

# ASPIRE – Involving patients and caregivers when designing a trial to evaluate the efficacy and safety of buloxibutid (C21) in individuals with idiopathic pulmonary fibrosis



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## Introduction & objectives

Over two thirds of clinical trials fail to recruit enough patients or suffer high dropout rates.<sup>1</sup> Participation in clinical trials can place strain on patients, and extensive trial-related activities cause patient discontinuation.

Recent findings of clinical trial simulations in patients with ILDs, including patients with idiopathic pulmonary fibrosis (IPF), identified several barriers to participation in clinical trials:<sup>2</sup>

- Visit frequency
- Visit length
- Visit flexibility
- Restriction in current medication
- Side effect of trial drug and background antifibrotics
- Assessment frequency and complexity
- Site accessibility

Vicore is now planning for the next stage of clinical development, the global phase 2b ASPIRE trial to confirm the reparatory potential of buloxibutid – an investigational drug in IPF. The trial has been designed with several central elements aspiring to create a patient and site-friendly experience, while ensuring high quality standards are maintained.

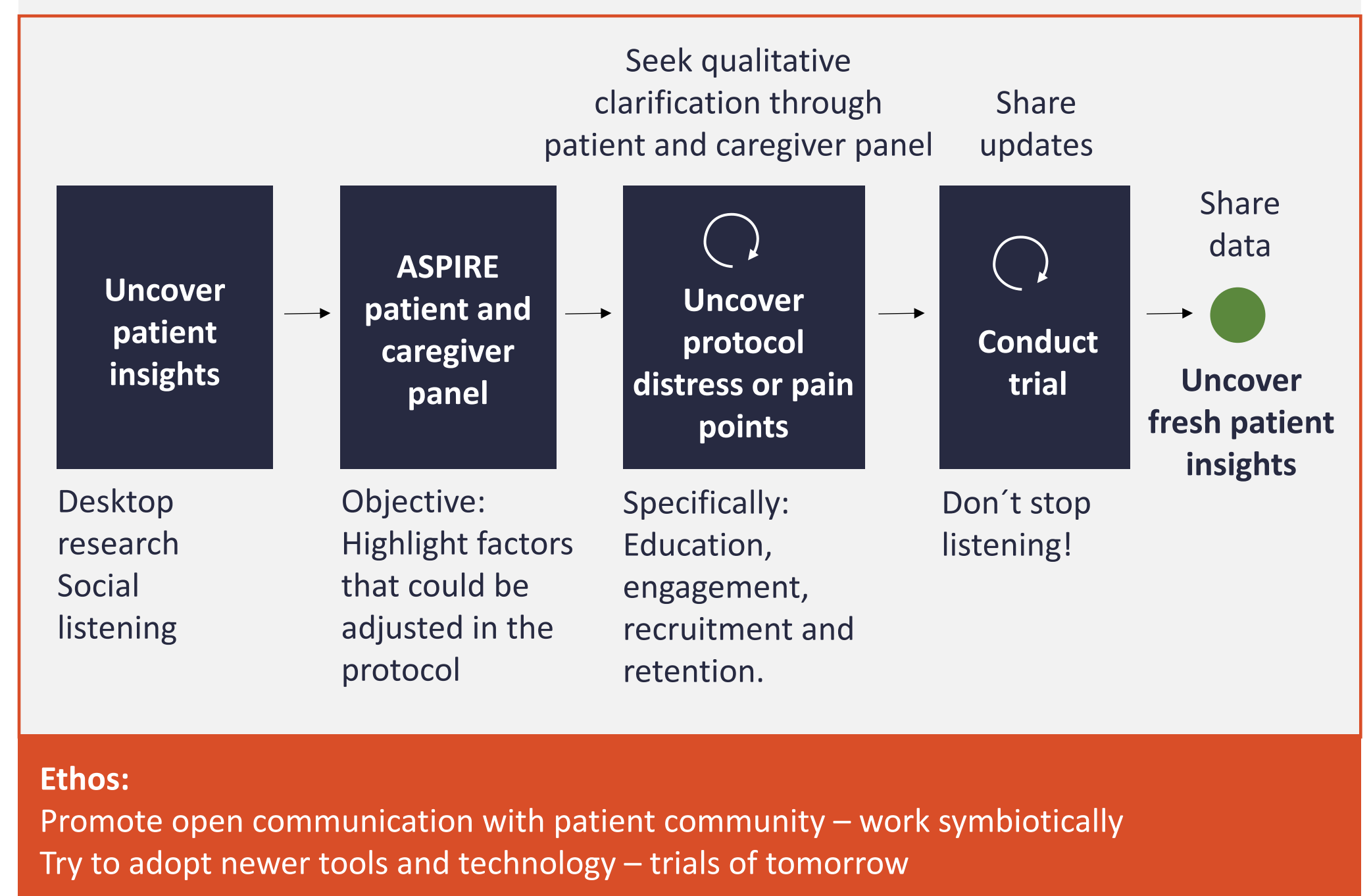
## Methods

Patient involvement was initiated early with representation in a trial advisory committee. Continuous patient and caregiver involvement is secured by the establishment of a patient and caregiver panel. Qualitative input is sought to ensure the selected trial outcomes are relevant to patients, and that trial participation is attractive and convenient.

## Results

In the ASPIRE trial, patients will continue standard-of-care treatment and a 2:1 allocation to buloxibutid versus placebo increases the chance of receiving active treatment. Trial visits are partly decentralised, i.e., several visits are conducted as phone or video call from patients' home and on-site visit frequency kept to a minimum, to reduce travel burden. Patient and caregiver input will continue through the panel during trial execution, including feedback on recruitment, potential amendments, and trial procedures. Patient-involvement activity will be documented and published to enable sharing of experiences and learnings.

### Aspiring to create a patient friendly trial, and then delivering on the promise.



## Conclusions

IPF patients need timely access to new, improved treatments which require scientifically rigorous trials that are holistic and patient centric. The ASPIRE trial aims to achieve these objectives through integration of patient and caregiver support strategies and patient empowerment.



<sup>1</sup> Desai M. Recruitment and retention of participants in clinical studies: Critical issues and challenges. *Perspect Clin Res.* 2020 Apr-Jun;11(2):51-53.  
<sup>2</sup> Jones S, et al. Clinical trial simulations in pulmonary fibrosis: patient-focused insights and adaptations. *ERJ Open Res.* 2023 May 30;9(3):00602-2022.

