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.

- Patient groups have increasingly been recognized as equal partners in the clinical trials enterprise.
- Many opportunities to collaborate exist across the research sponsors and patient groups.
- It is not always clear what types of patient group engagement activities should be pursued. It can be challenging for research sponsors and patient groups to identify priorities independently, and even more challenging to jointly make a decision.

Methods

- CTTI developed a simplified, 3-step decision-making process that can help patient groups and research sponsors align engagement activities that provide the highest value.

Results

Updated Engagement Activities

Building on prior work and incorporating feedback from semi-structured interviews, CTTI developed a refined list of patient group engagement opportunities:

- Advocacy for policy and funding issues
- Input on meaningful clinical endpoints
- Input on relevance of research to patients
- Financial support for research
- Benefit-risk and patient-preference studies
- Data Safety Monitoring Board members
- Clinical trial networks
- Participant feedback on trial experience
- Increased awareness about trials
- Study recruitment and retention strategy input
- Collaboration on post-marketing studies and…
- Support interpreting and disseminating study results
- Surveillance initiatives

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

1. Evaluating Potential Benefits and Investments

The interview findings led to identifying 13 factors to consider when estimating the potential benefits and investments associated with engagement opportunities that organizations may wish to pursue. These 13 factors are listed in Table 1 and 2 and provide examples to consider when weighing the benefits and investments.

2. 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-steps in their decision-making process:

- Priority Setting: The Prioritization Tool will provide a list of high-value opportunities for research sponsors and patient groups to work together, considering:
  - Potential benefits
  - Potential investments

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Conclusions

An 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.