



# REPRIEVE

## PARTICIPANT NEWSLETTER



### From the entire REPRIEVE team, we want to extend a sincere thank you for your participation in REPRIEVE!

REPRIEVE is closing to follow up upon the recommendation of the Data and Safety Monitoring Board (DSMB), an independent advisory group to the National Institutes of Health (NIH) that provides recommendations about starting, continuing, modifying, and stopping the study. The decision is based on an observed 35% decrease in major heart-related events, including heart attacks and strokes, in participants taking pitavastatin compared to placebo. There was also a 21% decrease in major heart-related events grouped together with death in those taking pitavastatin compared with placebo. Of note, there were no unexpected safety concerns among those taking pitavastatin.



Members of the REPRIEVE Team at the REPRIEVE Investigator's Meeting during CROI 2023.

Like other statin studies, there was a modest increased risk of diabetes mellitus and the anticipated increase in muscle aches and pains. However, very few participants left the study for these effects, and importantly,

there was no effect of pitavastatin on liver function tests or severe muscle disorders. The DSMB recommended that the study stop early due to the demonstrated benefits of taking pitavastatin and to share the positive results. REPRIEVE investigators are exploring ways to make pitavastatin available to study participants, in line with regulatory requirements.

As you may remember, REPRIEVE began in 2015 and enrolled 7769 volunteers aged 40 to 75 years in 12 countries across Asia, Europe, North America, South America, and sub-Saharan Africa. REPRIEVE is the first large-scale clinical trial to test a way to prevent heart-related disease in people living with HIV with low-to-moderate traditional heart disease risk.

Your contributions as a participant in REPRIEVE have been extremely valuable. Decades of research and advances in HIV treatment have drastically reduced AIDS-related complications and deaths, and now we better understand how to support the heart health of people living with HIV. This could not have been achieved without you, our REPRIEVE participants! Findings from REPRIEVE will have lasting benefits for your generation and future generations of people living with HIV. We are incredibly grateful for your participation in REPRIEVE!

Thank you from REPRIEVE Leadership!

### REPRIEVE Facts

REPRIEVE is the largest randomized study among people living with HIV.

Before REPRIEVE, there were limited strategies to help prevent major heart-related events in people living with HIV.

#### What have we learned so far?

- > A daily dose of pitavastatin lowers the risk of heart-related disease in people living with HIV
- > Pitavastatin is safe and well-tolerated in people living with HIV

#### What will we still be able to learn from data that you have contributed from your participation?

- > What are the effects of pitavastatin on cholesterol levels and levels of inflammation in relation to heart-disease events?
- > Does taking pitavastatin slow the build-up of plaque in the arteries of the heart over time?
- > Are there effects of pitavastatin to reduce the risk of other medical problems like kidney disease, liver disease, and cancer?

These are just a few of the questions we hope to answer based on analyses that will be carried out in the very near future. All REPRIEVE publications are posted on our website, [www.reprievetrial.org](http://www.reprievetrial.org)

Please follow up with your local research site to learn when the primary results and others are available from REPRIEVE.



## Meet Other REPRIEVE Participants!

REPRIEVE would not have been successful without the continued participation and engagement of our participants, for whom we are incredibly grateful. Although there are thousands of REPRIEVE participants in 5 continents, below are experiences from a few of them.

### Janice Jarrells

RUTGERS, NJ

What has been your experience with REPRIEVE?

*REPRIEVE is one of the easier studies I have participated in! I feel very comfortable, maybe because the study is straightforward and there was good pre-education. I went to a meeting in Washington DC during the early recruitment phase and meeting the REPRIEVE team was a plus! I feel proud to be helping people living with HIV understand what HIV can do and maybe already doing to the body, especially longtime survivors.*



What is the value of the REPRIEVE trial to you?

*Knowing that all trials aren't successful, I feel that REPRIEVE is one of the successes. My reasons for saying this is because of the pre-education, protocol discussions, community awareness and a community advisory board.*

Looking forward to the final results of REPRIEVE and future publications, what are your hopes for how the trial will inform the field?

*I expect REPRIEVE will tell us how HIV is impacting our heart health and ways we can prevent or improve the impact*

### Dave and Darcy

VANCOUVER ISLAND, BC

What has been your experience with REPRIEVE?

*The study has been uneventful in regard to our experiences, we have had no negative reactions to the study or the medication and enjoy seeing Dr. Conway (the investigator at our study site) and all the people associated with the study on a regular basis.*

What is the value of the REPRIEVE trial to you?

*The study allows us to participate in a valuable research process and somehow give back to others that have participated in other studies that have benefited us.*

In what ways is REPRIEVE different from other trials you have participated in?

*The only difference we find with REPRIEVE and other studies we have participated in is the length of it, it is a longer study but no more difficult than others to be active in. We appreciate the fact that we are helping gain knowledge.*

## Focus on Findings

*Your participation in REPRIEVE has contributed to research about HIV and heart disease and has allowed REPRIEVE investigators to publish reports from your data collected at entry. Below is a summary of an article we published in 2022:*

Heart disease risk is commonly assessed by whether a person has certain heart disease risk factors, like high cholesterol. But alternatively, risk can be assessed by cardiovascular health through the American Heart Association's Life's Simple 7 (LS7) score.

- Included in this analysis were 735 REPRIEVE participants with an average age of 51 years.
- This analysis found that:
  - People with poor cardiovascular health as shown by a low LS7 score were up to 20% more likely to have fatty build-up in the blood vessels that supply the heart.
  - Poor cardiovascular health was also associated with up to a 25% higher level of inflammation in blood proteins.
- These findings provide useful information on the critical question of why PWH experience increased risk of heart disease. Future studies of LS7 may help to guide clinical care and help to reduce cardiovascular morbidity and mortality in PWH.

Please follow up with your local research site to learn when the primary results and others are available from REPRIEVE.



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