# Help us find out what outcomes for pulmonary sarcoidosis are the most important.

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## Who is this study for?

**Patients** - who have experience of living with pulmonary sarcoidosis.

**Health professionals** - who have experience of treating pulmonary sarcoidosis.

**Researchers** - who will use the core outcomes in their research).

**Industry representatives.**

## We invite you to take part in an online research study.

- We would like to invite you to take part in the FSR SCOUT study.
- Before you take part it is important for you to understand why the study is being done and what taking part will involve.
- Please read this information sheet carefully.
- Please get in touch if something is unclear or if you would like more information.

## Contents


1. What is an outcome?
2. Why are we doing this study?
3. What does taking part involve?
4. What happens at the end of the study?
5. Will I get paid for taking part?
6. Other information.
7. Contact information.
8. Link to the online survey.


This survey focuses on pulmonary sarcoidosis. Future surveys, for other types of sarcoidosis, will be conducted by the Foundation for Sarcoidosis Research.

FSR-SCOUT

Sarcoidosis Clinical Outcomes Taskforce

UNIVERSITY OF LIVERPOOL

## Contact us

If you have any questions and would like more information about the FSR-SCOUT study please contact Nicola Harman: **scout@liv.ac.uk**

## What is an outcome?

When new treatments are developed and tested, researchers look at the effect those new treatments have on patients by measuring an "outcome".

For example, in a study testing a treatment about the common cold, an 'outcome' might include 'being able to breathe through your nose more easily.'

**An outcome is something that is measured to help decide if a treatment is working or not.**

## Why are we doing this study?

At the moment, different research studies, of treatments for pulmonary sarcoidosis (sarcoidosis that involves the lungs), often measure different outcomes. This makes it difficult to find out which treatments might be best for patients as the results of different studies cannot be compared or combined.

The FSR-SCOUT study needs your help to find out what outcomes are so important that they should always be measured in studies for pulmonary sarcoidosis. We call these the **core outcomes.**

If all future studies for pulmonary sarcoidosis measure these core outcomes, and measure them in similar ways, the results of the studies can be easily compared and combined. This may help new, effective treatments become available to patients more quickly.

## Does it matter how an outcome is measured?

It is important to remember that in this study we are interested in "what" outcomes should be measured. That means deciding which outcomes are the most meaningful to you when deciding if a treatment for pulmonary sarcoidosis is working or not.

There might be different ways to measure these outcomes or a new tool might need to be developed. Deciding how each outcome should be measured is important and will be decided in the next stage of the study.

## What does taking part involve?

The study will be run online and involves taking part in two surveys.

You can find out more about each survey and future steps on the next pages.

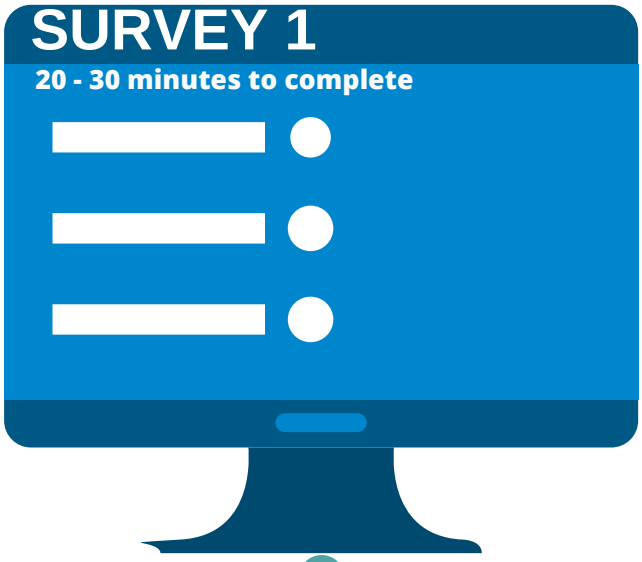
## More information on outcomes

You can watch a short [3 minute] video explaining what core outcomes are, why they are important and how patients and health professionals are involved in developing them here: **https://youtu.be/AlLc2yN0pII**

## Survey 1 15-20 minutes to complete

In the first survey, you will be shown a list of outcomes. For each outcome we want you to rate how important you personally think it is to measure that outcome in all future research of treatments for pulmonary sarcoidosis.

At the end of the survey, you can also suggest other important outcomes that you think are missing from the list.




Survey 1 will be open for around 6 weeks from the <date>. If you register to take part but haven't completed the survey, we will send you a reminder email around two weeks after the survey opens and another a few days before the survey closes.

Week 2 reminder email if not already completed

Once the deadline for completing the survey has passed, we will analyse everyone's responses. This usually takes around 2 weeks. We will then email you an invitation and instructions on how to take part in the second survey.

Reminder email if survey not already completed

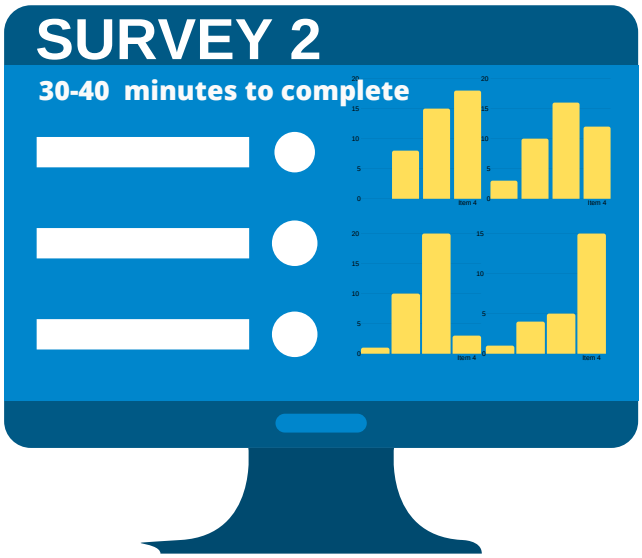
## Survey 2 20-30 minutes to complete

In the second survey, you will see the same list of outcomes from survey 1 with a reminder of your own rating in round one. But this time, you will also see a chart that shows you how the groups of people who took part in the first survey rated that outcome.

Now, when you rate the outcome, we'd like you to think about how you and the other groups of people taking part in the first survey rated each outcome.

This is a chance for you to consider the opinions of others and to reflect on your own previous ratings.

We are trying to find out which outcomes patients, health professionals, researchers and industry representatives can agree must always be measured.




**Your opinion in both survey 1 and 2 is extremely important in developing the core outcome set. It is very important that you complete both surveys.**

# What happens after the surveys have been completed?

## Face to face meeting

After the second survey has ended, we will combine the information from the two surveys and analyse the results. Once we have done this, we will invite a group of patients, healthcare professionals, researchers and industry representatives to a face to face meeting to discuss the results and agree the final core outcomes.

Unfortunately not everyone who completes the survey will be able to attend the face to face meeting. However, it you would like to be considered for a place you can tell us at the end of the second survey. Further information about what the face to face meeting involves will be sent to those interested in taking part.

## Sharing the results of the study

The results will be analysed and published in a medical journal at the end of the study. We will also share a summary with relevant patient and professional organisations.

You will not be identified in the publication unless you have told us at the end of the second survey that you would like to be acknowledged for your contribution. If this is the case, your name will be included in a specific acknowledgements section of the publication. We will not present your individual thoughts on outcomes in the publication; rather all results will be presented according to the different groups that took part (i.e. patients, healthcare professionals and researchers).

When you register to take part, you will be able to tell us if you would like to be sent the results of the study. These will be sent by email when the results have been published. This can sometimes be several months after you have taken part.

## Next steps

After this stage of project, to decide the core outcomes, has been completed a second stage will decide how best to measure each of the core outcomes recommended for use in research studies. Taking part in the online surveys now does not mean that you have to take part in future project stages. However, when you register to take part you can tell us if you would like to be kept up to date, by email, with opportunities to take part in the future.

Online survey 1 and 2 to decide what outcomes are the most important to measure in future research.

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Face to face consensus meeting to review the results of the surveys and agree the core outcomes.

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Publication of the agreed core outcomes in a medical journal and summary sent to study participants.

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Second phase of the project - deciding how each of the core outcomes should be measured.

# Other important information

## Are there any risks in taking part?

We do not expect there to be any major risks, although occasionally some patients can find it upsetting thinking about outcomes related to their condition. If you do feel uncomfortable completing any part of the questionnaire or during the consensus meeting you can stop taking part at any time and, if you would like to, provide feedback on any areas of concern.

## Will I get paid for taking part?

There is no payment for taking part in the online survey. If you are invited to take part in the face to face meeting at the end of the study, we will cover your travel expenses to attend.

## What if there is a problem?

If you are unhappy, or if there is a problem, please let us know by contacting the study coordinator, Nicola Harman (scout@liv.ac.uk) and we will try to help.

If you remain unhappy or have a complaint that you feel you cannot come to us with then you should contact the University of Liverpool Research Ethics and Integrity Office at ethics@liv.ac.uk.

When contacting the Research Ethics and Integrity Office, please provide details of the name of the study (FSR-SCOUT, Sarcoidosis clinical outcomes task force), the ID number (5211 ) and the details of the complaint you wish to make.

## Will my participation be kept confidential?

Yes. Your responses to the survey and contributions at the face to face consensus meeting will be labelled with a number rather than your name, to maintain confidentiality, and will only be looked at by members of the study team. Your email will only be used to contact you about this study.

Your responses to the surveys will be stored on a secure server at the University of Liverpool for ten years after the study ends.

## Ready to take part?

If you are ready to take part please visit the link below to register and complete survey 1.

**https://delphimanager.liv.ac.uk/SCOUT/**

If you have any questions, would like more information about the FSR- SCOUT study or have a question about how to complete the Delphi survey please contact

**Nicola Harman**

**scout@liv.ac.uk**

You can expect to recieve a reply within one working day.