CLINICAL TRIALS TRANSFORMATION INITIATIVE

CTTI TOOL
STAKEHOLDER IDENTIFICATION AND ANALYSIS TOOL

Clinical trial stakeholders include not only the potential participants you hope to enroll in the study but also the other individuals whose time and effort are needed to develop and execute the project. Potential stakeholders will vary from trial to trial and they should be identified and prioritized based on the needs of each project.

The goal is not to engage each and every potential stakeholder. Rather, the following tool is intended to help you identify and prioritize the stakeholders **you** may need to engage to ensure the success of **your** clinical trial. Begin with a list of potential stakeholders and then prioritize those stakeholders based on their influence, importance to the project's success, current attitudes toward the project, and your plans for engaging them. While identifying and prioritizing your stakeholders, consider the following questions (and how you will obtain the answers):

1. How is the unmet need defined by the stakeholders?
2. Is the scientific question important to them?
    - How will the outcome affect them?
3. Will your project require any behavioral or mindset change (from participants, investigators, study staff, etc.)?
    - How can you influence these changes in behavior or in mindset?
4. Are subjects already diagnosed, at risk, aware, unaware, ready (or not) to change?
5. Who may be resistant to change or difficult to engage? Who has a vested interest in maintaining or changing the status quo?
    - Who is in a position to help you engage them?
    - Are there specific benefits of your project for these individuals that could help in engaging their support and action?

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STAKEHOLDERS & RESOURCES	STRATEGY			TACTICS
Characteristic	**Why this group is important to a successful trial (e.g., their role)**	**What do we need them to know and to do? What do we need to know about their current attitude(s) or concerns?***	**How can they help us develop a viable study?****	**How and when should/can/will we engage them? How frequently will we need to communicate with them to maintain their engagement?**
Participants				
Patients (diagnosed)				
Patients (at risk)				
Healthy persons				
Families of patients				
Patient Groups				
Advocacy organizations				
Support groups				
Patient advocates				
Providers & Clinicians				
Investigators				
Referring providers				
Community providers				

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Community (Local, Regional, or National, depending on trial context)***				
Culture				
Race				
Ethnicity				
Language				
Gender				
Age groups				
Socioeconomic status				
Trial Management Staff				
Statistical PI				
Data management staff				
Monitors				

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Site Staff				
Site PIs				
Co- (sub-)investigators				
Study coordinators				
Data coordinators				
Regulatory coordinators				
Allied Health Staff (e.g., those whose workflow will be impacted by trial implementation)				
Lab				
Radiology				
Nursing				
Pharmacy				

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Others				
Regulatory authorities				
IRB				
Payers/Insurers				
Funders				
CROs				
Vendors				
Institutional/organizational Commercial Unit (e.g., marketing department)				
Regulatory Affairs and Strategy				

CRO: contract research organization; IRB: institutional review board; PI: principal investigator.
*Regarding attitudes and objections, don't assume – verify by **asking** stakeholders, informally or formally.
**What are their capabilities, assets, knowledge, or expertise that can contribute to the development of a viable clinical trial?
***See Global Advocacy for HIV Prevention. Good Participatory Practice (GPP) Guidelines. http://www.avac.org/good-participatory-practice

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APPENDIX: EXAMPLES OF HOW STAKEHOLDERS CAN HELP TRIAL DESIGNERS

Stakeholder Group	Examples of how can they help you develop a viable study
Participants	
Patients (diagnosed) Patients (at risk) Healthy persons Families of patients	All potential participants and/or their support systems (e.g., family, caregivers) may be able to provide input regarding the interest of the study question to the patient population, unmet medical needs, the therapeutic burden, lived experience of the disease or disorder (e.g., the patient journey), meaningful clinical endpoints, patient-reported outcomes, the schedule of events, patient tolerance for risk vs. anticipated benefit, development of communication materials (e.g., consent, marketing messages, information sheets), and mechanisms for the dissemination of results back to participants. Consider having at least one person from this group on steering committees, advisory boards, protocol and consent working groups, and/or Data Safety Monitoring Boards.
Patient Groups	
Advocacy organizations Support groups	As above, plus direct-to-constituency outreach as an honest broker, assisting in the selection of optimal study sites, educating and motivating the patient community regarding the importance of clinical research and/or a specific study, developing meaningful and resonant outreach material, returning lay-language trial results to participants, etc.
Providers & Clinicians	
Investigators Referring providers Community providers	As scientists in search of the best evidence-based treatment options for their patients, investigators and clinicians should be enlisted to assist in developing meaningful study questions, reality-checking the inclusion/exclusion criteria, and developing the schedule of events to minimize the burden on study subjects.

Community	
Culture Race Ethnicity Language Gender Age groups Socioeconomic status	With the growing emphasis on patient-centered care and patient-focused drug development, as well as the need for improved diversity in clinical trial participation, any or all of these groups may need to be consulted/included in your formative research, study planning, implementation, execution and results dissemination. Because each of these populations may have different historical and cultural interpretations of research and/or healthcare, it will be important to carefully consider their perceptions and engage with them as you would any other stakeholder as described in these recommendations.
Trial Management Staff	
Statisticians Data management staff Monitors	Statistical and data management staff can provide input on data parsimony, adaptive trial designs, etc. Monitors can help engage study coordinators and obtain their critical feedback regarding protocol design and communication strategies.
Site Staff	
Site PIs Co-(sub-)investigators	Site investigators should be enlisted to provide input on the study question and meaningful endpoints, the outcome of which will help them engage in shared decision-making with their patients throughout their healthcare journey. They should also be consulted for input on realistic inclusion and exclusion criteria, the schedule of events, and data points.
Study coordinators, regulatory coordinators, data coordinators	As boots-on-the-ground staff with direct interaction with subjects, study coordinators are an often overlooked and underutilized wealth of knowledge and experience regarding patient preferences, tolerances for risk and burden, realistic eligibility criteria, site performance, efficiency, and start-up processes. They should be enlisted to provide meaningful input on the protocol, schedule of events, eligibility criteria, consent forms, and other communication material. They may also be helpful in identifying and developing the patient pathway, as well as recruitment budget needs.
Allied Health Staff (e.g., those whose workflow will be impacted by trial implementation)	
Lab Radiology Nursing Pharmacy	Allied health staff whose workflows may be impacted by trial activities should be engaged and/or consulted to provide input on feasibility and demand on their time and resources. These staff may also be able to provide input on patient preferences and tolerance for risk and, burden of participation, scheduling of procedures and visits, etc.

Others	
Regulatory authorities	Early consultation with regulatory bodies can help ensure that the project plan is appropriate
IRB	Central and local IRBs (and/or ethics committees) can provide guidance on risk/benefit burden for participants, and concerns regarding the protection of human subjects.
Payers / Insurers	Payers should be consulted during protocol development, especially if there are concerns about the standard of care vs. experimental treatment costs and what will be covered during the trial. Payers may also have established standards of evidence that could impact whether or not a trial's data will support coverage when a product is approved.
CROs Other Vendors	CROs and other trial vendors (e.g., recruitment firms, digital technologists) can provide insight into feasibility, available market data, site experience, and participant availability. Early engagement with these vendors may help eliminate downstream recruitment barriers.
Institutional/organizational marketing department	The institutional or organizational marketing department has expertise in developing effective communication strategies delivered via the most appropriate channels. They may also be in a position to offer guidance on market research strategies that could be employed in engaging a broad pool of patients with a particular disease or condition to better understand the disease burden, perspective on existing therapies, et al, leading to enhanced trial design.