



What You Should Know about Clinical Research Studies

Clinical research studies aim to answer specific questions about how medicines work in the individuals who take them. You should feel fully informed about what to expect from your participation in a clinical research study.

Researchers use clinical research studies to:

- Answer specific health questions
- Learn about the effects and safety of investigational medications
- Help find new ways of using approved medications

Regulations and policies have been developed to help protect the rights, safety, and well-being of people who take part in clinical research studies and to help ensure that these studies are conducted according to strict scientific and ethical principles. Before a clinical research study can begin, an institutional review board (IRB) or ethics committee (EC) must review and approve the study.

Participation in any clinical research study is completely voluntary, and you may withdraw from a clinical research study at any time for any reason. Before participating in a clinical research study, it is important to weigh the potential risks and benefits of participation. The study team will inform you of the potential risks and benefits of study participation, as well as possible side effects. To make an informed decision, gather as much information as possible and talk to your healthcare providers about any questions you may have.

During the study, you will work with a study team that may include study doctors, study nurses, and other research staff. Travel and food reimbursement may be available – please speak with your study doctor to find out.

Thank you for considering the Flex Study.



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Has Dermatomyositis (DM) Left Its Mark on You?



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About the Flex Study

Adult dermatomyositis has a way of leaving its mark on you, whether it's the painful, itchy heliotrope skin rash or muscle weakness that causes daily discomfort. But what if there was a way to potentially alleviate the symptoms of this condition? The Flex Study is investigating a medication to reduce the effects of DM. It's time to leave your mark on DM.

The purpose of this study is to evaluate the effectiveness and safety of an investigational medication compared to standard of care on reducing symptoms in patients with DM. Those who are determined to be eligible to participate and who decide to enroll will be randomly assigned to receive



the investigational medication or the placebo. The placebo used in the Flex Study looks the same as the investigational medication, but it does not contain active ingredients. Neither the participants nor the study doctor will know who has been assigned to receive the investigational medication or placebo.

The total duration of the Flex Study is between 104 and 128 weeks, and it consists of three periods:

- A four-week screening period to determine study eligibility
- A randomized controlled treatment period, during which participants are enrolled in either Part A **or** Part B:
 - Part A lasts 26 weeks and includes five visits to the study site
 - Part B lasts 50 weeks and includes eight visits to the study site
- An open-label extension period that lasts 74 weeks and includes 11 visits to the study site
 - All participants receive the investigational medication in this period

Learn more and see if you may qualify.

DMFlexStudy.com



About the Investigational Medication

The investigational medication is called ravulizumab. "Investigational" means that it has not been approved by country-specific regulatory health authorities to be used for dermatomyositis and its use is being allowed for research purposes only. Participants will be assigned at random to receive either the investigational medication or the placebo. Neither the participant nor the study team will know which treatment option has been assigned, but in case of an emergency, they can quickly find out. Both the investigational medication and the placebo are administered as intravenous (IV) infusions.

Who Can Join?

We are looking for male and female adults 18 years of age and older with a clinical diagnosis of DM to take part in this clinical research study. Interested individuals must have had an inadequate response or be intolerant to two or more DM treatments. Individuals will be evaluated to determine their eligibility to participate. Individuals who are eligible and decide to take part will receive the investigational medication (or placebo), study-specific medical exams, and study-specific laboratory tests at no cost.

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