

# The HALT Study

## What is the HALT Study?

The HALT study is a pivotal placebo-controlled study to determine the effectiveness of TRIV202 in managing left ventricular hypertrophy associated with feline subclinical Hypertrophic Cardiomyopathy (HCM) over 12 months.



## What Cats are Eligible to Participate in the HALT Study?

As for any clinical study, there is a detailed list of inclusion and exclusion criteria to ensure that the HALT study findings are valid and robust, and that the safety and welfare of the participating cats are protected. Male, and surgically spayed female, cats with an echocardiography-confirmed diagnosis of subclinical HCM (i.e. that do not yet have outward symptoms of their heart disease) may be eligible if they meet these additional criteria:

- **Body weight  $\geq 2.5$  kg (5.5 lb)**
- **Age  $\geq 18$  months and  $< 15$  years at enrolment**
- **Willing to take oral medications**
- **Elevation of cardiac biomarkers (NTproBNP) – to be confirmed by blood sample at the HALT study clinical site**
- **Otherwise healthy; e.g. non-diabetic, no chronic infections**
- **Their owner provides consent after being informed of the risks and benefits of participation in the study**

HALT study Investigators (all veterinary cardiologists) will carefully examine all cats to determine whether they are suitable for inclusion in the study in consideration of a detailed list of criteria. For more information please contact your nearest HALT clinical site.

## How long will my pet be in this study?

The study period is approximately

**12 MONTHS**

## What are the study groups?

Two study groups are used in this study, and you will not know which of the groups your cat is enrolled in. The groups include a placebo group that receives a pill with no active compound, and a treatment group that receives a TRIV202 pill. This study is masked, meaning some of the individuals helping with the study, including you and the Study Veterinarian, will not know which treatment group your cat has been assigned to. The placebo and TRIV202 pills look identical, and they are to be given by mouth once weekly.

## What tests and procedures are required to determine if my pet can take part in this study?

At your first visit to the clinic, your cat will undergo a thorough physical examination, blood and urine tests, electrocardiography, and diagnostic imaging (ultrasound and X-ray evaluations). Additional tests may be performed at the discretion of the Study Veterinarian, and your cat may receive a mild sedative if required to reduce stress. You will also be asked to complete a quality-of-life questionnaire. None of these procedures will be carried out until all the risks and benefits of taking part in the study are explained to you, and you have provided your informed consent for participation in writing.



## What else is involved in taking part in the study?

Taking part in a clinical study like HALT is a big commitment. In addition to the first (screening) visit, you will return to the clinic with your cat for follow-up evaluations 5 times over the course of the following year. You will also return to the clinic in the days following the screening visit to collect the first supply of study drug; however, your cat does not need to accompany you for this visit. You must continue to dose your cat with the study medication, as well as any other medications deemed necessary by your Study Veterinarian, for the one-year course of the study. It is essential that owners registering for HALT are able to meet these requirements so that we can accurately assess the benefits and risks of treatment with TRIV202 when the study concludes.



## What are the costs of my pet taking part in this study?

There are no costs to you for participating in this study. All study related activities (physical exams, blood work, urinalysis, Echocardiography, ECGs, etc...) will be provided at no expense to you. Compensation for travel to the clinic for required visits will not be provided, however at the completion of the study and given all protocol related instructions are followed correctly, you will be compensated **\$500** for your time.

