

Effective Engagement Between Sponsors & Patient Groups: A Structured Process from the Clinical Trials Transformation Initiative (CTTI)

Background

CTTI is developing an open-access, web-based “Prioritization Tool” to assist sponsors and patient groups with identifying high-value opportunities to collaborate. The tool incorporates a simplified, 3-step decision-making process incorporating insights from semi-structured interviews, pilot-testing, and multi-stakeholder project team discussion.

Results

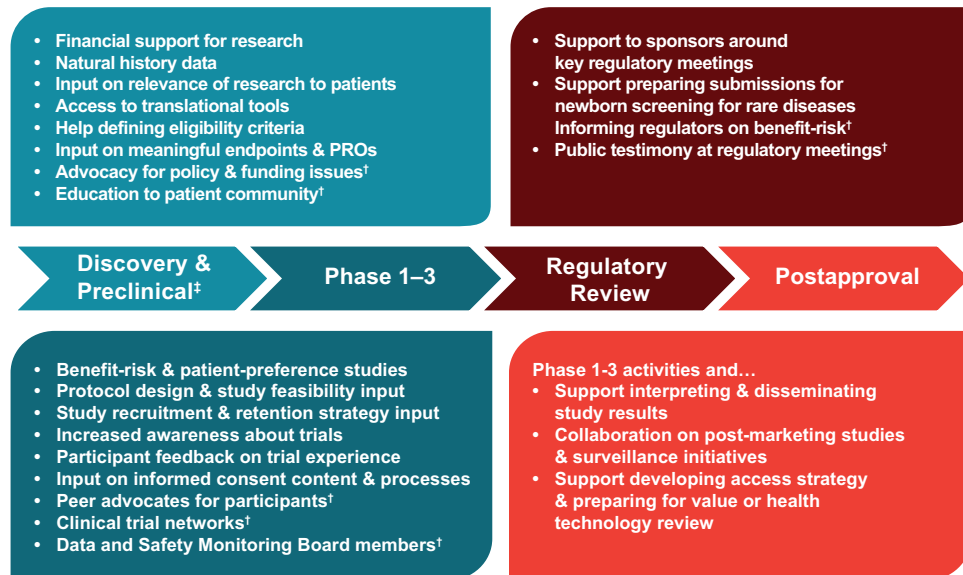
Updated Engagement Activities

Building on prior project work and incorporating feedback from semi-structured interviews, CTTI developed a refined list of patient group engagement opportunities. Figure 1. The Prioritization Tool will provide this list as a starting point for discussion between research sponsors and patient groups that are interested in working together.

Evaluating Potential Benefits and Investments

The interview findings identified factors and examples to consider when estimating the potential benefits and investments associated with engagement opportunities. Table 1.

Figure 1. Patient Group Engagement Across the Clinical Trial Continuum*
Patient groups have potential to enhance the quality and efficiency of clinical trials by providing:



*Updated 2018; adapted from Parkinson’s Foundation materials | †Patient group activities typically undertaken independently or with partners other than sponsors | ‡Includes early planning for trials

Table 1: To identify high-value opportunities for research sponsors and patient groups to work together, consider:

Potential Benefits	Potential Investments
<p>Scope of impact on patient population or organization For example, some patient group engagement activities might have potential to impact a large segment of the patient population or several future trials.</p> <p>Necessity of patient group involvement For example, some research activities might only be possible with the involvement of patient groups.</p> <p>Necessity for advancing medical product development For example, some patient group engagement activities might be critical to conduct in order to advance development of a medical product.</p> <p>Reputational benefits For example, some patient group engagement activities might be perceived by patients and other stakeholders in the community as “the right thing to do.”</p>	<p>Financial resources needed For example, some patient group engagement activities might be longer term and require continual financial investment.</p> <p>Staff time and expertise required For example, some patient group engagement activities might require a large number of staff, time, and/or highly-skilled personnel.</p> <p>Potential patient burden For example, some patient group engagement activities might necessitate interacting directly with patient populations and require a great deal of their time and effort.</p> <p>Additional organizational commitment needed given existing infrastructure For example, some patient group engagement activities might demand a great deal of commitment from the organization to establish necessary infrastructure and processes.</p> <p>Reputational risks For example, some patient group engagement activities might pose a potentially serious risk to the reputation of the sponsor or patient group if they are carried out or not done well.</p>

Prioritization Process



Identify RELEVANT engagement activities

- Starting with their own list and/or the list of engagement activities above, patient groups and research sponsors—working either together or independently—will filter down to those that are relevant to the situation of interest.
- Users will be provided examples of each activity and encouraged to identify their own fit-for-purpose implementations.



Evaluate BENEFITS and INVESTMENTS associated with each activity

- For each relevant engagement activity, users will rate likely investments and benefits as High, Moderate, or Low.
- Evidence-based factors identified by CTTI (see Table 1) will be provided as a starting point for consideration.



Identify MUTUALLY BENEFICIAL activities

- This process generates a Priorities Matrix (Figure 2) identifying the relevant activities that have the highest “value” (benefit vs. investment).
- Research sponsors and patient groups interested in working together can compare and discuss priorities to arrive at opportunities that are of high value for each (Table 2).

Priorities Matrix: The Prioritization Tool assists research sponsors and patient groups in quickly prioritizing relevant activities based on benefits vs. investments. Figure 2.

Example Joint Prioritization Outcome:

Table 2 shows an example of how a patient group and research sponsor might assess three activities identified as relevant to their potential collaboration.

Figure 2. Priorities Matrix

		Benefit	
		High / Moderate	Low / None
Investment	Low / None	Highest Value Activities	Moderate Value Activities
	High / Moderate	Moderate Value Activities	Lowest Value Activities

Table 2. Example Joint Prioritization Outcome

Engagement Method	Impact on Value Drivers	Patient Group	Sponsor
Input on relevance of research to patients	Facilitating benefit-risk assessment, focus groups, and survey studies requires small investments for patient groups and industry sponsors while the potential benefits of this information are great. The resulting information may improve study designs, leading to shorter study durations, lower risk, and lower costs.	High benefit / Low investment	High benefit / Low investment
Help defining eligibility criteria	Assisting in the definition of study eligibility criteria requires little investment for patient groups and sponsors but may have great benefit by more precisely defining the study population, providing a potential to improve the study design and reduce study duration, costs, and risks.	High benefit / Low investment	High benefit / Low investment
Financial support for research to identify target molecules	Funding target molecule identification requires a significant investment for patient groups with low probability of success. However, the benefit-to-investment ratio is larger for sponsors due to the minimal investment required on their part even if the likelihood of success is low.	Moderate benefit / High investment	High benefit / Low investment

Contact details

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To learn more about CTTI’s Patient Groups & Clinical Trials work, please visit <https://www.ctti-clinicaltrials.org/projects/patient-groups-clinical-trials>