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Randomized Trial to Prevent Vascular Events in HIV



It's Official!
REPRIEVE is closed to accrual.
Trial Status

7557 participants are enrolled 10618 participants were screened 125 sites enrolled participants

### 130 sites screened participants Sites from 11 countries enrolled participants

We could not have reached this MAJOR milestone without the dedication from clinical sites and participants participating in REPRIEVE.

Thank you for all your efforts to enroll and we look forward to continuing the collaboration!

### June 24th, 2019: Next DSMB Meeting

The timeline below lists important tasks and deadlines for the upcoming Data and Safety Monitoring Board (DSMB) review of the REPRIEVE trial.

Please mark these important dates in your calendar and note that Monday, April 22nd is the next important deadline.

Task		Deadline* (2019)
Sites	Last date for the occurrence of an evaluation for which complete data will be included in this DSMB review	April 22 <sup>nd</sup> (Monday)
Sites	All data for visits through April 22nd entered	Apr 29 <sup>th</sup> (Monday)
Sites	All adjudication packets for potential MACE events with a work-up complete by April 22nd submitted to DCC (MGH)**	May 3 <sup>rd</sup> (Friday)
Sites	All outstanding queries resolved	May 13 <sup>th</sup> (Monday)
Sites	Respond to last minute outstanding queries	May 31st (Friday)
	DSMB Meeting	June 24 <sup>th</sup> (Monday)

<sup>\*</sup>Deadlines are Close of Business on the given date unless otherwise noted.

# We Need Your Help With the 2019 Participant Newsletter!





Vol. 3 | 2018

The REPRIEVE CCC publishes a participant newsletter each year with the goals of providing study updates and maintaining study engagement. Including the voice of REPRIEVE participants is essential.

REPRIEVE participants have shared that they appreciate reading about other

<sup>\*\*</sup>Please ensure that you have responded to all queries and clarifications from the DCC regarding source documents submitted for potential adjudicated events. This will ensure that the DCC is able to submit complete packets to TIMI for adjudication prior to the DSMB.

REPRIEVE participants' outlooks on the trial.

Do you have a participant that would want to share why participating in REPRIEVE is important? If so, please email us at <a href="mailto:reprieve.news@fstrf.org">reprieve.news@fstrf.org</a>.



participant files.

#### Return of the ECG Machines

We have alerted IQVIA that ECG machines are able to be returned. You should receive an email with further instructions the week of April 1st from IQVIA's Machine Logistics Department.

To prepare to return your machine:

- 1. Make sure your site has transmitted all ECGs to IQVIA.
- 2. Confirm the original ECG tracings are available in
- 3. Confirm that your site has no outstanding queries that require resolution.

#### Expectations of sites prior to shipping:

- Sites are expected to pack the ECG machine and accessories in the original box including all accessories (cables and power cord).
- Sites are not expected to return unused electrodes or paper.
- Sites need to return the device to the equipment warehouse as per instructions that will be provided.

Please make every effort to return your ECG machine as soon as possible so that the Clinical Coordinating Center does not incur unnecessary rental fees.

### Introducing REPRIEVE-EU (EU5332)



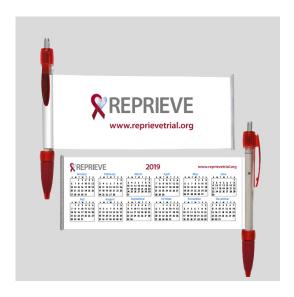


REPRIEVE Leadership is excited to be collaborating with the European treatment network for HIV, hepatitis and global infectious diseases (NEAT ID) to bring REPRIEVE to Europe! Esteban Martinez, MD will act as the Chief Investigator of EU5332 and will work closely with Joan Albert Arnaiz, Sara Varea, Pilar Callau, and Alexandre Nieva of the CTU Team in Barcelona, Spain (pictured above).

- 13 sites are open and 2 additional sites are scheduled to open across Spain
  - Accrual target of 250 participants
  - Study status: 22 participants enrolled!

Please join us in welcoming the EU5332 team!

#### **Retention Tools Are Available!**





REPRIEVE Retention Champions shared with us that *pens, participant newsletters, thank you cards, and birthday cards* are helpful tools to promote retention. The REPRIEVE CCC has developed these REPRIEVE-branded tools and are available to all sites (for free!). If you would like to request some tokens of appreciation for your site, please email Emma Kileel at <a href="mailto:ekileel@mgh.harvard.edu">ekileel@mgh.harvard.edu</a>.



#### Save the Date! Tuesday, April 16th, 2019 1:00 - 2:00 PM ET

For the March Monthly Site Call!

Watch for the email announcement with

more details.

REPRIEVE (A5332): Are you up to date?

For A5332 please use:

Bratesol Version 4.0 dated 03/38/2018

V4.0 LOA #1 dated 05/16/2018

MOPS Version 4.0 dated 10/16/18

A5332 LPC for ACTG Sites Version 4.0 dated 03/22/2018

A5332 LPC for Non-ACTG Sites Version 4.0 dated 07/23/2018

These documents are on the A5332 PSWP

## Mechanistic Substudy of REPRIEVE (A5333s): Are you up to date?

For A5333s please use

Protocol Version 4.0 dated 03/28/2018 MOPS Version 4.0 dated 04/10/2018 A5333s LPC Version 4.0 dated 03/23/2018 These documents are on the <u>A5333s PSWP</u>

# 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 <a href="mailto:reprieve.news@fstrf.org">reprieve.news@fstrf.org</a>







#### REPRIEVE Trial Clinical Coordinating Center

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Our mailing address is: reprieve.news@fstrf.org

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