Establishing a Collaborative Approach with Patient Advocacy Groups (PAGs) for Effective Clinical Trial Execution

Communication Considerations for Industry:

The following strategies outline a collaborative approach with Patient Advocacy Groups (PAGs) for effective clinical trial execution:

Partner in assessment of communication channels. It is vital for Industry to partner in the assessment of existing and/or non-existing channels within the PAG that are appropriate for clinical trial education and matching/recruiting patients to clinical trials. This involves identifying needs, opportunities, as well as the necessary structure and business model to facilitate their individual requirements. There should be collaboration with a portfolio of clinical trials to streamline the process of matching patients to the most suitable clinical trials.

Engage early. Engagement with PAGs should occur during the trial design process, not solely at the recruitment stage. Additionally, input from PAGs can significantly contribute to making the trial design more patient-centric, ultimately enhancing its appeal and facilitating recruitment.

Co-Create Study Materials. Work with PAGS to co-create study materials, incorporating terms, images, and concepts that are easily understood and resonate with the affected population. Ensure that the materials are inclusive of all backgrounds, identities, and groups, using culturally appropriate language.

Simplify information. Simplify information by avoiding medical jargon and overwhelming lists of side effects, while present materials at a 3-4 grade educational level. Lastly, one should stress the importance of proactive information-seeking about clinical trial participation, emphasizing that all questions are valuable.

Collaborate during recruitment planning. Collaborate with PAGS to design the recruitment plan, leveraging their channels such as newsletters, targeted emails, social media, and events. Additionally, seek input from PAGs on communication channels that are commonly used by the affected population, including those favored by underrepresented groups.

Leverage PAG expertise in patient lived experience. Demonstrate respect for the patient by acknowledging the potential trauma of diagnosis (if appropriate) and empathizing with emotional reactions. Use patient-centric language, preferring terms like "participant" over "subject". Understand the perspectives of the intended audience to craft messages that resonate with them. Provide a comprehensive list of resources for patient education, drawing from sources like CISCRP, as well as options for patient outreach through internal opted-in databases, websites, registries, etc.

Align on patient recruitment tactics. Lastly, develop and share a list of patient recruitment tactics, outlining expectations, required resources, and response rate projections for each tactic. Ensure fair compensation and other benefits for the PAG, reflecting appreciation for their time, effort, and other associated costs. This not only demonstrates respect for their invaluable contributions but also motivates continued collaboration.

Communication Considerations for PAGs:

The following strategies outline a collaborative approach with biopharmaceutical companies (Industry) for effective clinical trial execution:

PAG collaboration with an Industry partner for clinical trial communications is crucial. The communications considerations for the Patient Advocacy Groups (PAGs) are multifaceted. Firstly, there's the pivotal question of why collaborating with an industry partner for the enhancement and dissemination of clinical trial communications is crucial. This involves a clear definition of needs and expectations.

For the PAG's constituents and the broader patient community, a partnership with Industry holds numerous benefits.

1. It ensures that the patient perspective is integrated right from the outset, avoiding it being an afterthought.
2. This, in turn, streamlines the construction of the clinical trial and subsequent recruitment efforts.
3. Additionally, it fosters awareness of clinical trial opportunities that could offer significant advantages to participants, such as access to healthcare and experimental treatments.
4. Ensuring the PAG's voice is heard from the start is fundamental for an inclusive and successful clinical trial, increasing the likelihood of enrolling and retaining the required number of participants to address the research questions effectively.
5. Furthermore, PAGs play a pivotal role in building trust within their communities, thereby facilitating enrollment and retention in clinical trials.

Such a partnership holds numerous benefits for the PAG itself. The advantages of partnership extend to the PAG as an organization. PAGs gain a stronger voice for their stakeholder community, along with increased membership and engagement by providing information regarding research opportunities. It's also crucial to communicate opportunities in a manner that is easily understood by the broader audience, keeping language at a layman's level. Additionally, this enhances organizational awareness of potential therapeutic options. Building relationships within the industry partner organizations can lead to additional engagements and different types of partnerships, further enriching the scope of collaboration.

PAGs can be leveraged for expertise in patient engagement. In terms of best practices for communication engagements, PAGs should actively seek the direct involvement of their patients as lived-experience experts, striving for diversity in backgrounds and identities to align with evolving FDA and healthcare community expectations. Adequate compensation and benefits for both the PAG and individuals participating in the engagement should be secured from the industry partner. It's imperative to have a candid discussion with industry regarding PAG comprehension of the patient recruitment process to establish mutual comfort with the tactics at play. Recognizing that industry partners may be large and complex organizations, subject to personnel changes and bureaucratic delays is key to managing expectations. Moreover, there may be constraints on the nature or content of communications due to regulations. Therefore, it's crucial for PAGs and patients to have a grasp of the regulatory environment in which sponsors operate.

PAGs can provide valuable input early on in study communication design. Finally, practical information on the types of communications typically generated for a clinical trial is invaluable. This encompasses informed consent documents for prospective participants, offering an opportunity to address complexities and ensure understanding. Recruitment materials, including brochures, social media posts, emails, and advertising efforts, are critical, with PAGs providing vital feedback, particularly in the disease area they represent. Additionally, various modalities like journal articles, conference posters, summaries, videos, and infographic reports are used to present trial results in plain language. Finally, understanding what should and shouldn't be included in a recruitment notice for a clinical trial is pivotal. PAGs are instrumental in tailoring recruitment materials to resonate with patients while adhering to regulatory requirements. As for pharmaceutical companies, various departments are typically involved in clinical trial communications and recruitment efforts, thus this is important for the PAG to know.

RESOURCES

Talking to Your Patient About a Clinical Trial | National Institutes of Health (NIH)

Creating a best practice template for participant communication plans in global health clinical studies | Trials | Full Text (biomedcentral.com)

Advancing Health Literacy in Clinical Research: Clear Communications for Every Participant | National Academy of Medicine (nam.edu)