



Clinical Trials: What patients need to know

A guide for patients, care givers
and health professionals



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<https://www.sjogreneurope.org/>



Why This Leaflet?

Clinical trials are essential in developing better treatments for conditions like Sjögren Disease.



Many patients and caregivers feel uncertain about what clinical trials really involve.

This leaflet aims to explain, in clear and simple terms, what clinical trials are, why they matter, and what you should know before taking part.

Sjögren Europe created this guide to empower patients to make informed choices and to encourage meaningful conversations with healthcare professionals.

What are Clinical Trials?

Every medication or treatment we use today — whether for Sjögren Disease or another condition — has gone through clinical trials to prove it is safe and effective.

Clinical trials are structured studies that help researchers find better ways to prevent, diagnose, or treat diseases. They play a key role in making new treatments available to the public — from over-the-counter medicines to advanced therapies.

They are not experiments on people. They are carefully designed and monitored by medical professionals, ethics committees, and regulatory authorities to protect participants and ensure quality results.

Some trials focus on testing new drugs, while others explore lifestyle changes, new diagnostic methods, or tools that support better care.

Clinical trials give you a chance to contribute to research and be part of progress — while remaining safe, respected, and informed.

Phases of Clinical Trials:

I. Is it Safe?

This is the first time a new drug or treatment is tested in humans. A small group of healthy volunteers or patients receives the treatment to evaluate safety, dosage range, and possible side effects.

II. Does it Work?

The treatment is given to a larger group of patients who have the condition. This phase looks at whether the treatment works and continues to monitor safety

III. Is it Better Than What We Have?

Hundreds or even thousands of patients are involved. The new treatment is compared to standard or placebo treatments. Results from this phase help determine whether the drug will be approved.

Each phase builds on the previous one and is designed to protect participants while gathering critical information.

IV. How Does It Perform Long-Term?

After approval, the treatment is monitored in real-world use to gather information about long-term effectiveness, side effects, and rare complications.



Why Join a Clinical Trial?

Joining a clinical trial is a personal decision. For some, it's a way to access new treatments. For others, it's a chance to contribute to science and help future patients.

01

Possible Benefits:

1. Access to promising new treatments not yet widely available
2. Close medical supervision and regular check-ups
3. Helping improve care for others with the same condition

02

Possible Risks or Challenges:

1. Unknown side effects or results
2. The new treatment may not work better than standard care
3. Time, travel, and commitment may be required

What's most important is that you feel comfortable, informed, and supported throughout the process.



Your Rights and Protections as a Participant

Taking part in a clinical trial is always voluntary. You have the right to make your own decision — and to change your mind at any time, without penalty.

01

Before enrolling, you will receive clear and detailed information about:

1. The purpose of the study
2. What is expected from you
3. Any possible risks or side effects
4. How your data will be protected

02

Your rights include:

1. Saying yes or no without pressure
2. Withdrawing at any point — even after the trial starts
3. Receiving respectful and transparent communication
4. Having your health and safety closely monitored

You are not just a participant — you are a valued partner in research.

How to Join & What to Expect



Informed Consent:

Before taking part, you'll receive an "informed consent form."

This document explains:

- The purpose of the trial
- What will happen if you join
- Any risks and possible side effects
- Your rights as a participant


If you're interested in joining a clinical trial, talk to your doctor or rheumatologist. They can help you find out if there's a trial that matches your condition and health status. You can also explore online platforms like the [EU Clinical Trials Register](#) or [EUPATI](#).

Taking part is always voluntary.

You should feel confident and supported in your decision.

Key Questions to Ask:

1. What is the goal of the trial?
2. What are the possible benefits and risks?
3. Will it affect my current treatment?
4. How often will I need to visit the clinic?
5. Can I leave the trial at any time?
6. What happens if I leave the trial?



Clinical trials are a vital part of advancing medicine — and patients play a key role in this progress.

Whether you're considering joining a trial or just want to learn more, there are trusted sources where you can find clear and reliable information

Learn More:

Sjögren Europe

www.sjogreneurope.org

EU Clinical Trials Register

www.clinicaltrialsregister.eu

EUPATI

www.eupati.eu

This leaflet was developed by Sjögren Europe, as part of our commitment to:

- Promote patient education
- Encourage informed decisions
- Support meaningful participation in clinical research