

INFORM: supporting informative trials

Prompts for funding panels

Each member of a funding panel has an important role in ensuring that trials funded through the panel are as informative as they can be.

Many funders provide guidance to panel members to help them judge which trials should be funded. The text below provides some prompts that could be shared with panel members, or which could be part of the chair's briefing, to help with this. The intention is that by asking these questions, the panel is more likely to fund trials that are informative.

Although aimed at funding panel members, all or most of these prompts will be relevant to members of other committees that review trials for approval, for example ethical review committees. This is especially true of the six 'Essential but brief prompts' (see below).

The numbers in curly brackets {} refer to the question numbers on the [INFORM Structured Grant Form for Trials](#).

Essential but brief prompts

Funding panel members are busy, and may have limited time to read long guidance documents. Some questions should always be asked though.

*To make an informative trial more likely, panel members should **always** reassure themselves that justifications for the following are in place for each trial they consider:*

1. Is there a clear, evidence-informed rationale for why the trial is needed {3}, {4}
2. Is there a clear, evidence-informed justification for who the trial participants will be and how they will be identified {7}
3. Is there a clear, well-justified explanation for the number of participants in the trial {8}
4. Is there a clear, evidence-informed rationale for the choice of outcomes, and that the trial is collecting these outcome data at the right time in the right way {11}, {12}, {13}, {14}, {15}
5. Is there a convincing, evidence-informed description of why trial delivery is feasible {18}, {19}, {20}, {21}

6. Is it completely clear that the team has the appropriate statistical and methodological competence to design, deliver and analyse the study {8}, {9}, {22}, {23}, {24}, {25}

More detailed prompts

Some funding panel members may be interested in more detailed questions, especially linked to their own areas of expertise.

To make an informative trial more likely, panel members may wish to consider the following questions in addition to the six essential questions listed above:

Design

1. Is clear evidence presented that demonstrates that the intervention(s) is worth evaluating? {3}
2. Are the intervention(s) and comparator clearly described? {10}
3. Is the research question(s) clear? {4}
4. Is there any suggestion that the trial explicitly or implicitly excludes some groups of people who epidemiological and disease data suggest are important to have in the trial population? {5}, {7}, {8}
5. Are the trial locations the right ones? {5}
6. Are participants allocated to each intervention and comparator in a way that reduces the risk of bias? {16} {17}
7. Would the trial design score as low risk of bias on a a risk of bias tool? {16}
8. Is there a clear, evidence-informed rationale for the choice of outcomes, and that? {6}, {11}, {12}, {13}, {14}, {15}
9. Does the analysis appropriately handle potential differences between different groups of participants? {7} {24}
10. Who is the named person(s) with statistical competence who acts as guarantor for the sample size calculations and analysis? {8}, {9}, {22}, {23}, {24}, {25}
11. Are there any potential conflict of interests? {34}

Conduct

1. Is there a clear, evidence-informed rationale for the choice of recruitment and retention strategies, along with evidence that the strategies will engage the right people and be effective in doing so? {7}, {18}, {19}, {20}, {21}
2. Is it clear who, how, when and where consent will be taken? {19}
3. Are there any potential concerns about the team's ability to collect outcome data, including baseline data? {11}, {12}, {13}, {14}, {15} Are the proposed day-to-day

management plans appropriate, and provide reassurance that the trial team understands what delivery of their trial demands? {28}

4. Is there a clear plan to ensure that all those involved in the trial will have the right training, especially those involved with recruitment, retention and data collection? {30}
5. Are there any concerns that external factors such as technology change may affect the intervention, comparator or other aspect of the trial during its lifetime, and is the team aware of this? {27}
6. What external oversight is planned? {26}, {29}

Knowledge mobilization

1. Is it clear that the team plan to register the trial? {31}
2. Is there a plan that unambiguously makes clear that all the results, regardless of what they are, will be made public and also shared appropriately with participants, including staff who helped deliver the trial? {32}
3. Is it clear how the trial team will make their trial data available to other researchers after the trial? {33}