

1by1by1 FINAL COUNTDOWN!!!



Randomized Trial to Prevent Vascular Events in HIV

Site Newsletter 10/23/2017

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REPRIEVE Trial Status: October 23rd

We had another amazing enrollment week, 63 participants were enrolled!

4768 participants are enrolled

278 participants are in screening

118 sites are open for enrollment

36 sites enrolled at least 1 participant in the past week

40 sites screened at least 1 participant in the past week

**Thank You to All Sites Enrolling
Participants Week of 10/16/2017!**

Brigham and Women's Hospital Therapeutics CRS
UCSD Antiviral Research Center CRS
University of Southern California CRS
Specialty Care Center CRS
Washington University Therapeutics (WT) CRS
Case CRS
Puerto Rico AIDS Clinical Trials Unit CRS
Penn Therapeutics CRS
Weill Cornell Uptown CRS
Weill Cornell Chelsea CRS
Wits Helen Joseph Hospital CRS (Wits HJH CRS)
Durban International CRS
Instituto de Pesquisa Clinica Evandro Chagas (IPEC) CRS
Hospital Nossa Senhora da Conceicao CRS
Gaborone CRS
Denver Public Health
Chiang Mai University HIV Treatment CRS
New Jersey Medical School-Clinical Research Ctr. CRS
Alabama CRS
Whitman-Walker Health CRS
University of Cape Town Lung Institute
Baystate Infectious Diseases Clinical Research
Wake Forest University
550 Clinic - University of Louisville CRS
Florida Department of Health Hillsborough County
UT Southwestern
Bluegrass Care Clinic/University of Kentucky Research FDN CRS
James J Peters VA Medical Center
Mount Sinai St. Luke's CRS
Toronto General Hospital
School of Medicine, Federal University of Minas Gerais CRS
Hospital Escola Sao Francisco de Assis
HGNI HIV Family Care Clinic HHFCC
Community AIDS Network/Comprehensive Care Clinic
Tropical Medicine Foundation
Centro de Referencia e Treinamento

1by1by1 Enrollment Challenge Standings



It's THE FINAL COUNTDOWN, only 2 weeks remain in the 1by1by1 Enrollment Challenge!

And we are so close to reaching the 75% enrollment milestone!!!

If 54 participants are enrolled each week between now and the end of the 1by1by1 challenge, we will achieve 75% of the 6,500 target enrollment. Only 107 participants are needed to reach this goal.

Remember, many sites will win!

- The site that enrolls the MOST participants during this challenge will be #1 of the 1by1by1 competition and win a \$200 gift card!
- Each site that enrolls 11 participants or more between July 1-October 31, 2017 will receive a \$100 gift card.
- Each site that enrolls 8-10 participants between July 1-October 31, 2017 will receive a \$50 gift card.

The clock started ticking on July 1st and will stop October 31st. Winners will be announced in the REPRIEVE Newsletter, week of November 13th!

Sites in the Lead!		
		Participants Enrolled Since 7/1
12701	Gaborone CRS	114
31946	Tropical Medicine Foundation	75
11201	Durban International CRS	73
31441	Byramjee Jeejeebhoy Government Medical College	66
12201	Hospital Nossa Senhora da Conceicao CRS	48
31927	HGNI HIV Family Care Clinic HHFCC	42
31802	Thai Red Cross AIDS Research Center	29
31784	Chiang Mai University HIV Treatment CRS	27
31864	UT Southwestern	26
31915	Federal University of Minas Gerais CRS	22
31954	Centro de Referencia e Treinamento	19
31917	Centro de Pesquisas Clinicas ICHCFMUSP CRS	18
11101	Wits Helen Joseph Hospital CRS (Wits HJH CRS)	16
8950	Family Clinical Research Unit	15
12101	Instituto de Pesquisa Clinica Evandro Chagas	13
31791	Whitman-Walker Health CRS	13
2101	Washington University Therapeutics (WT) CRS	12
31792	University of Cape Town Lung Institute	12
901	Univ. of Miami AIDS Clinical Research Unit	11
31868	Vancouver ID Research and Care Centre Society	11
31925	Hospital Escola Sao Francisco de Assis	11
31918	Hospital Federal dos Servidores do Estado	10
5802	The Ponce de Leon Ctr. CRS	10
11701	Chennai Antiviral Research and Treatment	10
7804	Weill Cornell Chelsea CRS	10
2401	Cincinnati CRS	9
6201	Penn Therapeutics CRS	9
31443	Trinity Health and Wellness Center	9
12301	SOWETO	8
31470	Denver Public Health	8
2501	Case CRS	8

Remember to Enroll in the Mechanistic Substudy (A5333s)!

For participating sites - the Mechanistic Substudy only needs to enroll **92 participants** to reach the enrollment target of 800 and we need your help to get there! Please remember to ask every participant screening for REPRIEVE (A5332) if they would also like to participate in the Mechanistic Substudy.

Enrollment strategies for the substudy include:

- Explain the purpose
- Explain the procedures in simple terms
- Explain the additional compensation
- Show pictures, such as a healthy heart and a heart with blocked arteries, a CT scan machine, etc.



Q: A participant reported at their month 4 visit they may start Directly Acting Antiviral Agents (DAAs) for the treatment of Hepatitis C (HCV). Can the participant continue on study medication if they start DAAs for HCV? Where do I document their use?

A: The participant may continue on study medication if they start DAAs for HCV.

Please note, DAAs for HCV are listed as precautionary medications on the Prohibited and Precautionary Medication list.

PRECAUTIONARY MEDICATIONS (redacted from the Prohibited and Precautionary Medication List located on the PSWP)		
Medication Category	Precautionary Concomitant Agents	Instructions Regarding Use During Study Participation
Directly Acting Antiviral Agents (DAAs) for Hepatitis C	All medications in this class.	<ul style="list-style-type: none">• Caution should be used when using new hepatitis C (HCV) DAAs in the setting of statin use.• Many of the new HCV medications have not been studied in combination with pitavastatin.• For new investigational HCV DAAs, please contact the core team at actg.corea5332@fstf.org for guidance regarding treatment initiation.

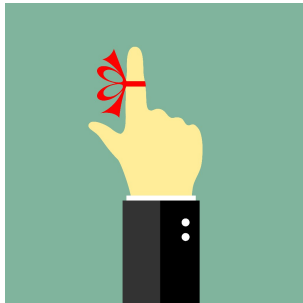
Please document concomitant use of DAAs on the Medications Log, as per section 5.3 of the REPRIEVE MOPS.

If the participant reports incident, active HCV defined as HCV infection manifest by HCV viremia that was not present at study entry, remember that this is a non-adjudicated event that needs to be reported as per section 6.2 of the REPRIEVE MOPS.

Q: We screened a potential participant today who has HCV, FIB-4 is 3.0, Fibrosure showed no cirrhosis. The participant is scheduled to start DAAs for

HCV treatment. If the participant completes their REPRIEVE entry visit next week, how long should we wait before starting HCV treatment?

A: The core protocol team defers to the clinical decision making of the site PI in conjunction with the participant's PCP. However, we would recommend considering delaying HCV treatment for approximately 4 weeks after study treatment initiation. This way, if the participant were to experience any side effects, the site investigative team and the clinical care team would be better positioned to determine whether symptoms were related to study treatment, HCV treatment, or other.



Reminder: BRI Holiday Closure

BRI will be closed on Friday, November 10th in observance of the U.S. Veterans Holiday. If you are shipping specimens during this week of November, please ship *only* on **Monday, Nov. 6 or Tuesday, Nov. 7.**

If your site is scheduled to ship the 3rd week of November, please note that ***BRI will be closed on November 23rd and 24th*** in observance of the U.S. Thanksgiving Holiday, sites shipping this week should *only* ship on **Monday, Nov. 20.**

If your site/laboratory is unable to ship during its designated week, you must make arrangements with the Repository Manager to ship on another date. To make arrangements with the Repository Manager, please email brirepository@afbr-bri.com.

Timeline for REPRIEVE DSMB Meeting

Meeting Date: Friday, December 15th, 2017

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 **ALL outstanding**

queries should be resolved by Friday, November 3rd.

Task		Deadline (2017)
	Latest date for the occurrence of an evaluation for which complete data will be included in this DSMB review	Sep 30 (Sat)
Sites	<ul style="list-style-type: none">All data for visits through Sep 30 enteredAll adjudication packets for potential MACE events with a work-up complete by Sep 30 submitted to DCC (MGH)*	Oct 13 (Fri)
Sites	All outstanding queries resolved	Nov 3 (Fri)
Sites	Respond to last minute outstanding queries	Nov 14 (Tue)
	<i>US holiday: Thanksgiving</i>	<i>Nov 23-24</i>
All	DSMB Meeting	Dec 15 (Fri)



TRAINING OPPORTUNITIES

New to REPRIEVE? Need a Protocol Training Refresher?

If you answered yes, please email Barbara Bastow BBastow@s-3.com for more details to join a protocol training refresher on **Tuesday, October 31st between 12:00 PM - 1:30 PM ET!**



Remember to include the following items with your shipments to BRI:

- LDMS-generated Shipping Manifest
- LDMS-generated Shipping Container Report (box map)

Do a 100% QA/QC of your storage box prior to shipping!

- Check the Global Specimen ID on your vials (the global ID is specific to each aliquot and ends with -001, -002, etc...).
- Each vial location in the physical box should perfectly match your Shipping Manifest and Shipping Container Report (box map).

If you have any lab-related question please email the REPRIEVE Lab Committee at reprise.labcom@fstrf.org

Miss the Last Monthly Site Call?

Topics covered by the team were:

- PREPARE Substudy Update
- LDMS Clarifications and Lab Tips
- FAQs to address ECG supplies, pregnancy prevention, and lost study medication

[Click here](#) to download slides



Monthly site calls are held the 3rd Tuesday of each month between 1:00 PM - 2:00 PM ET

Added Sweeteners & Heart Health in HIV

Katie Fitch, MSN, FNP-BC, REPRIEVE CCC Project Manager and colleagues recently published an article in [Open Forum Infectious Diseases](#) that evaluated the association between aspartame, an artificial sweetener, and coronary plaque in individuals with HIV.

Learn more about the article, added sweeteners, and heart disease in this month's **My Heart Matters Blog** located on the REPRIEVE Follow YOUR Heart website (link & image below)

Please share this important resource with your participants and colleagues!

[Click here](#) to go to the blog



REPRIEVE

<http://followyourheart.reprievetrial.org/news/>



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[Printable Advertisement Materials](#)

[My Heart Matters: Blog](#)



ANAC

Association of
Nurses in AIDS Care

November 2 — 4, 2017
The Fairmont Dallas

Will you be attending the ANAC Conference in Dallas? We would love to see you there!

Sara Looby, PhD, MSN, co-PI of the Women's Objective/Follow Your Heart Campaign will be presenting "U.S. Cardiovascular Disease in HIV: Traditional Risk Factors and Beyond" on Thursday, November 2nd between 10:45 - 11:45 AM. [Click here](#) for more details.

Katie Fitch, MSN, Project Manager of the REPRIEVE CCC will be having **Office Hours in the hotel lobby** ([click here for location](#)) on Thursday, November 2nd between 4:30 - 5:00 PM, stop by say hi and grab some REPRIEVE swag!

REPRIEVE (A5332): Are you up to date?

For A5332 please use

Protocol:

Version 3.0 dated 01/28/2016

Clarification Memo #1 dated 04/04/2016
Clarification Memo #2 dated 04/12/2016 (corrects an error in CM #1)
Clarification Memo #3 dated 12/27/2016
Letter of Amendment, Version 3.0 #1 dated 08/17/16
Letter of Amendment, Version 3.0 #2, dated 04/14/17

MOPS:

MOPS Version 3.0, dated 09/20/2017

A5332 LPC for ACTG Sites:

Version 3.0 dated 09/21/2017

A5332 LPC for Non-ACTG Sites:

Version 3.0 dated 09/21/2017

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

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

For A5333s please use

Protocol: Version 3.0 dated 01/28/2016

MOPS: Version 3.0 dated 06/05/2017

A5333s LPC: Version 3.0, dated 09/21/2017

These documents are on the [A5333s PSWP](#)



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

We welcome suggestions and ideas for upcoming newsletters. Please submit any comments or suggestions to the REPRIEVE News Team at reprieve.news@fstf.org.

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