Figure 7). All reported that they were involved in guideline development activities. Seven (70%) reported that they facilitated the inclusion of results in evidence synthesis or systematic reviews. Five (50%) developed plain language summaries, infographics or other formats to communicate the results of the trial.

Smaller numbers reported other activities. Four each reported conducting evidence synthesis or systematic reviews themselves, or facilitating the inclusion of a trial in a new or updated guideline. Three each reported developing dissemination plan, conducting projects to implement evidence into clinical practice, or conducting replication trials based on trials conducted by other investigators. One each reported conducting a survey or observational study to identify willingness to implement findings by clinicians or policy makers, conducting projects to implement evidence into policy, or conducting replication trials based on trials conducted by their own CTN or Coordinating Centre.

No respondents reported conducting research into methods to implement evidence into clinical practice or policy.

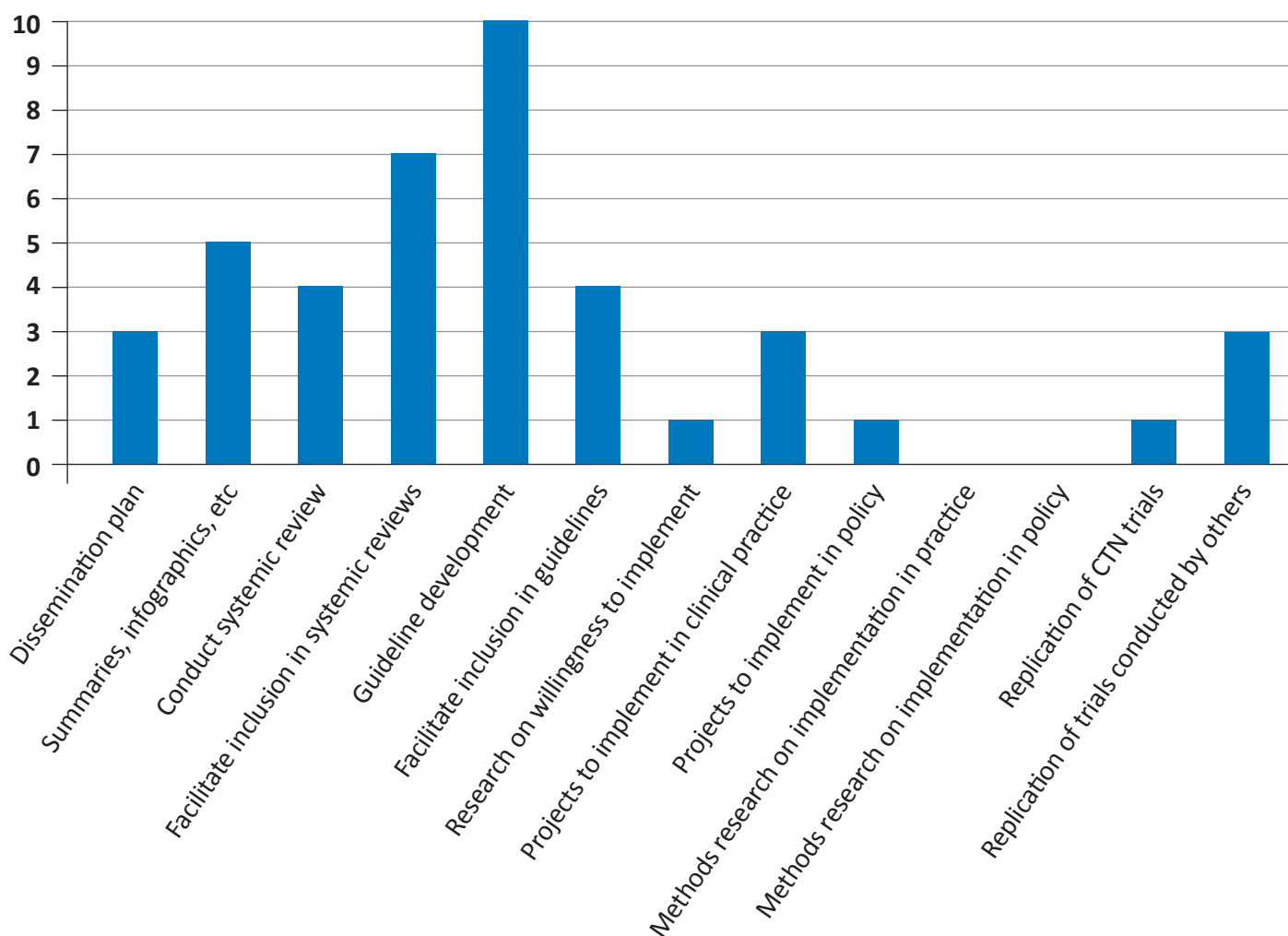


Figure 7: Engagement in implementation activities

When asked to describe these activities in more detail, three respondents provided more information. Two noted that they presented results at conferences, one noted publication in peer reviewed journals (although it can be assumed that all groups aim for publication as an outcome of their trials). Two noted that they took opportunities as they arise to include results in relevant guidelines and policies. One noted the importance of foundation work prior to the trial (such as a systematic review and/or observational study) to ensure the question asked by the trial is meaningful to clinicians and policy makers.

Six participants responded to a question on awareness of other organisations outside their CTN or Coordinating Centre who were involved in undertaking implementation activities in relation to their trials, and what methods or processes they used. Four (67%) noted the work of guideline developers, and one each (17%) noted the work of professional associations, systematic review authors, local clinical decision makers and investigators conducting replication trials. One respondent was unable to comment on these activities.

MEASUREMENT OF IMPLEMENTATION AND IMPACT

Nine participants responded to a question about accessing external sources of information to measure whether implementation had occurred for an intervention supported by a trial they had endorsed or conducted – that is, was the intervention taken up into policy or practice? Three (33%) reported using surveys of current practice. Two (22%) reporting using publication metrics. One each (11%) reported using web searches, Pharmaceutical Benefits Advisory Committee (PBAC) or Medical Services Advisory Committee (MSAC) coverage decisions, conference presentations or guidelines. Four (44%) reported not using any sources to identify this information.

Seven participants responded to a question about accessing external sources of information to measure impact – that is, did the implementation of an intervention supported by a trial they had endorsed or conducted make a difference to health, economic or other outcomes? One each (14%) reported that they used Australian Institute of Health and Welfare (AIHW) data, practice surveys or a return-on-investment analysis. Four (57%) reported that they did not use any sources to access this information.

Participants were then asked what activities they conducted themselves, where a trial had been identified as appropriate for implementation, and to provide any additional description of these activities – to which seven responded. Three (43%) conducted economic analysis of the impact of trials on health outcomes or of health system productivity, one noting that they aimed to mandate these studies for all major trials. Two each (29%) conducted observational studies or audits to assess actual uptake of an intervention support by a trial (one noting that these were small surveys of members for internal use), conducted qualitative studies to assess barriers to and facilitators of implementation, or developed case studies that outline the impact of trials on health outcomes or health system productivity for dissemination (one noting that they were new to this activity).

Participants were also asked what challenges or barriers to measuring implementation and impact they had experienced, and eight responded. Four (50%) noted the availability of resources (time and financial). One each (13%) noted the availability of registries to measure data, staff skills, and uncertainty about the requirements of funders. Two (25%) reported no challenges or barriers.

IDENTIFYING PRACTICAL TOOLS AND GUIDANCE OF ASSISTANCE

Participants were asked to rank in order what practical tools or guidance would be useful to their CTN or Coordinating Centre to assist in activities related to implementability and impact, and to rank them in order of preference, to which twelve participants responded. Tools and guidance to help make trials more implementable were ranked most highly, followed by tools and guidance to measure impact and implementation. Tools to help calculate the potential impact of a trial were ranked third, with tools and guidance to help identify which trials are appropriate to implement, ranked lowest.

DISCUSSION

SUMMARY OF KEY FINDINGS

The results of the survey indicate that many CTNs and Coordinating Centres consider a variety of issues likely to enhance the implementability of their trials, including trial planning, populations, interventions and outcomes, although fewer establish these methods as formal policies for all trials to follow. Factors least consistently considered included consultation with policy makers in planning the trial, ensuring the inclusion of participants in regional and remote areas, using core outcomes sets and routinely collected data, and measuring process indicators.

Most CTNs and Coordinating Centres reported overall commitments to timely, transparent and complete publishing of the trial's findings, although it may be of interest to establish the timelines achieved in practice as there was little consensus on a specific timeframe that would be feasible for all trials to meet. Least commonly used was the methodology of writing trial reports initially without the results, to enhance complete and unbiased reporting. Few CTNs had explicit forums within the work of the groups through which these issues were routinely discussed.

There was little agreement on how a CTN or Coordinating Centre would identify whether the results of a trial warranted active implementation efforts. CTNs or Coordinating Centres were frequently involved in guideline development work, or facilitated the inclusion of trial results in evidence synthesis, but only a minority were actively involved in other implementation activities. This reinforces the understanding that implementation work is largely located outside the frame of organisations whose focus is conducting clinical trials, although only a small number of groups were able to name external organisations actively pursuing this work in relation to their trials.

Similarly, there was little active work to identify sources of data on either the implementation or the impact of trials, although some groups had examples that may be applicable across groups. A minority of groups had conducted active research themselves to obtain this information, and some barriers were identified to this area of work.

When considering what support they would prefer to receive, respondents ranked guidance on enhancing implementability most highly, again supporting the understanding that conduct and reporting of the trials is their main focus, followed by assistance in measuring impact and implementation.

STRENGTHS AND LIMITATIONS OF THE SURVEY

The sample size provides a small number of specific examples of CTN and Coordinating Centre activity, and the results should be treated with caution. It is likely that responses were more likely from groups with an interest in issues around implementation and impact, and so the responses may be an overestimate of activities in this area. However, we believe the findings of the survey remain useful in understanding the types of practice that most likely to be common among groups, and in planning guidance and practical tools to support CTNs and Coordinating Centres in future implementation activities.

CONCLUSIONS

There is broad understanding and agreement among CTNs and Coordinating Centres around many areas of good practice that are likely to enhance the implementability of trials, although there remain opportunities to expand these activities and build them into routine practice, and an appetite among groups for further practical tools and guidance. Activities around assessing the appropriateness of implementation, and activities to measure implementation and impact are less widespread, representing further opportunities to assist CTNs and Coordinating Centres in thinking through and acting on these issues. Informed by an additional literature review of good practice, ACTA will proceed to develop such guidance and continue to work with members to enhance their work.

APPENDIX 1

SURVEY INSTRUMENT

Implementability of Trial Results

This is a short survey on the implementation of clinical trials results from the Australian Clinical Trials Alliance (ACTA).

The purpose of clinical trials is to improve health or healthcare systems by generating robust evidence about the effects of interventions in response to relevant clinical questions. As such, trials that are intended to guide decision-making by clinicians and policymakers should maximise their capacity to be used achieve this goal. This is an area of importance to trialists, and also of substantial interest to Government and funders.

ACTA has established an Impact and Implementation Reference Group to work on these issues. This survey aims to gather information from Clinical Trials Networks and Coordinating Centres about what is already being done in this area, to allow sharing of good practice and to inform the development of practical guidance and tools.

Implementation of research findings is in many cases outside the scope of activity of Networks and Centres, although some researchers are engaged in both areas of activity.

Nevertheless, ACTA is interested in exploring the roles of Networks and Centres in:

- **Enhancing the implementability of trials**, that is, characteristics of the design, execution and reporting of a clinical trial that increase the capacity for the evidence generated by that clinical trial to be used in policy and healthcare decision making, as well as by other researchers.
- **Identifying trials for which implementation may be appropriate**, including into policy or practice.
- **Measuring the implementation and impact** of key trials where implementation activities have occurred.

Any information you choose to provide will be used by members of the Reference Group and ACTA staff to inform the development of guidance. Your information will be treated confidentially. Any information included in documents for publication will be de-identified. If we wish to share any examples in an identifiable way, we will seek your explicit consent.

Thank you in advance for your participation. This survey should take about 15 minutes.

1. Please tell us who you are. These questions allow us to understand a bit more about who has responded and the network they represent. Identifying information will only be used to re-contact you should we need to. If you consulted colleagues to answer these questions, please state their role as well.

Name	<input type="text"/>
Role (job title within network or centre)	<input type="text"/>
Clinical Trial Network or Coordinating Centre	<input type="text"/>
Email	<input type="text"/>

2. What type of interventions does your Network or Centre generally study?

- Generally single interventions (e.g., drug or device)
- Generally complex interventions (e.g., bundle, strategy, process or behaviour change intervention)
- A combination of the two

Question 3: Does your Network or Centre conduct **late phase trials**?

Late phase trials are defined as clinical trials intended to estimate the effectiveness of a candidate intervention in comparison to alternative interventions or standard practice, and in large enough groups of people to provide precise and applicable estimates of the effects (both positive and negative) on health outcomes. Late phase trials are intended to provide the information required to inform decisions about whether the candidate intervention should be adopted into practice or policy, should the results prove definitive.

- Yes
- No

In the following questions, we will ask you about aspects of the planning and design of late phase clinical trials conducted by your Network or Centre.

4. Issues around **trial planning**:

	Required by network or centre	Often done	Rarely done	Have considered but not done	Have not considered this component
Trial protocol is comprehensive and complete (e.g. using tools like SPIRIT to inform planning)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Trials are explicitly categorised as pilot, early, or late phase (or similar categorisation that identifies interventions that, if effective, would be ready for implementation)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Policy makers are consulted	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Clinicians and health service providers are consulted	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Systematic reviews or other evidence synthesis are considered or undertaken prior to trial design	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

5. Issues around the trial **population**:

	Required by network or centre	Often done	Rarely done	Have considered but not done	Have not considered this component
Participant population is representative of the community of interest (e.g. gender, ethnicity, age, socioeconomic)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Participant population includes people with comorbidities	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Possible effect modifiers to be analysed in the trial are planned (e.g. patients at different levels of risk), and the participant population includes sufficient numbers to allow analysis of these effects	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Trial entry criteria reflect information that is readily available in actual clinical practice (e.g. diagnostic information)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

6. Issues around the trial interventions and comparators:

	Required by network or centre	Often done	Rarely done	Have considered but not done	Have not considered this component
Care settings in the trial include delivery for regional and remote populations	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Interventions are delivered in the same way that they would be delivered in actual practice (e.g. delivered by routine clinical staff)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Comparator interventions reflect current practice	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Evidence that comparator interventions reflect current practice is obtained using of surveys of clinicians' beliefs about practice	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Evidence that comparator interventions reflect current practice is obtained using observational studies of actual practice	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

7. Issues around the trial **outcomes**:

	Required by network or centre	Often done	Rarely done	Have considered but not done	Have not considered this component
Core outcome sets are used where available (e.g. COMET, ICHOM)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Routinely collected outcome data are used (including clinical quality registries)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Outcome measures are used that are known to be sufficient to change practice or policy (based on previous trials or surveys of clinicians and policy-makers)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Intervention fidelity is measured (i.e. whether the interventions were delivered as per the trial protocol)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Process indicators are measured (barriers or enablers that may explain why and how the intervention did or did not work, e.g. RE-AIM framework)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Economic evaluation is included	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Consent for data re-use for future research is obtained	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

8. Issues around **reporting**:

	Required by network or centre	Often done	Rarely done	Have considered but not done	Have not considered this component
Interests are transparently declared	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The trial protocol is published	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Trial methodology is reported completely to enable assessment by others (e.g., using tools like CONSORT)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Trial report is written using a template manuscript excluding the results, to ensure neutral use of language prior to analysis of results	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Trial results are reported completely to minimise reporting biases	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Information relevant to applicability is completely reported, including descriptions of the population and context of the trial	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Trial interventions are reported in enough detail to enable replication in practice (e.g. using tools like TIDieR, TIDieR PHP, GREET, or other protocol documentation)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Trial is published, regardless of results	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Requests for further information about the trial are responded to	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

9. Do you have any policies or guidelines within your network about **timeframes to report** your results? (For example, publish primary endpoint data within one year of data lock.) Please detail:

10. When and how are issues such as these considered by your Network and Centre?

- Peer review of projects
- Review by a Scientific Committee or similar
- Through formal written policies
- Other (please specify)

11. Does your Network or Centre formally assess **whether trial results warrant active implementation** into policy or practice? If so, what criteria do you use?

- | | |
|---|--|
| <input type="checkbox"/> Agreement that the trial found a result large enough to be clinically meaningful. | <input type="checkbox"/> An economic assessment of the costs and benefits or return on investment of the intervention |
| <input type="checkbox"/> A gap between the intervention supported by the trial and known current practice | <input type="checkbox"/> Feasibility of implementation of the intervention |
| <input type="checkbox"/> An assessment of the certainty of the body of evidence to which the trial contributes, (e.g. through a systematic review and GRADE assessment) | <input type="checkbox"/> Likelihood that the proposed intervention will be acceptable and persuasive to clinicians and consumers |
| <input type="checkbox"/> Other (please specify) | |

12. Does your Network or Centre engage in the following activities relating to any of the trials you endorse or conduct? (Select all that apply):

- | | |
|--|--|
| <input type="checkbox"/> develop a dissemination plan | <input type="checkbox"/> conduct projects to implement evidence into clinical practice |
| <input type="checkbox"/> develop a plain language summary, infographic or other format to communicate the results of the trial | <input type="checkbox"/> conduct projects to implement evidence into policy |
| <input type="checkbox"/> conduct an evidence synthesis or systematic review | <input type="checkbox"/> conduct research into methods to implement evidence into practice |
| <input type="checkbox"/> facilitate the inclusion of results in evidence syntheses or systematic reviews conducted by others | <input type="checkbox"/> conduct research into methods to implement evidence into policy |
| <input type="checkbox"/> contribute to guideline development | <input type="checkbox"/> conduct replication trials (based on a trial conducted by your own Network or Centre) |
| <input type="checkbox"/> facilitate the inclusion of a trial in a new or updated guideline | <input type="checkbox"/> conduct replication trials (based on a trial conducted by other investigators) |
| <input type="checkbox"/> conduct a survey or observational study to identify willingness to implement findings in by clinicians or policy makers | |

13. Please provide a brief description of the activities you have selected under Question 11. Feel free to provide a link to websites or published papers if easier.

14. To the best of your knowledge, which organisations outside your Network or Centre are involved in undertaking implementation activities in relation to trials you have endorsed or conducted? What methods or processes do they use?

The following questions are about activities relating to the measurement of implementation and impact of trials you have endorsed or conducted.

15. What external sources of information, if any, do you access to measure **whether implementation has occurred** for an intervention supported by a trial you have endorsed or conducted (that is, was an intervention taken up into policy or practice)?

16. What external sources of information, if any, do you access to **measure impact** (that is, did the implementation of an intervention supported by a trial you have endorsed or conducted make a difference to health, economic or other outcomes)?

17. Have you experienced any challenges or barriers to measuring implementation or impact? Please describe:

18. Where a trial has been identified as appropriate for implementation, does your Network or Centre:

- Conduct observational studies or audits to assess actual uptake of an intervention support by a trial
- Conduct qualitative studies to assess barriers to and facilitators of implementation
- Conduct economic analysis of the impact of trials on health outcomes or of health system productivity
- Develop case studies that outline the impact of trials on health outcomes or health system productivity for dissemination

19. Please provide a brief description of the activities you have selected under Question 17. Feel free to provide a link to websites or published papers if easier.

The following questions relate to ways in which ACTA can support you in your work and share good practice among ACTA members.

20. What practical tools and guidance would your Network or Centre find useful to assist in activities related to implementability and impact? (please rank from 1, most useful, to 4, least useful):

- Tools and guidance to help make your trials more implementable
- Tools and guidance to help you identify which trials are appropriate for implementation (by yourself or others)
- Tools and guidance on measurement of impact and implementation
- Tools and guidance to help you calculate the potential impact of a trial, such as the economic return on investment

21. Are there any case studies from trials in your network where implementation and impact have gone well that you would like us to use as an example of good practice in any future guidance? Please describe:

22. Would you be willing to participate in a short teleconference or video-conference (duration estimated at 30 mins) to allow us to ask further questions regarding these issues?

- Yes
- No

23. If you obtained input from other members of your network in answering these questions, please identify their roles below:

- | | |
|--|--|
| <input type="checkbox"/> Executive Officer/Network Manager | <input type="checkbox"/> Director/Board member |
| <input type="checkbox"/> CEO/General Manager | <input type="checkbox"/> Lead investigator |
| <input type="checkbox"/> Chair of the Board | <input type="checkbox"/> Other investigator |
| <input type="checkbox"/> Other (please specify) | |

Thank you for participating in this survey. Please remember to press the SUBMIT button below.

Your response is invaluable to our understanding of how best to support the implementation of trials for the greatest impact. We look forward to sharing the findings with you and your network or centre in the near future.

Should you have any further comments or questions please do not hesitate to contact us at acta@clinicaltrialsalliance.org.au



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