

# ASPIRE – a patient friendly trial evaluating whether C21 improves lung function in IPF

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## 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. Vicore understands that to meet patients' needs, increasing patient involvement in all stages of the research process is required, as achieved with COMPANION<sup>2</sup>, their digital therapy clinical study. 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, which led to the recommendation of patient-friendly changes.<sup>3</sup>

### Examples of patient and caregiver barriers to trial participation:

- Visit frequency
- Visit length
- Visit flexibility
- Remote visit option
- Restriction in current medication
- Side effect of trial drug and use of background antifibrotics
- Assessment frequency & complexity
- Site accessibility
- Visit guide and reminders



Vicore Pharma is now planning for the next stage of clinical development, a global phase 2b clinical study. The ASPIRE trial aspires to confirm the clinical evidence for C21 in IPF. The trial has been designed with several central elements aimed at creating a patient and site-friendly experience, while ensuring high quality standards are maintained.

 A randomized, double-blind, placebo-controlled, parallel-group, multicentre trial of 2 doses of C21

 52 weeks treatment duration

 People with IPF on standard of care (SoC) or not on SoC

 Primary endpoint – change from baseline in FVC

## Methods:

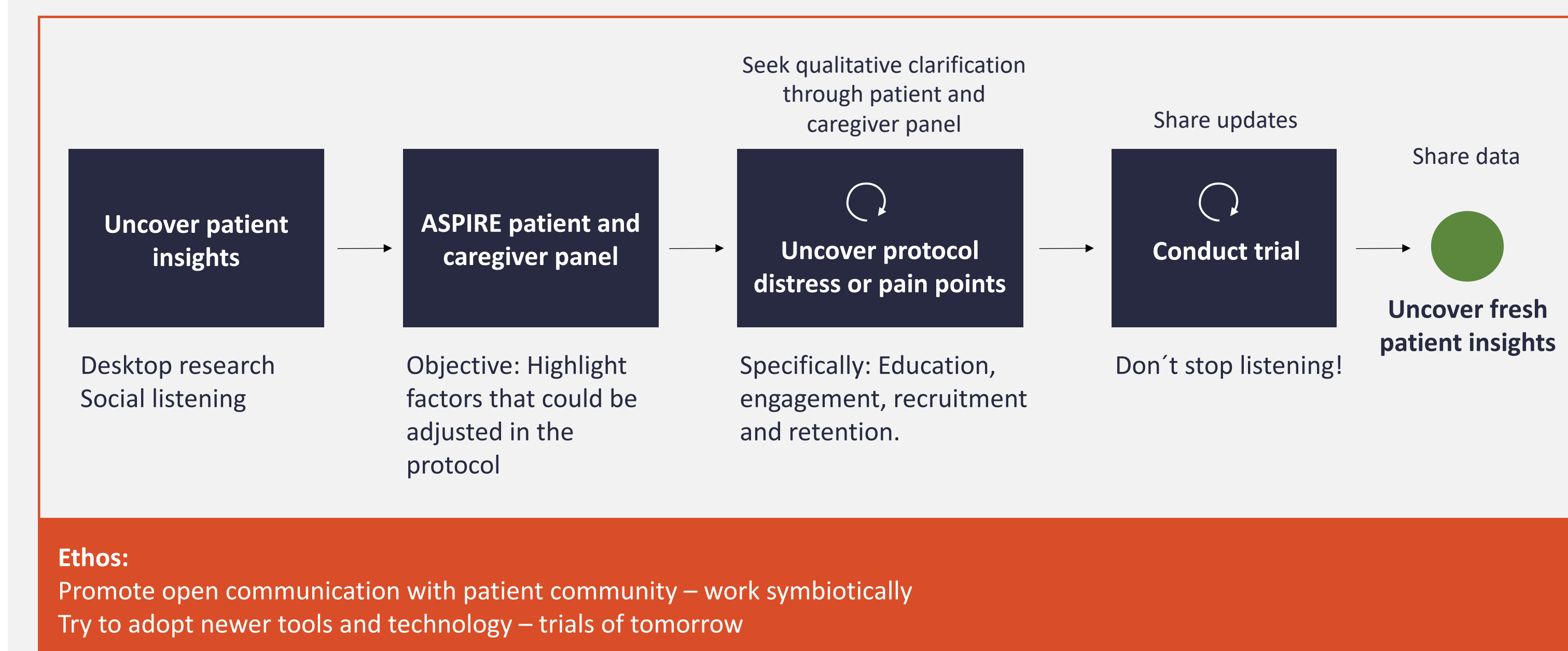
Vicore is collaborating with patients and caregivers to design and execute the IPF ASPIRE trial: a 52-week, randomized, double-blind, placebo-controlled, parallel group, multicentre Ph2b trial investigating the reparatory potential of C21, a novel candidate drug targeting the underlying fibrosis by stimulating the protective arm of the renin-angiotensin system. Patient and caregiver involvement was initiated early with representation in a trial advisory committee. Continued patient and caregiver involvement is secured by the establishment of an advisory panel. Input is sought to ensure the selected trial outcomes are relevant to patients, and that trial participation is attractive and convenient.

## Trial design:

In the ASPIRE trial, patients will continue standard-of-care treatment and a 2:1 allocation to C21 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, reducing travel burden. Patient and caregiver input will continue during trial execution, including feedback on recruitment, potential amendments, and trial procedures. Patient-involvement activity will be documented to enable sharing of experiences and learnings.

## Results:

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



## Conclusions:

IPF patients need timely access to new, improved treatments which requires 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.



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<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. doi: 10.4103/picr.PICR\_6\_20. Epub 2020 May 6. PMID: 32670827; PMCID: PMC7342339.

<sup>2</sup> [https://vicorepharma.com/mfn\\_news/vicore-launches-companion-a-clinical-study-investigating-the-benefit-of-digital-therapy-on-anxiety-in-patients-with-idiopathic-pulmonary-fibrosis-ipf/](https://vicorepharma.com/mfn_news/vicore-launches-companion-a-clinical-study-investigating-the-benefit-of-digital-therapy-on-anxiety-in-patients-with-idiopathic-pulmonary-fibrosis-ipf/)

<sup>3</sup> Jones S, Flewett M, Flewett R, et al. Clinical trial simulations in pulmonary fibrosis: patient-focused insights and adaptations. *ERJ Open Res* 2023; in press (<https://doi.org/10.1183/23120541.00602-2022>).