Early Learnings from Semi-Structured Patient Interviews in the ASPIRE trial

Ceri Banks[1], Gry Willum Hagelund[1], Christophe Giot[1], Louisa Channouf Jacobsen[2], Sofie Gro Sondergaard[2], Tine Panduro[3]
[1]Vicore Pharma AB, Stockholm (Sweden), [2]Quotes Health, Copenhagen (Denmark), [3]Oxford Respiratory Trials Unit, (UK)

Background

Clinical trials in IPF are associated with substantial patient burden and a high risk of discontinuation. While patient input on the operational features of clinical trials is frequently collected through post-hoc satisfaction surveys, it is less commonly embedded as a systematic process.

Buloxibutid is an orally administered investigational product with anti fibrotic, vasodilatory, and anti inflammatory properties. In the Phase 2a AIR trial, stabilization of forced vital capacity (FVC) and improvements in lung function were observed in patients with IPF. Buloxibutid is currently being evaluated in the Phase 2b ASPIRE trial, a randomized, global, 52-week study.

Objectives and Methods

Patients' insights were gathered through semi-structured telephone interviews, conducted approximately two months after randomization (n=12). The objective of these interviews was to explore patient motivations, perceived value of participation, and challenges. Interviews were conducted independently of trial operations, transcribed, pseudonymized, and analysed.

Results

Qualitative analysis identified key challenges included uncertainty related to blinded treatment allocation and the impact of dosing schedules. For 92% of patients, the main reason for participation was to potentially benefit from treatment.

The primary motivation to continue their participation in the ASPIRE trial was the potential benefit from the treatment in 83% of patients selected. Other motivations were trust in site staff, and access to specialist care.

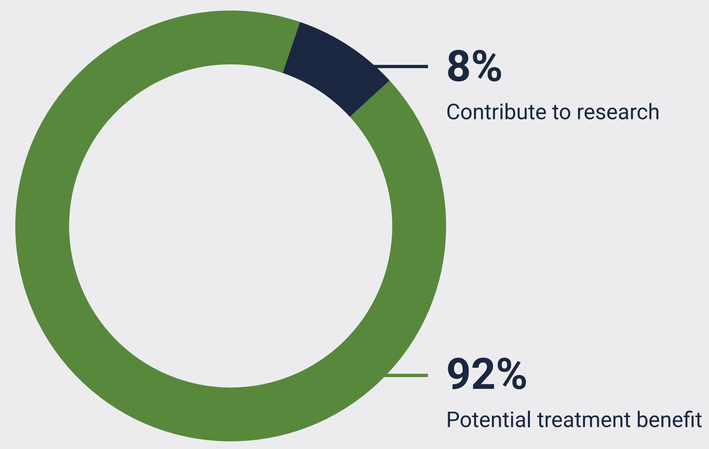
Participants were asked what aspects of the trial made it patient friendly. 75% of participants cited a positive experience with staff.

All the patients agreed that they were well informed about the study goals and trial procedures with the average score being 4.8 in a scale of 5 (5 being the best experience).

The overall experience was also rated and showed 4.6 in a scale of 5 (5 being the best experience) across all 12 interviewees.

ASPIRE Patient Interview Results – Summary Infographic

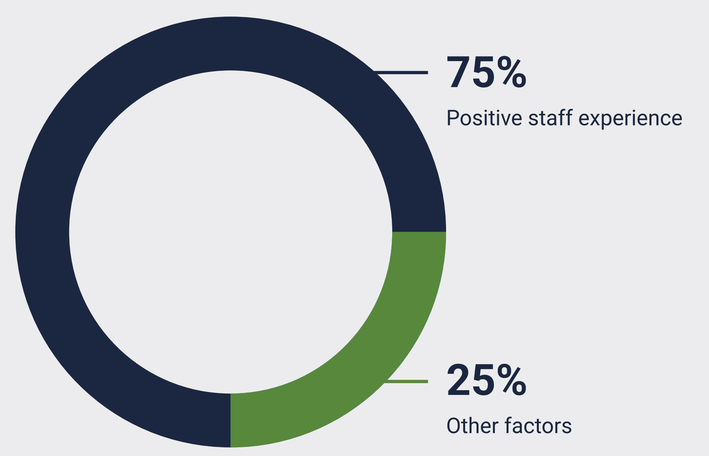
Reasons for participating



"it may help somebody else in the future"

- Trial participant

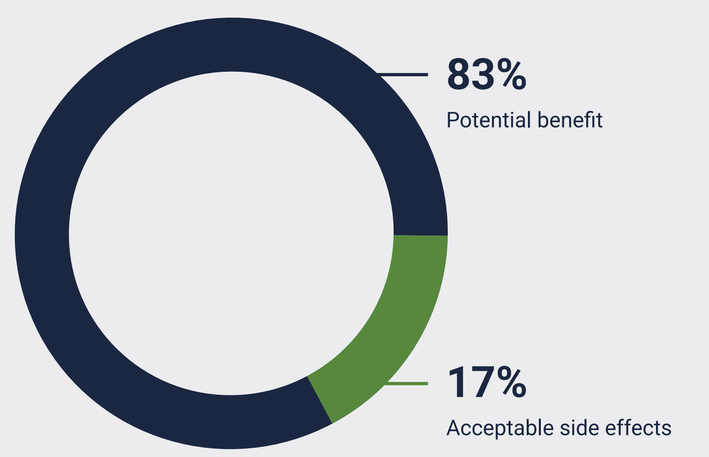
Patient-Friendly Aspects



"Everything was done smoothly and seemed well coordinated"

- Trial participant

Motivation to Continue



"If I can improve the quality of my lung function, that will give me the type of life I want."

- Trial participant

Conclusion

- Patients reported a high level of understanding of the trial and overall satisfaction with trial participation.
- Embedding a patient-centric approach to trial conduct through semi-structured patient interviews in the Phase 2b ASPIRE trial enabled identification of patient relevant challenges without compromising trial integrity. These insights may help inform the design and conduct of future IPF clinical trials.

ASPIRE

The research was fully sponsored by Vicore Pharma AB, Kornhamnstorg 53, SE-111 27 Stockholm, Sweden. vicorepharma.com.

vicore pharma