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Engaging PAH Patients in the Drug Development Process

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Background: Patient engagement is more than simply asking patients to volunteer in clinical research studies. Greater understanding of the motivations of PAH patients for participating in clinical trials is needed. Effective engagement strategies require an ongoing effort to involve patients from study concept and design to execution and beyond. Taking patient needs and insights into consideration is critical to the development of new medicines. It's proven that when companies adopt patient engagement strategies:

- Trials enroll faster
- Patient retention is improved
- Study volunteer feedback is more positive
- Long-term savings across drug development lifecycle can be realized

However, patient engagement isn't the standard approach due to a lack of internal company buy-in, time, authority to implement, and fear around how to properly engage.

Methods: A review was conducted of industry guidelines, regulatory standards, industry case studies and published research. The results of this research informed the patient engagement approach for ELEVATE 1, a PAH clinical research study.

Results: While planning for Altavant's inaugural clinical development program in patients with PAH, ELEVATE, patient centricity was at the forefront. The approach focuses on empowering patients to make an informed decision to participate in a study by developing educational content that is trustworthy, compelling and relatable. Relationships are being built with patient advocacy groups to gain critical insights and help raise awareness of the study. Patient engagement activities, such as, but not limited to, tweet chats, patient advisory panels, and plain language summaries are being piloted. Qualitative feedback on these approaches will be collected from patients, clinical research center personnel and advocacy groups. Key success measurements include the number of protocol amendments, percent of non-enrolling sites, recruitment timelines and drop-out rates. This data will be used to inform the corporate approach to drug development.

Conclusions: This patient engagement focus will spark a shift from...

- Patients who are lacking information to patients who have easy access to credible, balanced, relatable information about clinical trials.
- Transactional engagement to an enduring dialogue.
- Clinical trial subjects to clinical trial participants, advocates and partners.
- If successful, this approach has the potential to ignite the PAH community's interest around clinical research - and, in turn, to bring new medicines to people faster.



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