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

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CLINICAL TRIALS **TRANSFORMATION** INITIATIVE

Background

CTTI is developing an open-access, web-based "Prioritization Tool" to assist sponsors and patient groups with identifying high-value opportunities to collaborate.

- Patient groups have increasingly been recognized as equal partners in the clinical trials enterprise.
- Many opportunities to collaborate exist across the research and development continuum.
- It is not always clear what types of patient engagement activities should be considered. It can be challenging for research sponsors and patient groups to prioritize activities independently, and even more challenging to jointly make a decision.
- CTTI developed a simplified, 3-step decision-making process that can help patient groups and research sponsors align on engagement activities that may provide the highest value.

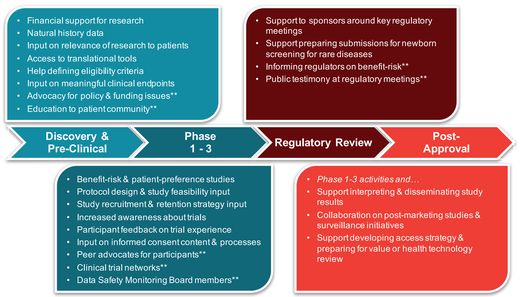
Methods

- A multi-stakeholder project team previously identified engagement opportunities across the research and development continuum.
- Using an online moderated pile sorting activity, semi-structured interviews were conducted with representatives from research sponsors (n=14) and patient groups (n=14) to understand how each defines "investments" and "benefits" of engagement opportunities.
- A draft Prioritization Tool was developed based on interview findings and multi-stakeholder team discussion.
- The draft tool was pilot tested with experts from research sponsors and patient groups.

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:



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 1) identified factors to consider when estimating the potential benefits and investments associated with engagement opportunities that organizations may wish to undertake together, and 2) provided examples to consider when thinking through the benefits and investments.

Contact details
To be notified when the web-based tool becomes available, please contact Zach Hallinan, CTTI project manager, at zachary.hallinan@duke.edu.

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

Potential Benefits	Potential Investments
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.* **Necessity of patient group involvement** *For example, some research activities might only be possible with the involvement of patient groups.* **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.* **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".*	**Financial resources needed** *For example, some patient group engagement activities might be longer-term and require continual financial investment.* **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.* **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.* **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.* **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.*

Designing a Straightforward Prioritization Process

CTTI is developing a web-based tool that will support research sponsors and patient groups in completing the following 3-step decision-making process:

Step 1

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.

Step 2

Evaluate BENEFITS and INVESTMENTS associated with each activity
- For each relevant engagement activity, users will rate likely investments and benefits as High, Moderate, Low, or None.
- Evidence-based factors identified by CTTI (see Table 1) will be provided as a starting point for consideration.

Step 3

Identify MUTUALLY BENEFICIAL activities
- This process generates a Priorities Matrix (see below) 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. See "Example Joint Prioritization Outcome".

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

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

Example Joint Prioritization Outcome: The figure below is an example of how a patient group and research sponsor might assess three activities identified as relevant to their potential collaboration.

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

Conclusions

As research sponsors and patient groups increasingly seek to collaborate, additional guidance and tools are needed to support engagement that is both meaningful and effective. This work will provide such a tool.