



# Community Newsletter

Issue 3 2019

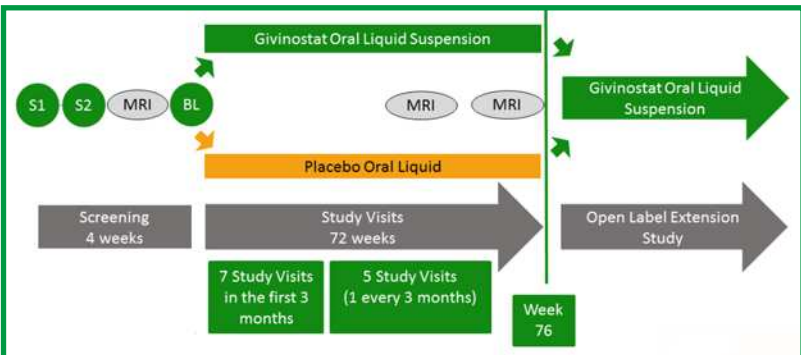
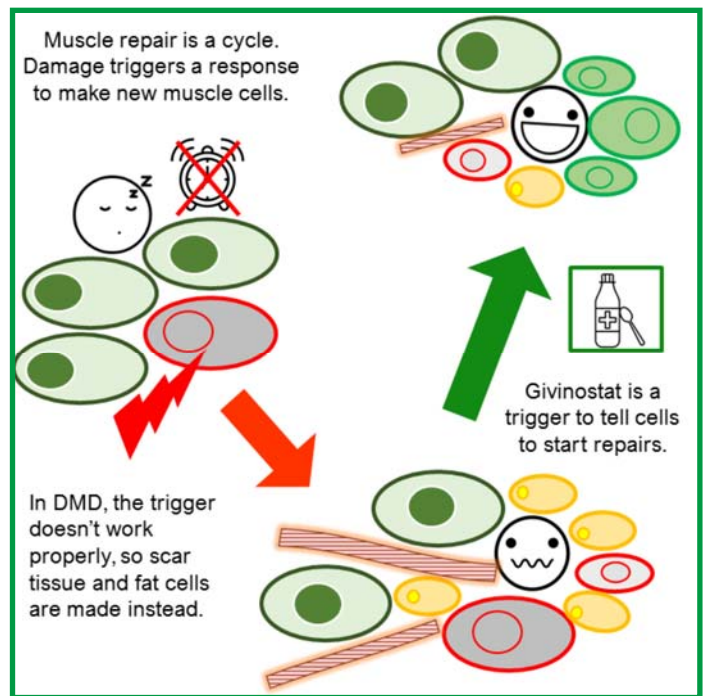
## What is Givinostat?

Givinostat is an investigational drug. It acts as an inhibitor to allow the natural muscle repair process to work more normally. We are testing whether taking givinostat would improve muscle repair and maintenance for people with DMD.

People with DMD lack dystrophin. Dystrophin normally prevents cell damage. It also holds together another group of proteins which control muscle regeneration. Without them, the signals to start muscle repair don't work properly. Givinostat is a trigger to tell the cells to start repairs.

Watch our 2019 webinar to learn more:

<https://youtu.be/TKaQ1JPiWvM>



## EPIDYS Phase 3 Trial

The trial is open to boys with DMD ages 6 and older who are walking, able to climb stairs, and meet other study criteria. People with any genotype can participate.

The purpose is to test whether givinostat affects the time to climb 4 stairs. Participants are randomly assigned to receive up to 72 weeks of givinostat or placebo. After the trial, everyone can enroll in an open label extension study.

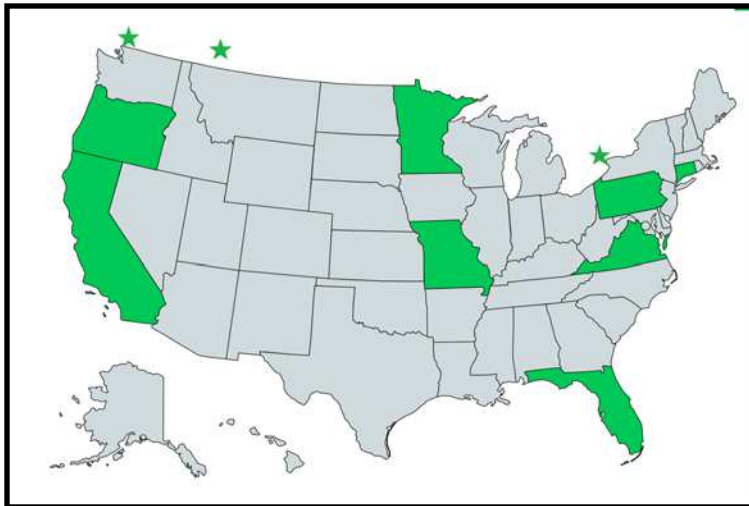
## Project Update

The EPIDYS trial opened in June 2017, and is being conducted at 40 study sites around the world. Our expert teams of scientists, clinical trial investigators, and site staff are working hard to learn more about givinostat.

We plan to enroll 240 people worldwide. Over **110 people** have enrolled and sites are still accepting new participants. You can ask your site about central travel support and optional home nursing.

You can learn more with us at community events and webinars this fall. For a site referral, email us at: [patientadvocacy@italfarmaco.com](mailto:patientadvocacy@italfarmaco.com).





## FIND YOUR SITE

The EpiDys study is open at **14 sites** in Canada and the US. Find all our open sites at: [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (NCT02851797).

**No site in your area?**

**Ask us about travel support.**

## Events Calendar

We're looking forward to meeting you at events in your area. If you can't attend an event in person, you can learn more at: [www.parentprojectmd.org/faqs/givinostat/](http://www.parentprojectmd.org/faqs/givinostat/)

### We hope to see you soon!

- September 12 CureDuchenne Webinar
- September 14 PPMD EndDuchenne Tour  
Wilmington, DE
- September 14 Jett Foundation Workshop  
Rochester, NY
- October 11—  
13 CureDuchenne Futures  
Conference  
Anaheim, CA
- October 26 PPMD EndDuchenne Tour  
Memphis, TN
- November 2 Jett Foundation Workshop  
Los Angeles, CA
- November 2 Jesse's Journey  
Defeat Duchenne Forum  
Calgary, AB
- November 9 CureDuchenne Cares  
San Antonio, TX

## Frequently Asked Questions

### How is Givinostat different from gene therapy?

Givinostat acts at a different place in the cell, than gene therapies do—not the DNA or RNA. Givinostat acts like one of the signals cells use in muscle repair. If effective, givinostat could preserve more muscle function for a longer time. We hope that in the future, givinostat could be used in combination with other therapies to make them work better.

### How do you take Givinostat in the trial?

People take either givinostat oral liquid suspension or placebo suspension twice a day by mouth after food.

*Thank You!*

We are grateful for the support of the DMD community who have helped us to make this clinical trial a success.

We would like to thank all the scientists, clinical trial investigators, trial site staff, patient advocacy groups, and all of the families who are hard at work to support this research.

We deeply appreciate everyone's commitment to learning more about investigational drugs for DMD.

Thank you!#

**Would you like to learn more?**

Email us: [patientadvocacy@italfarmaco.com](mailto:patientadvocacy@italfarmaco.com)

