

What is an informed consent form (ICF)?

The Informed Consent Form (ICF) describes the study and how data collected may be shared for study purposes. By signing an ICF, you are agreeing to participate in the study. Please read the form carefully and, if there is something you do not understand, ask the study doctor or a study team member.

For patients younger than the legal age to consent:

As the caregiver, if your child, at the time of enrollment into the study is younger than the legal age for consent in your state, you can provide assent on behalf of your child.

When your child reaches the legal age for consent in your state, they will be invited to read again the purpose of the study and have a chance to provide their own personal consent.

Questions?

To speak to a study representative, contact the SPARKLER Study toll-free at:

866-974-3979.

Hours of Operation:

M – F 9:00am – 5:00pm, ET

For more information visit

www.FILSPARI-registry.com

or scan the below QR code:



An Observational Study for Patients Treated with FILSPARI

Information for Patient and Families

What is the SPARKLER Study?

This is an observational research study for adults and pediatric patients aged 8 years and older who have been identified as receiving treatment with FILSPARI® (sparsentan). FILSPARI has been approved by the U.S. Food and Drug Administration (FDA) to slow the decline of kidney function in adult patients with primary immuno-globulin A nephropathy (IgAN) who are at risk of disease progression and to reduce proteinuria in adults and pediatric patients aged 8 years and older with focal segmental glomerulosclerosis (FSGS) without nephrotic syndrome.

The SPARKLER Study is sponsored by Traverre Therapeutics, Inc which is responsible for the initiation and financing of the study. Traverre Therapeutics has contracted United BioSource, LLC (UBC) to manage the day-to-day activities of the study.

The purpose of this study is to collect information on any potential liver-related problems that you may experience while taking FILSPARI.

The information that is collected from this observational study will assist in assessing whether FILSPARI may cause Drug-Induced Liver Injury (DILI). It is not known whether FILSPARI causes DILI, which is why it's important to collect the data in this observational study to help us understand more about whether patients are more likely to experience these liver events.

An observational research study means participants will continue to receive care as decided by their healthcare providers. Participation in this study will not change your treatment or medical care in any way.

Who can participate in the study?

To participate in this study, participants must:

- Be 8 years or older
- Plan to begin FILSPARI treatment or have started FILSPARI treatment within the past 12 months
- Be willing and able to sign an Informed Consent Form (ICF) or have parent/legal guardian consent

What will participation involve?

Participation will last for approximately 2 years. Your doctor will continue to make treatment decisions for you and conduct standard of care visits. There will be no additional visits or procedures beyond those scheduled as part of routine care.

Your doctor will receive a brief phone call every 3 months during the study to check for any changes in your health.

Why participate in this study?

Participants may help others by increasing the understanding of the potential for drug induced liver injury in patients treated with FILSPARI. Participation may benefit patients in the future by providing new safety and medical information.

Your participation in the study is strictly voluntary. You may withdraw from the study at any time.

Will my privacy be protected?

The doctor and their staff will respect the privacy of all participants who take part. All personal medical information will be kept strictly confidential. Further information about privacy, is provided in the Informed Consent Form.