

IMPACT Network Endorsed Clinical Trials

The IMPACT Network's vision is to ensure optimal health of mothers and babies through addressing important clinical questions, thereby supporting evidence-based decision-making by consumers, health practitioners and policy makers.

This document outlines the criteria for endorsement of trials by the IMPACT Network; the purpose of endorsement is not only to ensure a consistent high standard of trial design, conduct, analysis and dissemination but also to ensure that research capacity and trial feasibility are optimised. It is recognised that clinical research through trials is necessary to evaluate existing or new interventions for their effectiveness and appropriateness. The number of potential trials exceeds the capacity for their completion because of the constraints of resources including adequate funding. For this reason the IMPACT Network, as a peak national organisation and a member of ACTA, has formulated an approach to the endorsement of clinical trials. It is recognised that there are many trials that address important issues in the pregnancy and newborn period.

The purpose of the endorsement process is to recognise those rigorously designed trials that are feasible and address the most pressing and urgent clinical questions.

Specifically, through endorsement of trials the IMPACT Network aims to:

- Increase collaboration and engagement with the IMPACT Network.
- Increase efficiency by decreasing duplication.
- Increase capacity, leading to better efficiency and economy of studies.
- Increases the IMPACT Network community's awareness of important trials by seeing which ones are endorsed.
- Promote the development of trials which focus on areas the IMPACT Network sees as key questions.

The development of new trials

1. Those individuals who develop a new **IMPACT** trial proposal will form the study trial steering committee.
2. Programmes of research proposing more than one individual trial will not be endorsed collectively. Each component of a proposed programme must be submitted separately for endorsement.
3. **IMPACT** trial proposal development should take into account any potential competition for recruitment with existing IMPACT Network endorsed trials and should not adversely impact upon the completion of a trial in progress.

Trial Endorsement Criteria

1. Multicentre collaborative trials are preferred, although single-centre trials may be endorsed.

2. **IMPACT** Trials should address an issue that is of major importance in which there is a recognised knowledge gap.
3. **IMPACT** trials should accord with the IMPACT Network's vision, mission and values statements and conform to these Terms of Reference and all other relevant IMPACT Network policies.
4. The IMPACT Network will only endorse trials prospectively, that is before they commence recruitment.
5. Successful competitive funding will not guarantee endorsement and it is strongly encouraged for trials to gain endorsement before submission of major funding.
6. **IMPACT** trial proposals should be developed in accordance with ICP, GCP or similar guidelines and should include:
 - Trial steering committee and administering institution(s).
 - A detailed protocol including a hypothesis, rationale and study aim(s)/objective(s).
 - Evidence of feasibility including proposed budget, funding strategy, and / or a demonstration of in-principle support from sites.
 - Consideration of all relevant ethical issues.
 - An intent to register the trial on a clinical trials registry.
7. The trial steering committee should include at least one member who has experience in completing a multicentre collaborative study.
8. To be eligible for endorsement, new and revised trial proposals must be presented at a minimum of one IMPACT Network meeting; presentation at an early stage of development is strongly encouraged.
9. To be eligible for endorsement inclusion of an appropriate consumer group should be demonstrated as should how their feedback has been incorporated into the trial design.
10. Where there is a known deadline for obtaining IMPACT Network endorsement of a trial proposal (such as for major grant submissions), applications should be submitted allowing sufficient time for review and revision if recommended.
11. Endorsement applications can be built around a grant application or a trial protocol or both but must provide a detailed rationale and research plan for the study, described above.
12. The trial may be conducted in association with one or more collaborating institutions. If collaboration has been formed at the time of submission for endorsement, these arrangements must be disclosed.
13. There must be a budget impact analysis that shows the expected impact of the study on the health care budget in terms of the prevalence of disease in Australia/NZ, the number of interventions and the health care costs that are involved.
14. The endorsement application must contain a systematic review of previously performed research as well as a search of appropriate trial registers.

Trial endorsement process

1. The IMPACT Network Steering Committee will endorse trials.
2. Proposals will be endorsed on merit, considering whether the study accords with the mission, vision and values, Strategic Plan, research strategy and research capacity of the IMPACT Network.
3. Applications for endorsement should be made using the standard IMPACT Network application for endorsement form and be accompanied by a single page synopsis and a declaration of any relevant potential conflicts of interest of IMPACT Network committee members.
4. A nominated member of the IMPACT Network Steering Committee will supervise the review of each submitted trial. Members of the IMPACT Network Steering Committee who have an established conflict of interest (e.g. a member of the management committee) will not be involved in either the supervision or the conduct of a review of an endorsement application. If the nominated lead Network member is conflicted, an alternative Network member will be nominated.
5. Studies will be presented at the IMPACT Network Steering Committee and discussed, including the feedback from any IMPACT Network meetings at which the trial was presented. The nominated member of the IMPACT Network Steering Committee will present the trial to the committee. The scientific merit, significance and feasibility of the proposed trial will be presented. Assessment of feasibility will include the resources required to conduct the study at the site level and proposed site payments. Large-scale trials should provide details about how sufficient resources will be raised to cover all reasonable site costs. If feasibility is considered to be questionable, the IMPACT Network Steering Committee may require demonstration of informed, in-principle support from the number of sites deemed necessary to successfully complete the study.
6. The IMPACT Network Steering Committee will vote and a majority will determine that the study is endorsed.

Conditions of Endorsement

Once endorsed by the IMPACT Network Steering Committee, the following conditions apply for the duration of the trial and for all prospectively defined sub-studies. The chair of the trial steering committee will be responsible for ensuring that these conditions are fulfilled.

It is the responsibility of the trial steering committee to obtain resources and conduct the proposed study in accordance with the IMPACT Network Terms of Reference and relevant policies applicable at the time of IMPACT Network endorsement, and where practical with future revisions. IMPACT Network Trials must be conducted with high professional standards and in compliance with codes of research conduct such as the Australian Code for the Responsible Conduct of Research produced by the NHMRC and the New Zealand guidelines on ethics in health research by the HRC.

1. The trial steering committee will nominate a member, usually the Chair, who is responsible for liaison with the IMPACT Network Steering Committee and it is the responsibility of the management committee to update the IMPACT Network with respect to any major design or administration changes that occur after endorsement is conferred.
2. The trial steering committee should meet and maintain records of their meetings (e.g. minutes or action points) with sufficient frequency to ensure good governance of the study. The records of the trial steering committee meetings will be made available to the IMPACT Network Steering Committee if requested.
3. The trial will be registered in an open access clinical trials registry (where applicable).
4. The trial will have free access to and are encouraged to use the IMPACT Network website. This will provide five trial specific pages that trial investigators are encouraged to use as the main trial website and as a public repository for trial related documents.
5. A trial update should be submitted for inclusion in a summary document that will be presented at an IMPACT Network meeting at least once per year, or more frequently if required by the IMPACT Network Steering Committee.
6. The IMPACT Network Steering Committee reserves the right to withdraw endorsement at any stage should the trial not progress adequately or if irresolvable conflicts of interest arise.
7. Manuscripts arising from the study will comply with the IMPACT Network Publication Policy outlined below.
8. Results of the primary study should be presented at an IMPACT Network/PSANZ scientific meeting, and it is preferred that this is the first presentation outside of the study investigators, however the importance of international presentations is appreciated.

Sub-studies of IMPACT Network Endorsed Trials

Sub-studies of an IMPACT Network Endorsed trial are encouraged. A sub-study is a nested observational or interventional study that involves new additional aims and collects additional data and / or additional study procedures in some or all of the subjects in the parent study. Post-hoc or secondary analysis of data from the parent study is not regarded as a sub-study and does not require submission for endorsement as a project but will require submission for endorsement prior to being submitted for publication.

1. Sub-studies should have the written support of the study trial steering committee.
2. The IMPACT Network Steering Committee should be informed of all sub-studies of endorsed trials. The nominated lead member of the IMPACT Network Steering Committee will determine whether or not submission for IMPACT Network endorsement is required.

Sharing of Data from IMPACT Network Endorsed Trials

The IMPACT Network Steering Committee encourages sharing of data, for example, to allow the conduct of individual patient data meta-analyses or other secondary analyses. It is expected that data from IMPACT Network endorsed trials are available to the researchers from 2 years after completion of the recruitment and follow-up for the primary outcome.

Proposals will be considered by a Data Sharing Committee that is determined by the Trial Steering Committee. To safeguard the scientific integrity and validity of any new studies which request data, sharing must receive approval from the DSC.

This process will include:

- Agreement of the responsibilities and rights of all parties.
- Review of a protocol for the proposed analysis, which will need to contain clear scientific justification for the particular project, anticipated outputs and timelines will be required.
- Independent peer review of the specific project will be required.
- Funds may be required to support the data extract and transfer.
- The appropriate regulatory permissions – ethical, legal and institutional – must be in place before the data can be shared.

IMPACT Network Reviewed Clinical Trials

The IMPACT Network seeks to support trials in maternal and perinatal health that are already underway, are of high quality but do not meet the criteria for endorsement as a key research question in IMPACT Network related areas of maternal and perinatal health or for some other reason do not wish to seek endorsement status.

These trials should:

1. Be led by or closely involve members of the IMPACT Network AND
2. Have been presented at an IMPACT Network meeting on at least two occasions at different stages of trial development and progress OR
3. Have applied for endorsement but did not meet all the criteria for full endorsement.

In such circumstances these trials will be identified as IMPACT Network Reviewed Trials. These trials will include the following in the acknowledgements section of manuscripts and presentations to indicate the support of the IMPACT Network: “This trial has been presented to, and peer reviewed by the IMPACT Clinical Trials Network for Mothers’ and Babies’ Health”.

IMPACT Network Reviewed Trials will have the same access to IMPACT Network trial webpages as IMPACT Endorsed Clinical Trials.