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# REPRIEVE

## Randomized Trial to Prevent Vascular Events in HIV

## December 2023 Table of Contents



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As we send out the final REPRIEVE Site Newsletter and mark this significant milestone in our journey together, **REPRIEVE Leadership would like to express our deepest gratitude** to every REPRIEVE site team for your dedicated participation.

Your unwavering commitment and hard work have been the driving force behind our shared success. **Your expertise, professionalism, and passion for advancing medical knowledge have made a lasting impact across the globe and, importantly, on the lives of people living with HIV.**

Thank you for nearly a decade of collaboration, excellence, and meaningful participation. While this marks the end of study closure activities, data analysis and dissemination have just begun! Read below for ways to stay in touch with REPRIEVE's activities and share this with people living with HIV in your local area.

Sincerely,
REPRIEVE Leadership

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## Stay in Touch and Subscribe to our Newsletter!

### *REPRIEVE Insights: Quarterly Updates on Milestones and Discoveries*

Although the REPRIEVE Trial is closing and this is the final site newsletter, data analysis is far from complete! In the near future, we plan to share results from the Mechanistic Substudy (A5333s) and more!

To keep up with the latest REPRIEVE news and additional study findings, sign up for the **REPRIEVE Insights** newsletter using the link below:
REPRIEVE Insights Newsletter Sign Up Form

***Please share this with anyone who participated in REPRIEVE at your site and anyone interested in receiving information about REPRIEVE***

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## Unblinding Information

The unblinding notification was sent to sites on November 20th, 2023. The Site PI and CRS Coordinator received an email from the REPRIEVE Data Managers with the information needed for unblinding. If you have any questions about this, please get in touch with Ken Wood (wood@frontierscience.org).

### Translations of *Template Unblinding for Participants Letter* are Available

The template unblinding letter for participants has been translated to Spanish, Portuguese, and French (Canada)

with more languages to come! You can use the links below to download these translations. To request translation to another language, please email Marissa Diggs (mdiggs@mgh.harvard.edu).

Spanish Unblinding Letter
Portuguese Unblinding Letter
French (Canada) Unblinding Letter

## Protocol Deregistration

- On or around January 1st, 2024: Clinical research sites must deregister the REPRIEVE protocol with DAIDS protocol registration after confirmation of study closure with IRB/EC.

Please see pg. 58 of the DAIDS Protocol Registration Manual for instructions.

Sites must submit a copy of the IRB/EC closure/termination letter for REPRIEVE to the DAIDS PRO for all deregistration requests. Upon completing the DAIDS deregistration process, a CRS will no longer receive safety information (i.e., safety reports, memos, investigator's brochures) from the DAIDS RSC Safety Information Center. Click here to review additional guidance.

## For REPRIEVE Protocol Specific (non-ACTG) Sites Only: Site/Lab Closure

DAIDS OCSO POs will be working to close REPRIEVE Protocol Specific (PS) sites.

- All PS sites will be closed starting December 4, 2023
  - FSTRF will be working with PS labs to close LDMS
- Close-out is expected to be completed by March 1, 2024
- A DAIDS Contract staff will be working with PS sites to facilitate close-out activities
- DAIDS has generated a streamlined CRS close-out process involving the use of a CRS close-out checklist
- Sites will be notified of their final CRS close-out status when all items on the checklist have been completed

**If the REPRIEVE CCC obtains additional funding for the observational study, sites will be contacted about reopening.**


## Payment Inquiry Resolution Deadline

Please know that all payment inquiries need to be resolved by **April 30, 2024**. Please contact the REPRIEVE Finance Team reprieve.finance@mgh.harvard.edu if you need assistance.

You may continue to contact the REPRIEVE Finance Team after this date for assistance with other matters, but April 30th is the deadline for payment inquiries to be resolved.

## We Need Your Help to Share REPRIEVE Participant Stories!

The results of REPRIEVE are making an impact across the globe, from changing guidelines to changing lives for people with HIV. For the first REPRIEVE Quarterly Newsletter, we would like to feature a REPRIEVE participant who can share what the results of REPRIEVE have meant for them. If there is a participant at your site who might be interested, please have them reach out to Katie Fitch (kfitch@mgh.harvard.edu) or Marissa Diggs (mdiggs@mgh.harvard.edu) at the REPRIEVE CCC.

## Translations of REPRIEVE Results Graphical Abstract

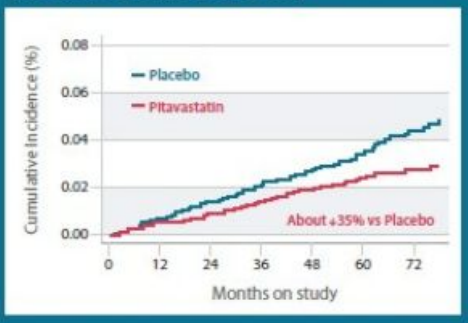
# How can people living with HIV (PWH) protect their heart health?

## People living with HIV (PWH) are at risk of developing cardiovascular disease.

The Randomized Trial to Prevent Vascular Events (REPRIEVE) enrolled **7,769** PWH around the world to test whether pitavastatin (vs. placebo) can prevent cardiovascular disease in this population.

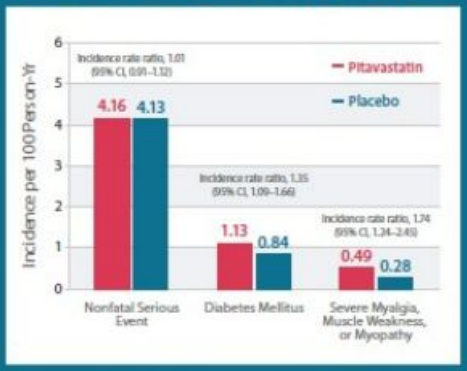

Each heart on the map represents a REPRIEVE clinical research site.

### Time to major adverse cardiovascular event (like first heart attack or stroke)




Pitavastatin reduced the incidence of the primary endpoint, major adverse cardiovascular events (MACE), by 35% compared to placebo over an average of approximately 5 years of follow up.

### Adverse events diagnosed during study period




Adverse events were similar between participants taking pitavastatin vs. placebo.

- Diabetes rates increased in the pitavastatin group, however pitavastatin reduced major adverse cardiovascular events even among PWH with diabetes.
- Muscle-related symptoms were higher in the pitavastatin group but were mostly mild and only 1% withdrew for muscle-related symptoms.

### Conclusion

In PWH at low-to-moderate traditional risk for cardiovascular disease, pitavastatin is safe, effective and prevents major adverse cardiovascular disease events like heart attack and stroke.

**DEFINITION OF TERMS:**

**Cumulative incidence** is the proportion of people who experience an event during the study period. This can be thought of as the risk of experiencing a major adverse cardiovascular event in this study.

**Incidence per 100 person-years** is the rate that people experience an event during the study period. Person-years is a measure of how much time the people have spent in the study.

A **95% confidence interval** (95% CI) is the range of values that we expect a data estimate to fall between 95% of the time if the study was repeated.

## For more information, please visit the REPRIEVE Trial website: www.reprievetrial.org

**Now available!** The REPRIEVE Team has developed a graphical abstract of the REPRIEVE primary results published in The New England Journal of Medicine. This graphical abstract has been translated to Spanish, Portuguese, and French Canadian on our new webpage. We hope this will be a helpful resource to spread the word about REPRIEVE's results!


# Webpage to Support REPRIEVE Results Sharing

The REPRIEVE CCC has launched a central webpage on which various REPRIEVE results materials are posted.

The materials include:

- Graphical abstract of trial results
- Statin guidance for PWH
- Slide templates for presentations to providers
- Slide templates for presentations to the community
- Participant FAQs, and more!

Visit this new page on the REPRIEVE website and share it with your community. Go to: https://www.reprievetrial.org/learnmore/results-of-the-reprieve-trial/.

***For future reference, all newsletters are available on the REPRIEVE Website***

**Like, comment, share, and retweet!**

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