

UNDERSTANDING DRIVERS AND BARRIERS TO PARTICIPATION IN CLINICAL TRIALS FOR PATIENTS WITH PULMONARY ARTERIAL HYPERTENSION (PAH)



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BACKGROUND

- Clinical trials are key to providing access to novel therapies and improving outcomes, but recruitment is challenging
- To our knowledge, patient perspectives regarding trial enrollment are not well understood
- We conducted a patient survey to better understand the needs of patients when considering clinical trial involvement

OBJECTIVE

- Identify factors that motivate or discourage patients living with PAH to participate in a clinical trial

METHODS

- A 33-question survey was administered through the Rare Patient Voice, an online platform comprising ~850 patients with PAH
- Patients were eligible to participate if
 - ≥ 21 years of age
 - currently treated with ≥ one PAH medication
 - diagnosed with PAH for ≥ six months, and
 - never participated in a clinical trial
- The survey protocol met regulatory guidance for patient-focused drug development and was approved by a central institutional review board (Advarra, Inc.). All respondents provided informed consent prior to survey initiation.

RESULTS

- 102 patients completed the survey

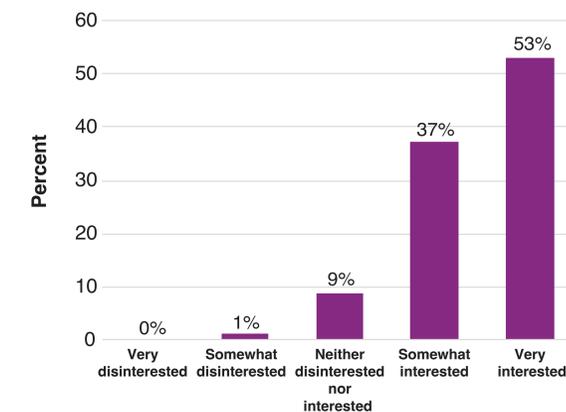
Table 1. Demographics and baseline characteristics (N=102)

Age, mean	51.4 years
Female, %	88
College or graduate degree, %	51
Time since PAH diagnosis, mean	8.3 years
Patient perception of disease status over past 60 days, %	
Getting a lot better	3
Getting a little better	8
Staying the same	69
Getting a little worse	21
Getting a lot worse	0
Number of current PAH medications, (1/2/3), %	25 / 38 / 37

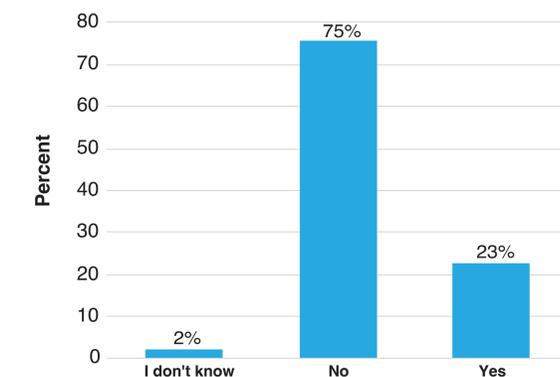
RESULTS

Figure 1. Patient interest in (A) and HCP communication about (B) clinical trial participation

A Q: How interested are you in participating in a clinical trial for PAH at some time in the future?



B Q: Has your doctor ever asked you if you wanted to participate in a clinical trial for PAH?



- Fifty-three and 37% of patients responded to be “very interested” or “somewhat interested”, respectively, in participating in a clinical trial (**Figure 1A**)

- Seventy-five percent reported not having discussion about clinical trial participation with their clinicians (**Figure 1B**); however, 93% reported they would welcome information and discussion.

- When asked how they would feel if a health care provider suggested clinical trial enrollment, participants provided the following top emotive responses: ‘interested’ (80%), ‘excited’ (41%), ‘good’ (30%), ‘grateful’ (28%), and ‘thankful’ (27%)

Figure 2. Top patient-reported factors encouraging clinical trial participation (Q: Which of the following would encourage you the most to participate in a clinical trial?)

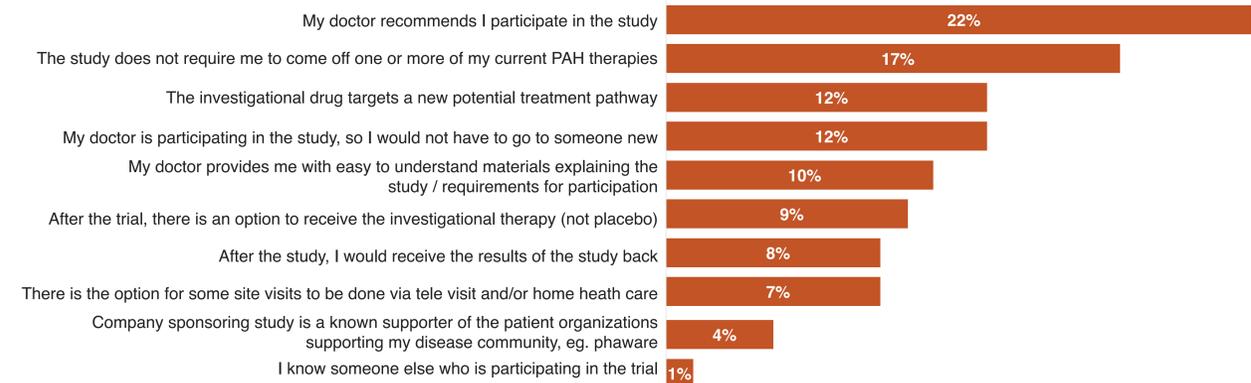
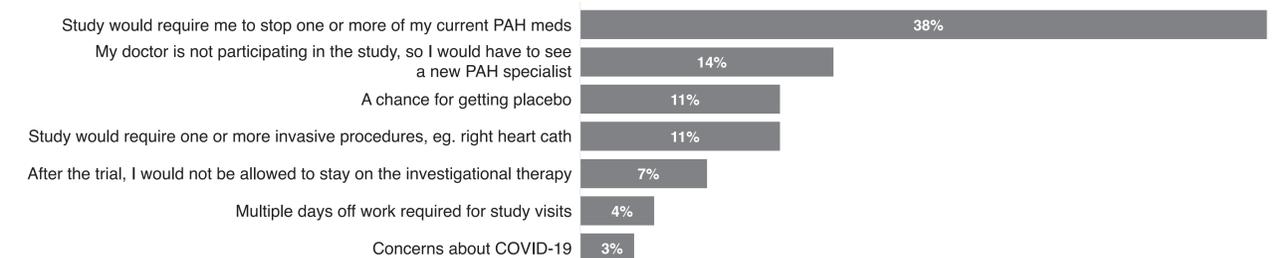


Figure 3. Top patient-reported factors discouraging clinical trial participation (Q: Which of the following would discourage you the most to participate in a clinical trial?)



LIMITATIONS

- Data regarding healthcare provider practice setting (academic vs community) was not available at the time of this survey
- Because only patient perspectives were captured, health care provider reasons for not offering study information is unknown

CONCLUSIONS

- To our knowledge, this is the largest survey of patients living with PAH who have never participated in a clinical trial
- Although living with PAH are interested in clinical trials, in this survey, three quarters of participants were not approached about clinical trial enrollment
- Most encouraging factors provided by respondents included doctor recommendation, ability to continue current PAH therapies, study drug targets a new pathway, and current health care provider is an investigator, allowing continuity of care
- Most discouraging factors included need to discontinue current PAH therapies, need to receive care from a new PAH specialist, possibility of placebo assignment, and requirement for invasive procedures
- Further education is needed for both patients and clinicians to encourage participation in clinical trials

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