valor
study

For adults living with dermatomyositis

valor
study

priovant
therapeutics

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Priovant Therapeutics - The VALOR Study - Study Schedule and Planner - 16-Feb-2022 - English (Principal) - V2.0

SCHEDULE AND PLANNER

THANK YOU FOR JOINING THE

VALOR Study

Your participation in this study is greatly appreciated, and we want to ensure all of your questions about the study experience are answered. This booklet explains what will happen at study visits, as well as helpful information and reminders. It also has space for you to keep track of scheduled appointments. It's important that you attend all study visits in order for the study doctor to monitor your health and understand how the study drug may be affecting your body.

You may or may not directly benefit from being in this study, but the information learned may help other people with dermatomyositis in the future. As with all medicines, there is a chance for side effects, which are undesired and unintended effects from a medicine. Your health will be closely monitored throughout the entire study.

For details about risks, benefits, and side effects, please reference your patient information sheet (the document you reviewed prior to signing the Informed Consent Form).

The study team will happily answer any questions you may have at any time during the study. Remember, participation is voluntary, and if you change your mind and choose to leave, you can do so at any time.

With much appreciation,

THE VALOR STUDY TEAM

What is the purpose of the VALOR Study?

The purpose of this study is to understand whether the investigational medicine **brepocitinib** reduces the symptoms of dermatomyositis in adults 18 to 75 years old.

Investigational medicine Investigational medicine 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.

How long is study participation?

You will be in the study for up to **116 weeks (27 months)** and have in-person visits **every 4 to 12 weeks for tests and health checks**.

Screening Period	Blinded Treatment Period	Open-Label Extension Period*	Follow-Up Period
Up to 8 weeks	52 weeks	52 weeks	4 weeks
At least 1 visit	11 visits	7 visits	1 visit

* Once you complete the Blinded Treatment Period, you may have the option to continue in the Open-Label Extension Period to receive brepocitinib. Your study doctor will notify you if you are eligible to participate.

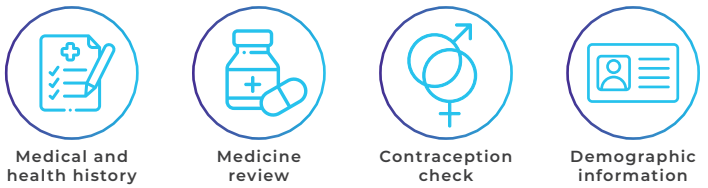
In addition to the visits listed above, your study doctor may ask you to come in for extra visit(s) if necessary to monitor your health.

What happens during the Screening Period?

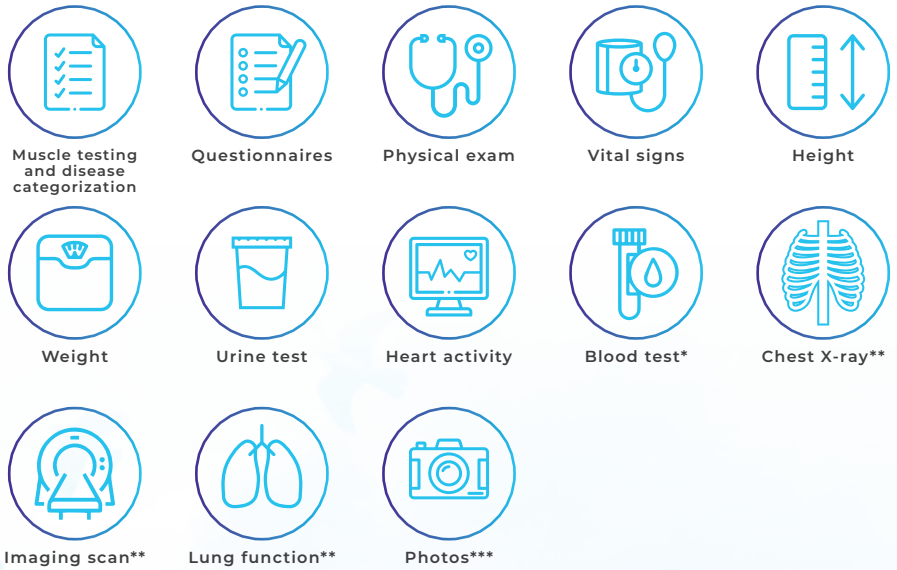
Study Visit 1 Scheduled date/time	

Now that you have given permission to join the study by reading the patient information sheet and signing the **Informed Consent Form**, the study doctor will collect information and run tests to make sure the study is right for you.

Health information collected



Tests and health checks



* Participants who can become pregnant will have their blood tested for pregnancy.

** Not all tests may be required. Your doctor will inform you which tests will need to be completed.

*** Photos to document disease on the skin may be taken at the discretion of the doctor.

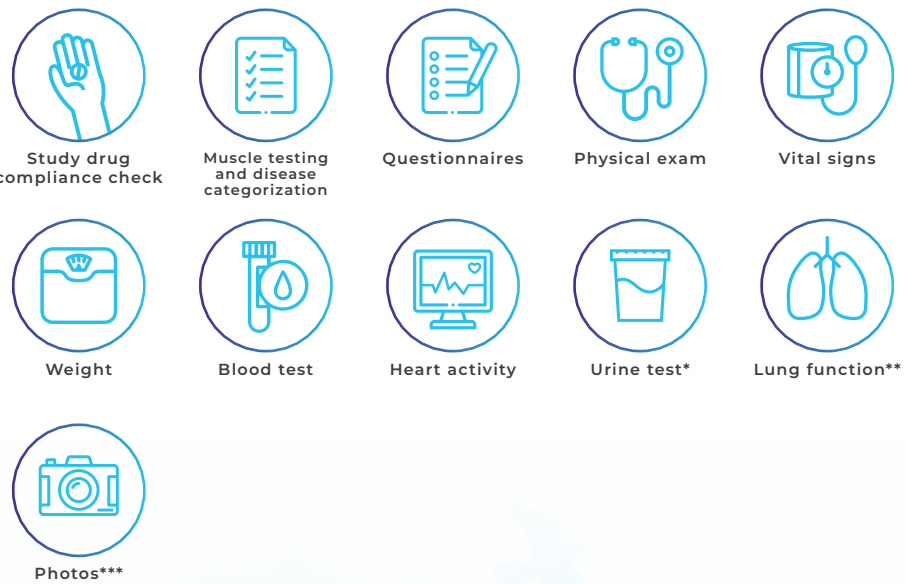
What happens during the Blinded Treatment Period?

Study Visits 2 to 12 (11 visits over 52 weeks)

These are tests and health checks you will have during the next 11 study visits. You will not have all of these tests at every visit.

Health information collected

Tests and health checks



* Participants who can become pregnant will have their urine tested for pregnancy.

** Not all tests may be required. Your doctor will inform you which tests will need to be completed.

*** Photos to document disease on the skin may be taken at the discretion of the doctor.

You will be continuously monitored throughout the study for any side effects.

What study drug will I take during the Blinded Treatment Period?

During Study Visit 2, you will be assigned by chance (like flipping a coin) to a study treatment group. This is known as **randomization**.

2 out of every 3 participants will receive **brepocitinib** (either 15 mg or 30 mg daily dose).

1 out of every 3 participants will receive **placebo***.

* The **placebo** tablets look like brepocitinib but contain no active medicine. This gives the researchers something to compare to brepocitinib in order to measure its effects.

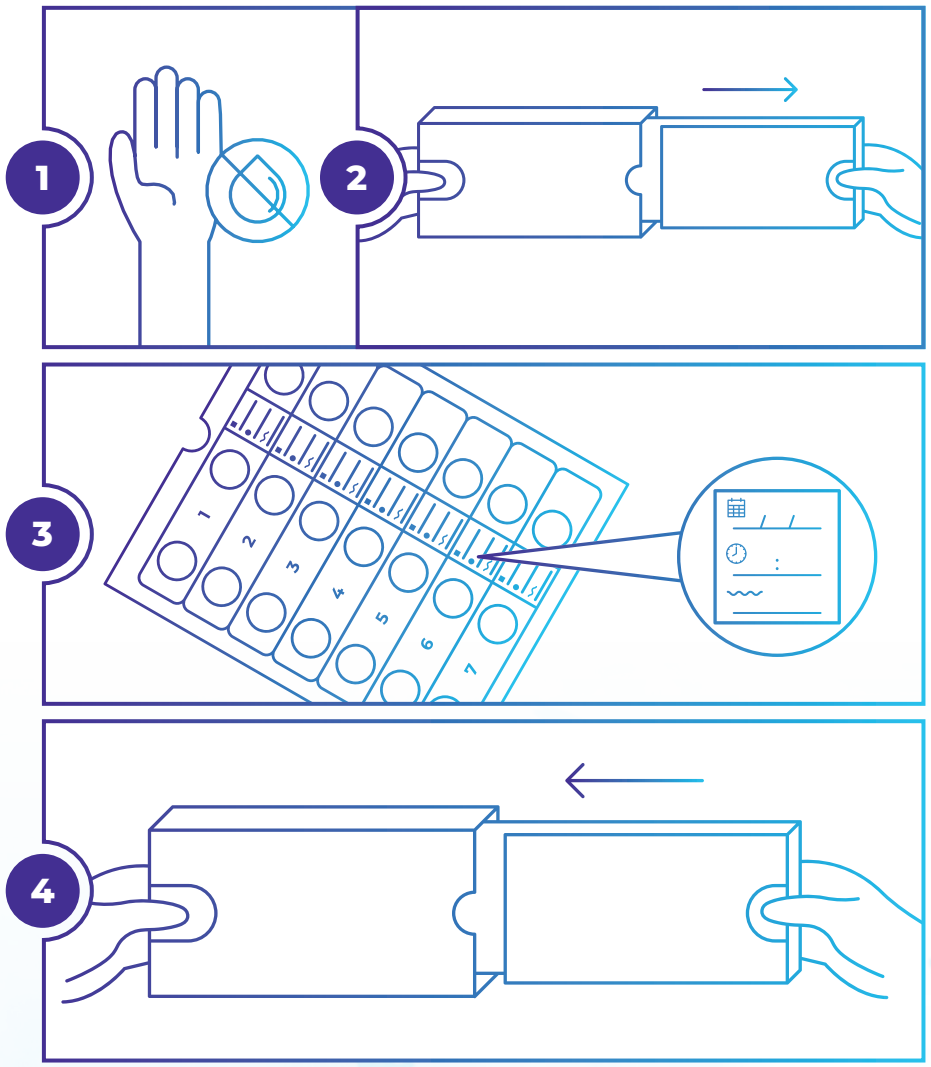
Neither you nor your study doctor or team will know which treatment group you are in. This helps keep the study fair.

You will continue to receive your existing medications in addition to study drug. Your study doctor will advise you on which medications you will continue to take.

How do I take the study drug?

The study drug comes in a child-resistant wallet containing 5 blister cards. Each blister card contains enough doses for 7 days.

1. Use dry hands while handling the medication wallet and blister cards.
2. To release the blister card, press and hold the tab on the left of the wallet while pulling the blister card to the right to remove it from the wallet.
3. Each row includes the three tablets that should all be taken at the same time. Push each one of the three tablets through from the front of the blister card onto a clean surface. Write the date and time you take each dose of study drug, as well as your initials, on the medication blister card. You will take your first dose at the study site and the study team will show you how to document your dose.
4. Close the blister card.



How do I take the study drug (continued)?

While taking the study treatment, **you should**:

- Take 3 tablets by mouth daily at the same time each day. Be sure to take all 3 tablets from the same row on the blister card.
- Take the tablets in the morning after breakfast whenever possible; the tablets may be taken with or without food.
- For study visits 2, 3, and 7, you will take the study drug at the study site (not at home). You will have a blood test to measure the amount of study drug in your body after you take the tablets.
- Write the date, time, and your initials on the corresponding row of the blister card each time you take your study dose.
- Bring empty, partially used, and unused blister cards back to the study center at each visit.
- Continue all other therapies, such as physical therapy, weight management, and/or an exercise routine, as directed by your doctor.
- Keep the study tablets out of the reach of children and others who cannot read the label.

While taking the study tablets:

- **DO NOT THROW AWAY** the empty blister cards. Return both used and unused blister cards to the study staff at your next study visit.
- **DO NOT** discard study drug, for example by throwing them in the trash or flushing them down the toilet.
- **DO NOT** give your study drug to any other person.

If you miss a dose and the time until your next dose is less than 8 hours, do not take the missed dose. Make note of the missed dose and put an "X" for that dose on the medication pack.

At study visits, the study team will check to make sure that you've been taking your study treatment as instructed.

Blinded Treatment Period

Use the tables on the next few pages to keep track of your scheduled visits and important reminders.

Visit 2 (Day 1)

Scheduled date/time	
Expected duration of visit	
Tests and health checks	
Reminders	After the study doctor confirms that you are eligible to participate in this study, the study site staff will provide you with your first dose of study drug at your study visit. You will receive instructions on how to document taking your dose every day at home. You will also receive a supply of the study drug to take home.
Notes	

*Participants who can become pregnant will have their urine tested for pregnancy.

**Photos to document disease on the skin may be taken at the discretion of the doctor.

Visit 3 (Week 4)

Do not take your study drug at home on the day of this visit. You will take your study drug dose at your study visit. Samples will be collected 5 times over 4 hours (at 30 minutes and at 1, 2, and 4 hours after taking your dose). This is to find out how much study drug has been absorbed by your body and how quickly it is removed from your body.

Scheduled date/time	
Expected duration of visit	
Tests and health checks	
Reminders	Bring all empty, partially used, and unused blister cards back to the study visit.
Notes	

*Participants who can become pregnant will have their urine tested for pregnancy.

**Photos to document disease on the skin may be taken at the discretion of the doctor.

Visits 4, 5, and 6 (Weeks 8, 12, and 18)

Scheduled date/time	Visit 4 (Week 8): Visit 5 (Week 12): Visit 6 (Week 18):
Expected duration of visit	
Tests and health checks	
Reminders	Bring all empty, partially used, and unused blister cards back to the study visit.
Notes	

*Participants who can become pregnant will have their urine tested for pregnancy.

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Visit 7 (Week 24)

Do not take your study drug at home on the day of this visit. You will take your study drug dose at your study visit.

Scheduled date/time	
Expected duration of visit	
Tests and health checks	
Reminders	Bring all empty, partially used, and unused blister cards back to the study visit.
Notes	

*Participants who can become pregnant will have their urine tested for pregnancy.

**Only for participants who have a history of lung disease.

***Photos to document disease on the skin may be taken at the discretion of the doctor.

Visits 8, 9, 10, and 11 (Weeks 30, 36, 42, and 48)

Scheduled date/time	Visit 8 (Week 30): Visit 9 (Week 36): Visit 10 (Week 42): Visit 11 (Week 48):
Expected duration of visit	
Tests and health checks	
Reminders	Bring all empty, partially used, and unused blister cards back to the study visit.
Notes	

*Participants who can become pregnant will have their urine tested for pregnancy.

**Photos to document disease on the skin may be taken at the discretion of the doctor.

Visit 12 (Week 52 or End of Treatment)

If you stop taking the study drug before completing the Blinded Treatment Period, you will have an End of Treatment visit within 7 days after your last dose of study drug. Do not take your study drug at home on the day of this visit. If you are eligible and continue to the Open-Label Extension Period, you will take your study drug dose at the study site.

Scheduled date/time	
Expected duration of visit	
Tests and health checks	
Reminders	Bring all empty, partially used, and unused blister cards back to the study visit.
Notes	Once you complete the Blinded Treatment Period, you may have the option to continue in an Open-Label Extension Period to receive brepocitinib. Your study doctor will notify you if you are eligible to participate.

*Participants who can become pregnant will have their urine tested for pregnancy.

**Photos to document disease on the skin may be taken at the discretion of the doctor.

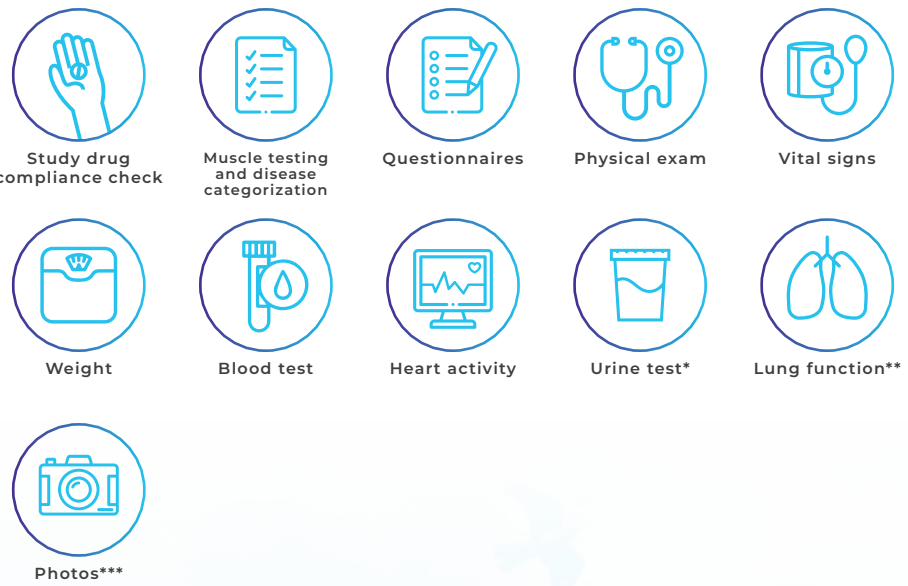
What happens during the Open-Label Extension Period?

Study Visits 13 to 19 (7 visits over 52 weeks)

If the study doctor confirms you are eligible and you choose to continue into the extension period, you will take brepocitinib 30 mg once daily for 52 weeks.You will also have 7 study visits with these tests and health checks. You will not have all these tests at every visit.

Health information collected

Tests and health checks



* Participants who can become pregnant will have their urine tested for pregnancy.

** Not all tests may be required. Your doctor will inform you which tests will need to be completed.

*** Photos to document disease on the skin may be taken at the discretion of the doctor.

You will be continuously monitored throughout the study for any side effects.

Visit 13 (Week 56)

Scheduled date/time	
Expected duration of visit	

Visit 14 (Week 60)

Scheduled date/time	
Expected duration of visit	

Visit 15 (Week 64)

Scheduled date/time	
Expected duration of visit	

Visit 16 (Week 72)

Scheduled date/time	
Expected duration of visit	

Visit 17 (Week 80)

Scheduled date/time	
Expected duration of visit	

Visit 18 (Week 92)

Scheduled date/time	
Expected duration of visit	

Visit 19 (Week 104)

Scheduled date/time	
Expected duration of visit	

What happens during the Follow-Up Period?

Study Visit 20 (1 visit)

You will return to the study center for tests 4 weeks after your final dose of study drug.

Scheduled date/time	
Expected duration of visit	

Health information collected

Tests and health checks

* Participants who can become pregnant will have their urine tested for pregnancy.

** Photos to document disease on the skin may be taken at the discretion of the doctor.

Glossary of important terms

Blood test: Blood samples will be taken for several blood tests, including safety tests. The blood tests tell us how your body is affected by the study drug and checks the levels of study drug in your blood. Participants who can become pregnant will have their blood tested for pregnancy.

Chest X-ray: This test is used to take images of your lungs and the inside of your body to check for infection or lung disease.

Contraception check: Participants who can become pregnant must avoid becoming pregnant during the study. Because brepocitinib is an investigational medicine, there are unknown risks that could affect an unborn child. The study doctor will confirm that you are using an appropriate method of contraception.

Demographic information: This includes your personal information and characteristics, such as your year of birth, sex assigned at birth, ethnicity, and race.

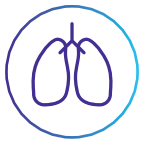
Heart activity: A test called an electrocardiogram (ECG) will be used to check the electrical activity of your heart. For this test, you will lie down and small, sticky pads (electrodes) will be attached to your chest. The pads are connected with wires to a computer that displays your heart's activity.

Height: You will need to remove your shoes, and a member of the study team will measure how tall you are.

Imaging scan: Some participants may have a CT (computed tomography) or PET-CT scan, which uses x-rays to take detailed 3D pictures of your chest and the area around your stomach and hips.

Glossary of important terms (continued)

Informed Consent Form: This document contains all the important information about the study. Before starting the study, you gave the study doctor permission to collect your health information for study purposes by signing the Informed Consent Form.



Lung function: You may have this test if you have a history of lung disease. You will breathe into a tube attached to a machine. This test measures how well air is moving in and out of your lungs and how much air your lungs can hold.

Medical and health history: The study doctor will ask questions about your health, including your dermatomyositis and any surgeries or medical procedures you may have had.

Medicine review: The study doctor will ask questions about medicines and vaccinations you are taking now or have taken in the past.

Muscle testing and disease categorization: Scoring systems are used to rate your health and your symptoms. The study team will use scoring systems specific to dermatomyositis to assess how your disease affects your body, skin, and muscle activity.

Photos: The study team may take photographs of the skin areas of your body affected by dermatomyositis.

Physical exam: The doctor will check different parts of your body, such as the heart, lungs, skin, eyes, throat, and abdomen.

Questionnaires: You will answer questions about how you are feeling, your symptoms of dermatomyositis, and how they affect daily activities and your quality of life.

Study drug compliance check: At each visit, the study team will check to make sure you are taking the study drug properly. It is very important to take the study drug as instructed, to record the date and time and initial each dose, and to bring back all unused study drug and any used or partially used blister cards to each visit.

Urine test: A sample of your urine will be tested for certain things, such as sugar, protein, and blood. Participants who can become pregnant will have their urine tested for pregnancy.

Vital signs: These include your blood pressure, (how your heart is pumping), heart rate (the number of times your heart beats per minute), breathing rate (the number of breaths you take per minute), and body temperature.

Weight: A member of the study team will weigh you on a scale while you are wearing light-weight clothing but with your shoes removed.

Study contact information

Contact the study team if you have any questions, notice any changes in your health, if you change or stop taking any medication, if you plan to receive a vaccine, or if you need to reschedule an appointment.

Study doctor's name: _____

Phone number: _____

Email: _____

Study coordinator's name: _____

Phone number: _____

Email: _____

Your study ID card also lists contact information. Keep this card with you at all times.

Clinic location for study tests

Test	Location
Laboratory tests: _____	
Chest x-ray: _____	
Heart activity: _____ (electrocardiogram)	
Imaging scan: _____	
Lung function: _____	

Special instructions: _____

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