Post-trial survey of participants of a Phase 3 clinical trial in SSc-ILD

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BACKGROUND

- SENSCIS® (2015–18) was a large Phase 3 trial with 576 participants that investigated the efficacy and safety of nintedanib versus placebo in patients with SSc-ILD.[1]
- The SENSCIS® clinical research sponsor (CRS) collaborated with a scleroderma patient community advisory board (CAB) regarding the design, implementation and conduct of the trial.[2]
- The CRS and CAB developed a post-trial survey for SENSCIS® participants.

AIM

- To gain experience in collecting real-world information and trial satisfaction data from patients to inform and improve future patient-centric clinical research.

METHODS

- SENSCIS® trial participants who were involved in the extension trial SENSCIS®-ON were asked to complete a post-trial survey covering nine multiple-choice questions about three main topics.
- A total of 125 participants contributed to the survey.
- Participants could select more than one option per question.

The SENSCIS® post-trial survey was an innovative approach to obtaining real-world feedback on improving future trial design and patient participation using multiple channels.

CONCLUSIONS

- The results highlight the importance of reaching patients who may not be actively looking for clinical trials and using multiple communication channels.
- These first learnings will help develop patient-centric approaches and improve communication with patients in future trials.

RESULTS

1. Recruitment

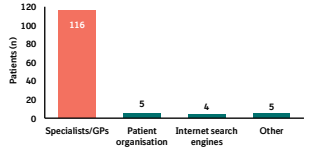
62% (n=78) of patients would pay attention to printed materials and contact a study site.

The most common sources of information about recruiting SSc trials were:

- Specialists/GPs (n=46)
- Internet search engines (n=20)
- Patient organisations (n=12)

51 patients reported not actively looking for trials.

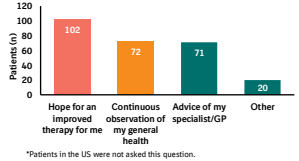
'How did you become aware of the SENSCIS® study?'



2. Motivation and retention

Most frequently selected responses	Patients, n
'Why did you participate in the SENSCIS® study?'	
Hope for an improved therapy	98
Specialist/GP recommendation	81
Hope for an improved therapy for other patients	64
'What did you particularly like?'	
Opportunity to receive an improved therapy	92
Opportunity to support development of an improved therapy	90

'Why did you stay in this study?'*



*Patients in the US were not asked this question.

Patients were motivated to contribute to research and help others living with SSc.

3. Challenges and wishes

'What did you like the least?'

115 patients would consider taking part in another study by the CRS in the future.

Most frequently selected responses	Patients, n
'What can the CRS offer to improve future trials?'	
More patient-friendly information	50
Opportunities to communicate with other trial participants	48
Availability of information material in multiple formats	46

These data suggest that operational support and patient education during a trial may improve the travel burden of patients and their concerns about potential side effects.

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2. Roennow A, et al. BMJ Open 2020; 10:e039473.

Abbreviations

CAB, community advisory board; CRS, clinical research sponsor; GP, general practitioner; SSc-ILD, systemic sclerosis-associated interstitial lung disease; US, United States.

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