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 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 straightforward, 3-step decision-making process that can help patient groups and research sponsors align engagement activities that may provide the highest value.

Methods
- A multi-stakeholder project team previously identified engagement opportunities within the research and development continuum.

- Using an online moderated pile sorting activity, CTTI developed a simplified, 3-step decision-making process that can help patient groups and research sponsors align engagement activities that may provide the highest value.

- A draft Prioritization Tool was developed based on feedback from semi-structured interviews.

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:

- Access to/ and financial support for translational tools
- Research to patients
- Designing regulatory studies

- Clinical trial networks
- Facilitating benefit-risk assessment, focus groups, and survey studies
- Patient-preference studies
- Staff time and expertise required
- Longer-term and require continual financial investment.

- Funding target molecule identification requires a significant investment for patient groups and sponsors but may have great potential benefits.

- Assistance in defining study eligibility criteria requires small investments for patient groups and industry sponsors.

- Assisting in the definition of study eligibility criteria requires little investment for patient groups and industry sponsors.

- The resulting potential benefits of this information are great.

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 each a tool.

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

<table>
<thead>
<tr>
<th>Potential Benefits</th>
<th>Potential Investments</th>
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</thead>
<tbody>
<tr>
<td>Input on informed consent content &amp; participant feedback on trial</td>
<td>Support preparing submissions for newborn surveillance initiatives at regulatory meetings</td>
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<tr>
<td>Study data recruitment &amp; patient-preference studies</td>
<td>Informing regulators on benefit-risk</td>
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<tr>
<td>Regulatory review of target molecules</td>
<td>Peer input on informed consent content &amp; participant feedback on trial</td>
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<td>Phase I - III input on relevance of study results</td>
<td>Public testimony</td>
</tr>
<tr>
<td>Facilitating benefit-risk assessment, focus groups, and survey studies</td>
<td>Support preparing submissions for newborn surveillance initiatives at regulatory meetings</td>
</tr>
<tr>
<td>Target molecule identification requires a significant investment for sponsors due to their potential benefits but may have lower probability of success.</td>
<td></td>
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<tr>
<td>Low / Moderate Low / None High / Moderate High / Moderate Low / None High / Moderate High / Moderate Low / None</td>
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