

3.1 Formative research activities

3.1.A. Definition

Formative research activities enable research teams to gain an informed understanding of local populations, socio-cultural norms and practices, local power dynamics, local perceptions, channels of communication and decision-making, and local history of research, as well as the needs and priorities of people who are locally affected by and able to influence the trial. Formative research activities usually constitute the initial phase of stakeholder outreach and engagement.

3.1.B. Relevance to good participatory practice

Collaborating with community stakeholders to devise questions, gather information, and analyse results related to formative research activities ensures that stakeholders' expertise and understanding of local perceptions, cultures, and traditions inform trial design and conduct. Collaborating with community stakeholders on formative research activities builds trust and lays the foundation for meaningful engagement.

3.1.C. Special considerations

1. Formative research activities can be conducted informally to gather information about local populations and research areas or formally as a part of approved, funded protocols.
2. Different sites will have specific needs regarding formative research activities. Whereas new trial sites may require extensive formative research activities, experienced trial sites may require more focused activities. Studying an experimental option new to the area, recruiting from a new location or population, gathering stakeholder feedback regarding previous trials, and the changing nature of cultures are all reasons why experienced trial sites may benefit from formative research activities.

3.1.D. Good participatory practices for formative research activities

1. Research teams identify key informants and relevant stakeholders that can assist in planning, implementing, and reviewing the process and results of formative research activities (see also Section 1.2).
2. Research teams designate trial site staff responsible for managing formative research activities.
3. Research teams and relevant stakeholders develop a formative research activity plan that describes:
 - a. Key information and questions that need to be gathered and answered in order to support effective planning and implementation of the trial.
 - b. The most appropriate methods to collect the required information.
 - c. Research team members and community stakeholders best suited to collect the required information.
 - d. Approval or notification processes that are required for specific activities.
 - e. Implementation plans, including timelines and required resources.
4. Research teams and relevant stakeholders discuss the findings and their implications for trial design, conduct, and development of meaningful stakeholder engagement.
5. Research teams document formative research activities and findings, including techniques used, information collected, areas where clarification or attention is needed, and how findings will inform the trial planning and implementation process.
6. Trial sponsors ensure sufficient funding and research teams create a budget and allocate funds and staff time to conduct formative research activities.