Patient Education Sheet

Clinical Trials – Getting Involved

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Clinical trials provide means for evaluating a new or existing treatment in patients to see if the treatment, usually a drug, is safe and effective and at what dose. Clinical trials are necessary before a therapy can be approved and offered on the market. Before enrolling in a clinical trial, always discuss participation with your doctor.

Why Consider Participating in a Clinical Trial?

Patients participating in a trial will:

- Help ensure a new treatment is developed to control symptoms or overall outcome of their disease.
- Gain access to a promising treatment that may provide unique benefit or meet unmet need.
- Get access to care at no cost.
- Help other patients.
- Participate in helping to advance science/medicine.

Am I Eligible to Participate in a Clinical Trial?

- Clinical studies are performed according to a plan design called a protocol which is unique to each project.
- Protocols define eligibility criteria of participants who can be enrolled. These criteria relate to such factors as age, gender, duration of illness, prior treatments, and other medications you might be taking, etc.
- Eligibility criteria fall into two categories:
    - Inclusion criteria which define the population of patients to be studied
    - Exclusion criteria which disqualify certain volunteers from participating due to age, other medical problems or other factors

Is it Safe to be in a Clinical Trial?

- Before participating, you will be provided with a document called an informed consent outlining risks and benefits and the study design (features of the protocol such as length of the study and number of visits). After reviewing that document, you might have questions, all of which should be answered.
- You have the right to withdraw from a study at any time and for any reason as is explained in all informed consent documents and by the personnel conducting the trial.
- The clinical trials program is typically monitored by an independent institutional review board that approves the study design and sites where the study is conducted.
- Most trials of new medications performed at multiple sites across the country are monitored on an ongoing basis by a data safety monitoring board.
- The FDA has oversight for the clinical trials process and periodically conducts audits at sites where trials are performed.

Please see the Patient Education Sheet on “Understanding Clinical Trials” for more information on clinical trials. This sheet is available online on the Foundation website at www.sjogrens.org/understanding-sjogrens/brochures-and-resource-sheets. Additional information and a list of specific trials currently available for enrollment can be viewed by visiting http://www.sjogrens.org/living-with-sjogrens/clinical-trials.

For more information on Sjögren's, visit the Foundation website at www.sjogrens.org, call 301-530-4420, email info@sjogrens.org, or write to the Sjögren's Foundation, 10701 Parkridge Blvd, Ste 170, Reston, VA 20191

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