



Community Newsletter

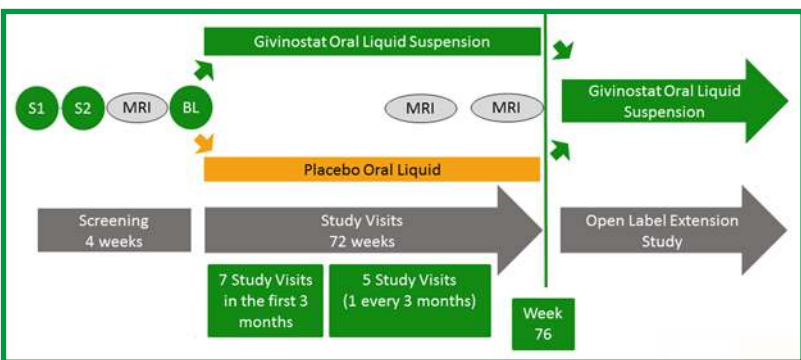
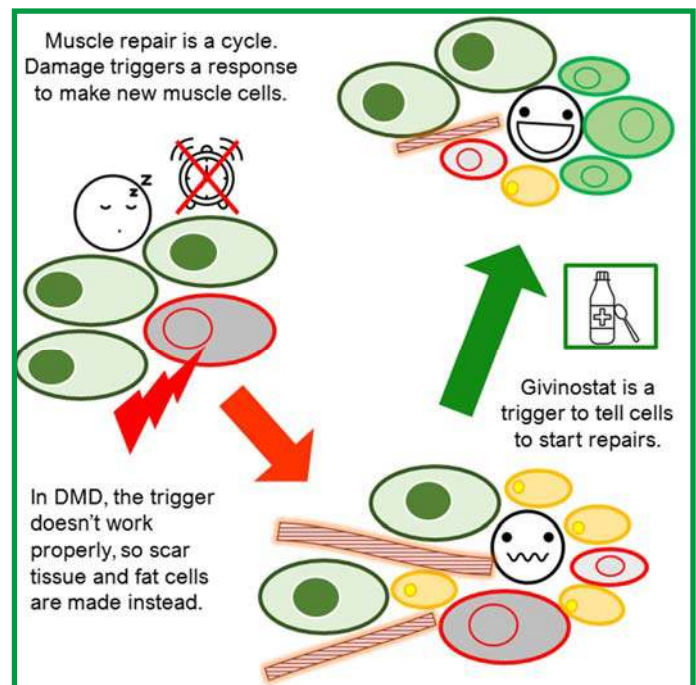
Issue 1 2020

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 a 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.

Sites are being added in the United States in 2020 and will appear on clinicaltrials.gov when they are ready for new patients.

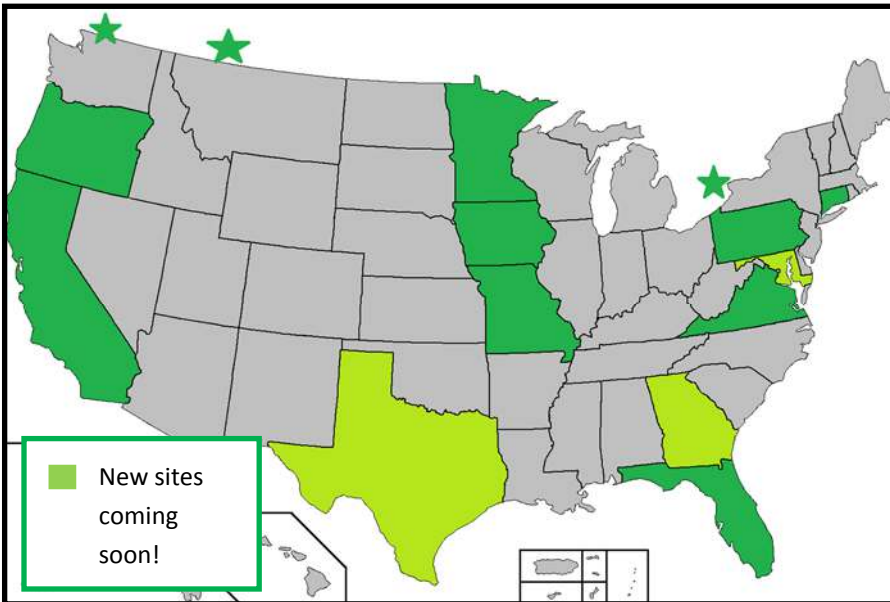
Project Update

The EPIDYS trial opened 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 **125 people** have enrolled and sites are still accepting new participants. Ask your site about travel support and optional home nursing.

For a site referral, email us at 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 (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/

We hope to see you soon!

January 25	Jett Foundation Workshop Worcester, MA
February 8	CureDuchenne Cares Houston, TX
February 22	Jett Foundation Workshop Portland, OR
March 7	Jett Foundation Workshop Philadelphia, PA
Mar 8-10	PPMD Advocacy Conference Washington, DC
March 14	PPMD EndDuchenne Tour Atlanta, GA
March 21-25	Muscular Dystrophy Association Conference Orlando, FL

Frequently Asked Questions

I am enrolled in other study that is ending. Can I do this study?

Yes. Talk with an EpiDys trial site about your situation. Boys can screen for this trial 3 months after their last dose of other investigational drugs (6 months for certain drugs). Your EpiDys trial doctor can help you with this process.

What should I do to get started?

If you haven't left your current study, talk to your study team. They will help you to leave the study safely. Then contact an EpiDys trial site. They can help you screen for the EpiDys trial with your specific situation in mind.

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. #

Would you like to learn more?

Email us: patientadvocacy@italfarmaco.com

