INFORM Good Practice Actions to strengthen research systems for informative trials

Read more about the mapping that led to this table in Trial informativeness across research practices: Initial findings from a mapping exercise. JCE 2026

Good practice actions to strengthen research systems for informative trials		
Design	***Key stakeholders***	***Rationale and implementation***
1. Set research priorities through evidence syntheses and stakeholder engagement to ensure trials address recognised needs • Research priorities should be informed by existing evidence and coordinated across stakeholders to ensure trials address recognised health needs and deliver meaningful benefits to target populations.	- Funder/sponsor - Investigator - Regulatory authority	**Important because…** Research priorities need to take account of existing evidence; this should be done in consultation with relevant stakeholders to ensure trials address recognised needs with tangible benefits for target populations. **Without this…** Failure to align research priorities with existing evidence and stakeholder input can result in trials focusing on areas of low relevance, leading to wasted resources and missed opportunities to address critical health needs. **How this can be best done…** Draw on multiple forms of existing evidence (such as systematic reviews, meta-analyses, scoping reviews, Value of Information (VOI) analysis, biological knowledge, preliminary data, pre-clinical data); coordinating with stakeholders (such as local healthcare professionals; people with lived experience of a condition or disease; relevant communities) to set research priorities carefully.
2. Conduct pre-funding scientific design assessments and regulatory consultations to minimise waste and address uncertainties before making funding commitments • Engaging funders and regulators early in a structured design review process	- Funder/sponsor - Investigator - Regulatory authority	**Important because…** It allows deliberation of the trial design before the approval process—which can be time-consuming and costly—and will reduce the likelihood of the trial failing or being uninformative. Having this step before funds are committed allows uncertainties to be addressed. **Without this…**

can foster shared understanding, strengthen the justification for the trial, and further support more informed funding decisions		Flaws in the trial design may go unchecked, leading to a trial that is funded, but ultimately fails to deliver. **How this can be best done…** Hold a pre-submission meeting that brings together sponsors, funders, regulators, and when feasible—ethics reviews, with the aim of carrying out a structured review of the trial design and methodology. Any uncertainties can be addressed before funds are committed.
3. Engage patients and communities from the outset to build trust, ensure relevance, and strengthen recruitment and retention • Engagement that begins early and is grounded in local context helps ensure trial questions reflect priorities that are important to patients and communities, interventions are acceptable, and participation is sustained through trust and shared ownership.	- Funder/sponsor - Investigator - Patient/community representatives	**Important because…** Through these interactions, trial hypotheses can be carefully crafted to address real priorities; interventions can be evaluated to ensure they are acceptable to those with lived experience. Trust-building is also important to help recruitment and retention of participants. **Without this…** Trials may fail to address priorities that are relevant to patients and communities or may implement interventions that are not acceptable or feasible from their perspective. This can lead to challenges in recruitment, retention, and overall trial success. **How this can be best done…** Engage patients and communities for collaborative partnerships that are grounded in local context from the earliest stage possible. The principles of research co-production are helpful when thinking about building trusted partnerships: avoiding tokenism; including listening to all perspectives; respecting and valuing all input; reciprocity; and a balanced power dynamic. This needs time. Perspectives from patients and community can inform recruitment and retention strategies, including effective communication with participants. Embedding patient and community members in advisory boards, and PPI input) within trial protocols creates an enduring source of valuable input.

4. Apply structured design tools, established frameworks, and Open Science practices (e.g., COMET, SPIRIT, pre-registration) to improve trial quality, transparency, and reproducibility • Using structured tools and Open Science practices embeds consistency and accountability across the trial lifecycle and supports further coordinated design, conduct, and reporting	- Funder/sponsor - Investigator	**Important because…** The overall quality and transparency of the trial are upheld. **Without this…** There may be gaps, inconsistencies and uncertainties, deeming the findings less useful and contributing to research waste. **How this can be best done**… Use tools, frameworks and guides from the earliest stage and throughout the trial lifecycle. Examples: Core Outcome Measures in Effectiveness Trials (COMET) Initiative; Enhancing the QUAlity and Transparency Of health Research (EQUATOR) Network; Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) checklist; PRO EDI; Consolidated Standards of Reporting Trials (CONSORT) statement; WHO Global Benchmarking Tool (GBT) for evaluation of national regulator systems for medicinal products. Follow OS best practice by pre-registering studies or submit registered reports before data collection to ensure accountability and transparency.
5. Ensure accountability, particularly from funders or sponsors, for robust, justified trial designs, supported by multidisciplinary teams and collaborative networks that include statistical expertise • Coordinated efforts and diverse practical expertise enable more rigorous, well-justified trial designs, with funder and/or sponsor accountability ensuring that design choices and team capabilities are well supported	- Funder/sponsor - Investigator - Collaborative networks	**Important because…** It drives the development of rigorous, well-designed trials and ensures that teams have the capacity to deliver reliable, informative trials. **Without this…** Studies risk being underpowered, poorly designed, or misaligned with clinical needs, leading to wasted resources and exposing participants to unnecessary risks and burdens, with no clear expectation of scientific or social value from the resulting research. **How this can be best done…** Build collaborative networks and bringing together diverse expertise (e.g. statistics, IT, clinical operations, financial aspects). In circumstances where access to expertise is limited, it mustn't be left out (e.g. in low resource setting; limited statistical expertise globally); funders can support buy-in of expertise.

6. Apply quality-by-design approaches targeting critical determinants of trial quality to strengthen design and reduce avoidable errors • A quality-by-design approach ensures that factors critical to trial quality are prospectively identified and managed to uphold trial integrity, participant safety, and the reliability of results	- Funder/sponsor - Investigator	**Important because…** Potential risks to quality are identified and mitigated during the clinical trial process. **Without this…** Avoidable errors may derail the clinical trial, put participants at risk, or result in findings that are unreliable and uninformative. **How this can be best done…** Plan a systematic and proactive strategy that uses risk assessment to identify potential sources of variability, and how these could impact the trial. Use monitoring activities to oversee aspects of the trial where there are potential risks. The European Clinical Research Infrastructure Network (ECRIN) hosts a toolbox of resources providing information on tools available for risk assessment, monitoring and study conduct, the institutions where they are used, and other relevant details such as links and user feedback.
Conduct	***Key stakeholders***	***Rationale and implementation***
7. Use future-proofing measures to safeguard trial integrity and ensure technologies remain relevant, reliable, and unbiased • Future-proofing involves anticipating changes in technology and research practice to maintain data integrity, minimise bias, and ensure that trial processes remain sustainable over time	- Funder/sponsor - Investigator	**Important because…** Integrity of the trial is safeguarded. **Without this…** There is a risk to data integrity and an increased risk of bias within the trial, which could compromise the validity of findings and expose participants to unnecessary risks, leading to wasted resources and diminished social value from the research. **How this can be best done…** Anticipate how technologies and practices might change during the trial. Use a “risk of bias” tool, such as the Cochrane Risk of Bias tool before the trial to identify and address areas of risk. The INSPECT-RS tool can be used for assessing trustworthiness of randomised controlled trials.
8. Assess feasibility through pilot studies, integration of qualitative evidence on	- Funder/sponsor - Investigator	**Important because…**

lived experiences into trial process design, and engagement with local health professionals • A comprehensive approach to feasibility combines practical testing with contextual understanding, drawing on lived experience and local expertise to anticipate barriers and refine trial delivery	- Local health professionals	There is a clearer understanding of how delivering an intervention in a real-world setting will go. **Without this…** A full-scale trial could be funded and run, but lacking the learnings from a pilot study, there are many ways for the trial to fail. **How this can be best done…** Carry out pilot studies assessing practical aspects (e.g. recruitment, adherence, acceptability, logistics). Barriers and enablers can be identified, and the trial design refined in response to these. Take account of lived experiences of people living with a disease or condition, including healthcare contexts and perceptions of usual care. Involve local health professionals to ground the pilot study in local context and to support effective recruitment and retention.
9. Provide continuous training, structured learning, and mentorship to build trial team competencies that go beyond current Good Clinical Practice (GCP) training • Building trial team capability requires ongoing, skills-based training and mentorship that translates GCP into consistent, high-quality conduct across all stages of a trial	- Funder/sponsor - Investigator - Professional bodies	**Important because…** Team competencies and capabilities are raised for delivery of a high-quality trial. **Without this**… There may be gaps in knowledge and missed opportunities, or risks which could violate the trial's integrity, undermining quality. **How this can be best done…** Plan for ongoing and structured learning for the team from the beginning and throughout the trial lifecycle. Plan for team members to develop skills with an emphasis on informed consent, compliance with protocols, and participant safety. Building skills around communication, cultural humility, inclusive practices and collaboration contribute to a broader strengthening of quality in trial delivery. Mentorship schemes can support professional development and the ability to apply knowledge and skills appropriately in the trial context.
10. Maintain oversight throughout the lifecycle of a trial through ethics review	- Funder/sponsor - Investigator	**Important because…** Transparency and rigour are upheld in the research.

boards, trial steering committees, and data monitoring to uphold scientific rigour and support evidence-informed analyses • Effective oversight ensures that ethical standards are upheld, emerging risk are managed, and analyses are guided by credible evidence, maintaining confidence in both the trial process and its outcomes	- Ethics bodies - Trial oversight committees	**Without this…** There is a risk to the ethics and quality of the trial. **How this can be best done…** Ensure oversight from ethics review boards, trial steering committees, and a committee for data protection and monitoring. Where multi-site trials cross jurisdictions, teams should aim to harmonise ethics submissions where possible to avoid duplication of effort. A trial steering committee can oversee that the trial is conducted in accordance with legislation, regulations, guidelines, and best practices and can advise on, or take action if there are potential research violations. A data protection committee can ensure compliance with relevant data protection laws and best practices to ensure robust data handling. Multi-site trials may have different data considerations across jurisdictions, or unique contextual factors such as the use of Indigenous data and knowledge.
Knowledge mobilization	***Key stakeholders***	***Rationale and implementation***
11. Ensure trial registration is monitored, and results are published in a timely and complete manner to maintain accurate records, meet ethical obligations, and reduce selective reporting and publication bias • Active monitoring of trial registration and reporting promotes transparency, protects research integrity, and ensures that all findings, regardless of outcome, contribute to the broader evidence base.	- Funder/sponsor - Investigator - Regulatory authority	**Important because…** Transparency and integrity are upheld. **Without this…** Trials may add to research waste. Failure to share and learn from research that does not produce a result in favour of the treatment under test has been recognised as a key source of clinical trial research waste and inefficiency. Selective or lack of reporting prevents the opportunity to build on previous research and can lead to duplication of effort. **How this can be best done…** Mandate that trials are registered prospectively, have a system for monitoring upkeep of records and reporting and ensure findings are published within a relevant timeframe.

12. Disseminate findings in accessible, inclusive formats, and mobilize knowledge to support equity and uptake into policy and practice • Timely and inclusive dissemination ensures that trial evidence reaches all relevant audiences, supports equitable translation into policy, and enhances the real-world impact of the research.	- Funder/sponsor - Investigator - Policymakers - Patient/community representatives	**Important because…** The results of the trial must reach all relevant audiences, and the information must be readily useable to inform policy. **Without this…** Changes may not be implemented, thereby rendering the trial wasteful, and it would be unethical to withhold the findings from relevant stakeholders. **How this can be best done…** Carefully consider who needs to be served by the research, and who needs to be included in the trial. Research teams can refer to the PRO EDI tool to ensure a core set of characteristics, and additional characteristics as relevant. Ensure that everyone is proactively given the opportunity to know about the trial findings. Engage with policymakers, practitioners and communities from early on helps to support uptake of the results into practice at local, national and international levels.