

Community advisory board input can make lay summaries of clinical trial results more understandable

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WHY DO WE NEED LAY SUMMARIES?



A trial summary for laypersons must be written for every clinical trial carried out in the EU¹



The trial sponsor is responsible for writing the lay summary



It must be published within 1 year of study completion



Saved on the EU Clinical Trial Information System, a publicly available database



Lay summaries share and explain clinical trial results in an easy-to-understand way for trial participants, patient and caregiver communities, and the general public



Trial sponsors are encouraged to collaborate with patient organisations, seeking their advice and input to make lay summaries easier to understand and recognising the essential role of patients in clinical research¹⁻⁴

DURING DEVELOPMENT OF THE SENSCLIS[®] TRIAL LAY SUMMARY, ADVICE FROM PATIENT ORGANISATIONS WAS GATHERED THROUGH A COMMUNITY ADVISORY BOARD

The community advisory board was formed based on the EURORDIS charter for collaboration in clinical research,⁴ formalised in a co-created memorandum of understanding mutually ratified by patient organisations and the trial sponsor



Over a 7-month period...



...representatives from 11 scleroderma patient organisations covering a range of countries and regions...



...participated in 3 structured meetings to review and advise on lay summary materials being developed

An iterative process was used to gather and collate community advisory board advice to help the trial sponsor prepare effective and meaningful lay summaries that are more understandable and more relevant for patients and the general public



Community advisory board
Provide overall advice on lay summaries



Trial sponsor LSG
Prepare drafts of:
• written lay summary
• lay summary video script



Trial sponsor medical + legal teams
Review and advise

Trial sponsor LSG assess all advice and revise materials
Iterative feedback process conducted over a series of 3 structured meetings



Upload to trial-sponsored website & publicly accessible trial database



Trial sponsor medical, legal and LSG teams
Final approval and sign-off



Community advisory board
Review and advise through moderated meetings

COMMUNITY ADVISORY BOARD ADVICE SUPPORTED DEVELOPMENT OF PATIENT-FOCUSED LAY SUMMARIES



Use neutral colour schemes and icons more representative of scleroderma patients

Changes were made to colour schemes, iconography and layout so lay summaries flowed better, were easier to follow and resonated with audiences

Make lay summaries available in patients' native language(s)



Written and video lay summaries are being translated into all participating country languages

Community advisory board input identified ways to make lay summary materials easier to understand and more relevant

First explain what lay summaries are

A stand-alone video called "What are lay summaries?" was created



Videos are an increasingly important source of information for people with specific health needs

The trial-specific written lay summary was accompanied by a video format lay summary

Some of the language is hard to understand, particularly for people with lower literacy levels

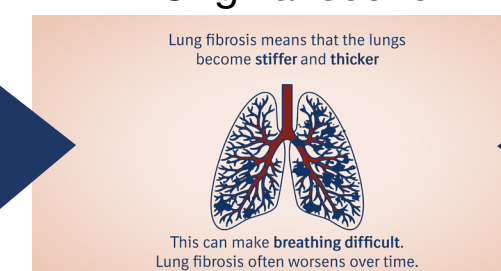
Language was simplified to an appropriate level for a lay audience



Revisions were made to improve clarity of lay summary materials in response to community advisory board advice

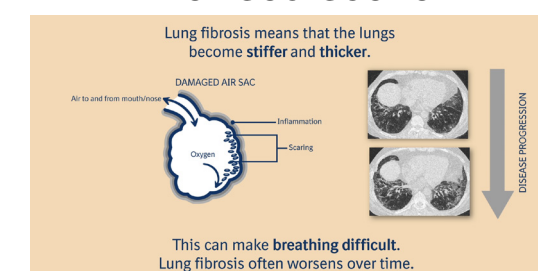
Original scene

Include medical images to show what worsening lung fibrosis really looks like



Illustrate what happens to the lungs when fibrosis occurs so it is easier to understand

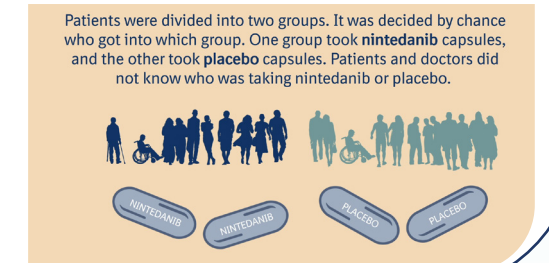
Revised scene



The red colour suggests danger and makes you feel anxious; use a neutral colour



It looks like the pills are bearing down on the people, like the medicine is more important



CONCLUSION: Structured collection and implementation of community advisory board advice can make lay summary materials more understandable for the patient community, their caregivers and the wider general public



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Abbreviations

EU, European Union; EURORDIS, Rare Diseases Europe; LSG, lay summary group.

Conflicts of interest

JW Speakers bureau: Four times as a patient advocate for employees of BI Int'l and BI MIDl; **MS** Educational grants: BI and Janssen; **AGo** Consultant: Payment made to the patient organisation (Scleroderma Research Foundation) for participation in advisory boards; **AK** Grant/research support: AS FESCA aisbl.; **AZ** Grant/research support: Lorem Vasculer, BI China, Jianke Pharmaceutical Co., Ltd., Kangjng Biological Co., Ltd., COFCO Coca-Cola. Consultant: BI. Speakers bureau: BI China; **AGI** Consultant: BI Int'l; **LM, TS, HF** Paid employees of BI Int'l; **KS-S** Paid employee of BI Pharma; **AR, EB, IG, APPG, CL, RJR** and **MPP**: None declared.

Disclosures

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