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# REPRIEVE

## Randomized Trial to Prevent Vascular Events in HIV



As follow-up to the questions raised on the REPRIEVE Site Call on January 19<sup>th</sup>, 2021:

- **Influenza vaccines are not required to be recorded on the Medications Log in OpenClinica.** The COVID-19 Treatment List has been updated to reflect this, the updated version is now posted on the A5332 PWSP.
- **COVID-19 vaccinations are required to be recorded in OpenClinica on the Medications Log and categorized as COVID-19 treatment.**

And don't forget, REPRIEVE participants are not excluded from receiving a COVID-19 vaccination.



During the month of February take a moment to remind REPRIEVE participants at your site of the importance of REPRIEVE to confront the emerging challenge of HIV-related heart disease!

By continuing their participation through the end of the trial we will be able to answer important questions such as:

1. Will pitavastatin lower heart disease risk in *both* women and men with HIV?
2. Does a daily dose of pitavastatin lower the risk of heart-related disease among people with HIV?
3. Do statins help to slow or prevent kidney disease in people with HIV?
4. Is COVID-19 a heart disease risk factor for people with HIV?



## Tools You Can Use!

**For new REPRIEVE staff**

[Click here](#) to download instructions on how to obtain access to portals and complete

training for new staff.

**Regarding the revised pitavastatin (Livalo) package insert, dated September 2020.**

[Click here](#) for an explanation and rationale to assist you when notifying your IRB/EC of the updated package insert.

**When explaining the A5332 (ACTG sites ONLY) and A5333s informed consent addenda to your participants.**

For A5332 (ACTG sites only) and sites participating in A5333s we have developed some Key Messages and FAQs to help you when explaining the new informed consent addenda regarding sharing of de-identified genetic information (Version 5.0, LoA #2), [click here](#) to download.



**Q: A participant tested positive for COVID-19 but was not hospitalized, do I record this on the AE Log?**

**A:** Yes, please record this on the AE Log even if there was not an associated hospitalization or death.

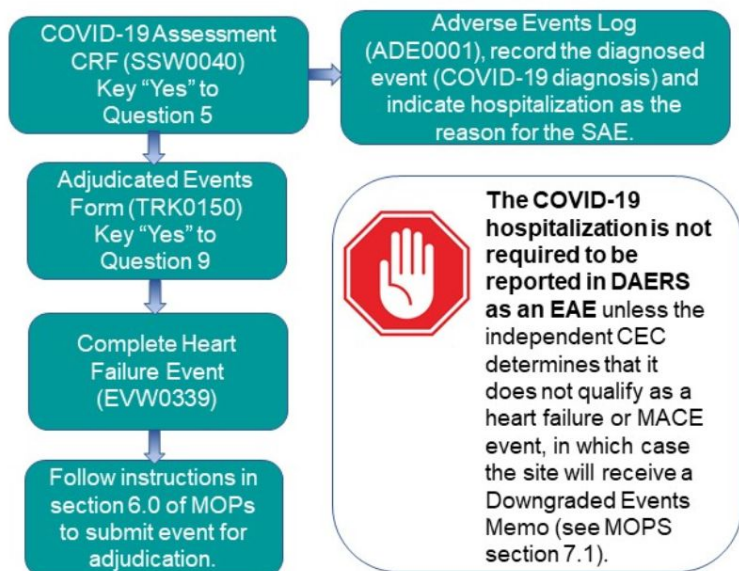
**Q: I was just notified that a participant died in an automobile accident, do I report this as an EAE in DAERS?**

**A:** No, do not report this as an EAE in DAERS. For REPRIEVE, all deaths are reported as adjudicated events to the DCC. See subsection 6.1 of the A5332 MOPS for more details. The revised MOPS (dated 020821) includes clarifications on the reporting of deaths.

**Q: A participant was hospitalized due to symptoms related to COVID-19. How do I report this event?**

**A:** Please use the workflow diagram below to assist you with reporting this event. A clarification on reporting of COVID-19 hospitalizations was made in subsection 4.2 of the revised MOPS (dated 020821). [Click here](#) to download the workflow.

## Reporting COVID-19 Hospitalizations



## Reminder: Expansion of Remote Source Document Verification (rSDV) to all DAIDS sponsored clinical trials

[Click here](#) to read the memo from DAIDS about rSDV.

Based on your site's clinical research operations/processes DAIDS is asking sites to select one platform from the following options to allow monitors to perform rSDV.

1. Veeva SiteVault
2. Direct EMR access
3. Site-controlled file sharing portal
4. Other 21CFR Part 11 and HIPAA compliant rSDV platform

If you haven't done so already, please select a platform to facilitate rSDV and communicate your selection to your DAIDS Program Officer as soon as possible.

If your site plans to use Veeva SiteVault, there are 2 webinars scheduled with Veeva.

1. Wednesday, February 24th 10:00AM ET
2. Thursday, March 4th 3:00PM ET

Veeva will be reaching out to sites shortly with more information about their platform and how to sign up.

If you have any questions about this, reach out to email Katie Fitch at [kfitch@partners.org](mailto:kfitch@partners.org).



## Look for REPRIEVE Science Spotlight Presentations at CROI!

The REPRIEVE Publications Committee is excited to share that 3 REPRIEVE abstracts were accepted at CROI for Science Spotlight presentations. If you are attending virtual CROI, be sure to check out the presentations by members of our REPRIEVE team below:

- Assessment of Obesity and Metabolic Profile by Integrase Inhibitor Use in REPRIEVE (ID 1734), *presented by Janet Lo.*
- Diet Quality by Global Burden of Disease Region in PWH in the REPRIEVE Trial (ID 1364), *presented by Katie Fitch.*
- Factors Associated with Systemic Immune Activation in a Global HIV Cohort (ID 2144), *presented by Markella Zanni.*

For those who will not be attending CROI, these presentations will also be presented during the next REPRIEVE site call - details below!



## Save the Date Next Team/Site Call! April 20th, 2021 1PM EST

1:00 PM HAITI (EST)  
1:00 PM PERU (PET)  
2:00 PM PUERTO RICO (AST)  
3:00 PM BRAZIL (BRT)  
8:00 PM BOTSWANA (CAT)\*\*\*  
8:00 PM SOUTH AFRICA (SAST)\*\*\*  
8:00 PM ZIMBABWE (CAT)\*\*\*  
9:00 PM UGANDA (EAT)\*\*\*  
11:30 PM INDIA (IST)\*\*\*  
1:00 AM 01/20/2021 THAILAND (ICT)\*\*\*

- We will feature a presentation by Pam Douglas, MD REPRIEVE CCC Co-PI! Dr. Douglas will present findings from a manuscript entitled, "Cardiovascular Risk and Health Assessments among People with HIV Eligible for Primary Prevention: Insights from the REPRIEVE Trial".
- In addition, the 3 Science Spotlight presentations mentioned above will be presented by the lead authors.

Details will be distributed shortly

\*\*\*We do not expect site staff to join these calls during their off-work hours. Instead we will update you on other scheduled calls, e.g., your calls with the ACTG NCC.

Remember that questions are always welcome at [actg\\_corea5332@fstrf.org](mailto:actg_corea5332@fstrf.org) and if there are slides used for a call, they are available on the PSWP in the Protocol Training >> Site Calls folder.

**REPRIEVE (A5332): Are you up to date?**

**For A5332 please use:**

*Protocol Version 5.0 dated 04/01/2019*

*Version 5.0, Clarification Memo 1 dated 04/03/2020*

*Version 5.0, Clarification Memo 2 dated 05/04/2020*

*Version 5.0, Letter of Amendment 1 dated 06/19/2020*

*Version 5.0, Letter of Amendment 2 dated 12/14/2020*

**Revised!** *MOPS Version 5.0 dated 02/08/2021*

*LPC for ACTG Sites Version 5.0 dated 05/04/2020*

*LPC for Non-ACTG Sites Version 5.0 dated 05/04/2020*

*These documents are on the [A5332 PSWP](#)*

**For future reference, all newsletters are available  
on the [REPRIEVE Website](#)**

*We welcome ideas and suggestions for future newsletters. Please submit any comments or suggestions to the REPRIEVE News team at [reprieve.news@fstrf.org](mailto:reprieve.news@fstrf.org)*



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