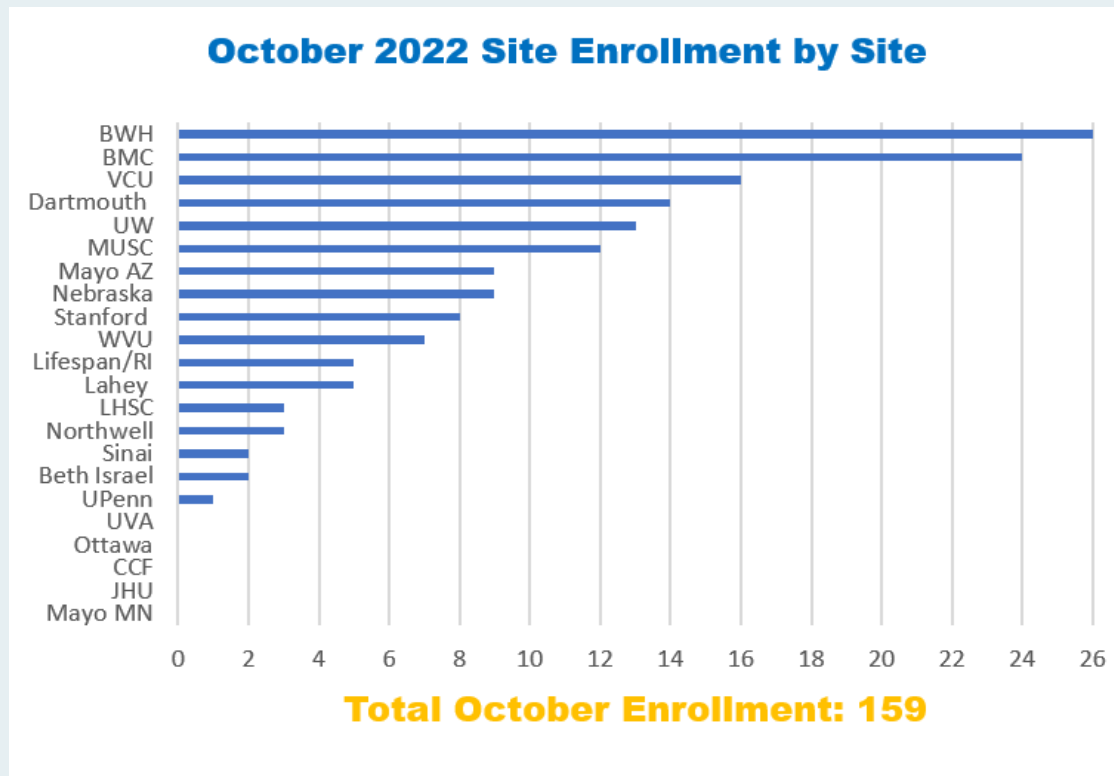


In this issue:

- Enrollment report
- Global Call
- PEPPER Puzzlers
- LTFU
- Statix Protocol
- Coordinator Profile

Recruitment

A better October after a slow summer – but we still have a lot of work to do!



Brian Gibbs – Set a new record for 1 month enrollment at BMC in August – then broke it again in October!

Eric McVey – Enrolled 1,000th patient at UVA in August.

Eric Jordan - Posted the highest enrollment this year at BWH in October.

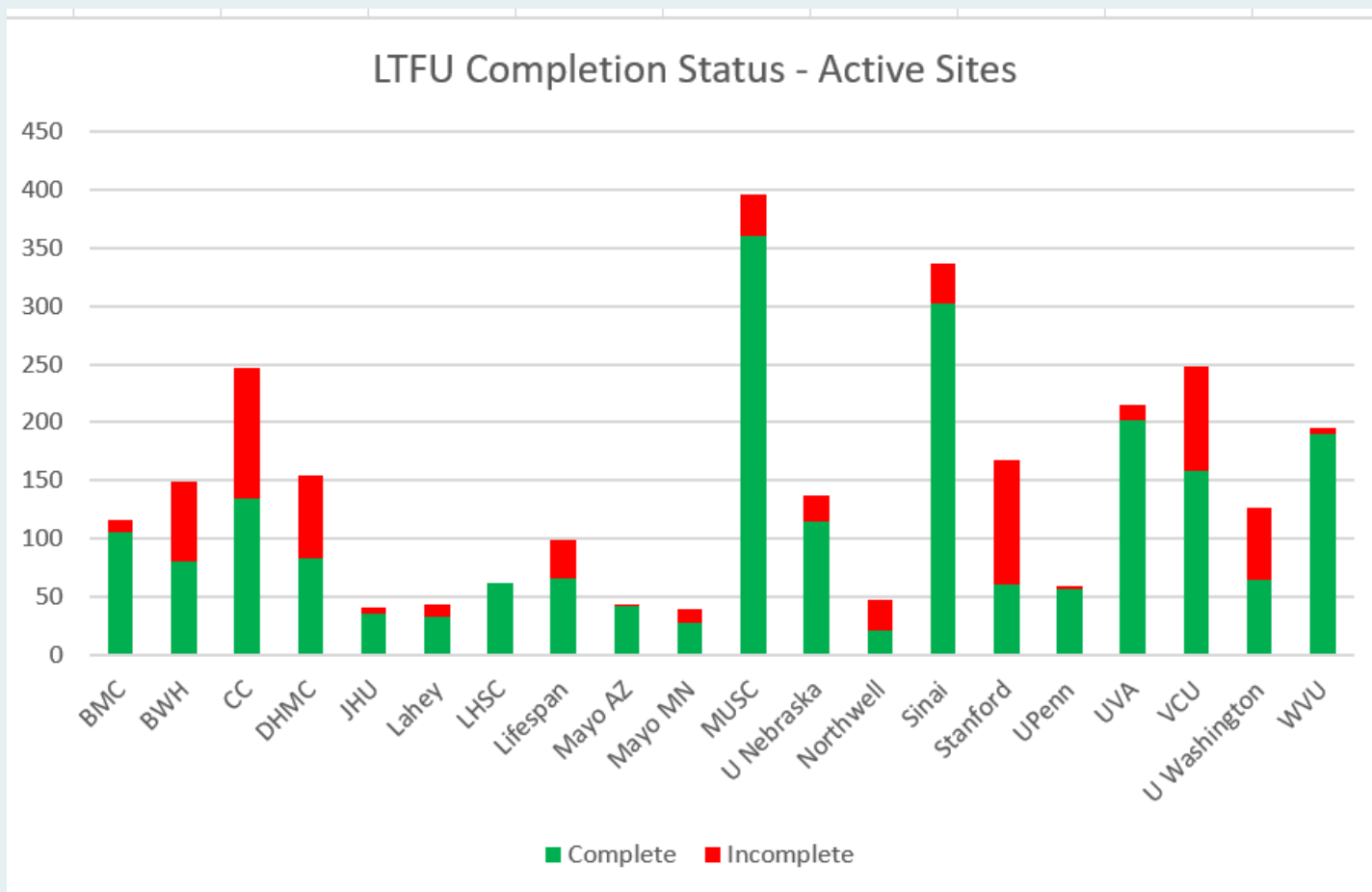
Melanie Morgan- Posted the 3rd highest enrollment of all sites for October at VCU.

Faviola Aguilar - Posted the highest 3 month average (Aug-Oct) for WVU over the past year.

Special Focus!

Lost to Follow Up

With the recent milestone reached of **15,000 enrollees** the study is poised for our next interim analysis in **March 2023**. It's important that we have as much data as possible for every participant. Please **pay special attention** over the next few months to reaching those patients who **missed their 6 month survey** in order to collect either their **full six month survey** or the **abbreviated survey**. If you cannot reach them, please do a **medical record review**. **The six month follow up is the most important data we collect for evaluating study endpoints.**



We Need *YOUR* Help!

Global Call



We had 19 Coordinators join us from 18 sites for our latest Global Call focusing on **Workflow: Best Practices**. Special thank you to **Anthony Lancellotti** for leading us off with a great presentation! Advice from fellow Coordinators focused on:

- **Organizing your Work**
- **Scheduling**
- **Communication with the Surgical Team**
- **Using your Enrollment Log**

Next up: Lost to Follow Up with **Faviola Aguilar**

Save the date!

December 12th @ 1:00 PM EST

December 14th @ 2:00 PM EST

**Special guest appearance
by Dr. Pellegrini!**



New Statix Protocol and Reminders



New! - In order to comply with HIPAA, Statix passwords should be changed every six months. However, there is not a function within Statix to remind you to do so. Going forward we ask you to **please change your Statix password whenever MUSC requests you change your REDCap password.**

Remember!

- If you need to withdraw a patient, use the **Report Withdrawn Report** in Statix rather than the attempt log.
- Submit the surgical adherence form **within 48 hours of surgery.**

PEPPER Puzzlers

These are **real life situations** that happened to Coordinators. What would you do?
What should you do according to protocol?

Statix contacted a Coordinator because a patient claimed their **surgery was cancelled** and they were not a participant. The Coordinator confirmed that the surgery **happened but that it had been rescheduled** from the original date due to COVID.

The Coordinator contacted the patient to confirm participation, however the **patient claimed she had not been told to take aspirin**, the drug she was randomized to, by anyone. Upon **examination of the medical record**, the Coordinator learned that not only had the patient been **given the initial aspirin dose prior to surgery** but also had been **given it in hospital** up to their discharge three days after surgery. Additional information also showed that she **received her aspirin dose** during her stay at a **rehab clinic post hospitalization**.

Given these conflicts between patient recollection and her medical record **what should be done?**

- a. Withdraw the patient. If she can't remember what happened, then she won't be able to fill out her survey accurately.
- b. Keep the patient in the study and ask her to fill out her survey.
- c. Keep the patient in the study but fill out a protocol deviation just in case the patient is right and she didn't receive her initial dose of aspirin pre-surgery.
- d. Tell the patient she is not remembering things correctly and she should fill out her survey as though she took all doses of aspirin.



See the bottom of page 5 for the answer!

Meet: Melanie Morgan

Site: Virginia Commonwealth University

What is your background?

I have a B.S. in Biology and Master of Public Health. I've been working in research since 2013 on a variety of health topics. I started out doing social and behavioral research and worked as a research assistant in graduate school. I then transitioned into clinical research, in which I like the clinical aspect and have been doing it ever since in different specialty areas, currently with orthopaedic surgery.



What do you enjoy most about working on PEPPER?

I think it's great to find out what's working best for which patients. I feel it's contributing to broaden knowledge of the 3 drugs. When I approach patients about the study, the vast range of different patient perceptions of the medications amazes me. It's also interesting how many patients were excited to do the study to see their chances at receiving something besides Coumadin, as when I first joined our Department, all of our patients were given warfarin postoperatively. I feel over the years people are more open to the different options, particularly Xarelto, than in the beginning of the study.

Favorite movie, music or food?

I stream everything I want to watch now with Netflix, Hulu, etc. I often watch The Masked Singer. I like all different kinds of music. I'm particularly a fan of early 2000's and before, especially 90's R&B. I like any Italian food, with chicken alfredo being one of my favorites.

Fun fact or hobby:

I enjoy movies, watching basketball, going dancing, and yoga. When I travel, I love going anywhere with a beach.

Anything else you'd like to share about yourself?

I'm getting excited about the holiday season coming up, as it is my favorite time of year for decorating, cooking, and spending time with family and friends.

PEPPER Puzzler – Answer

The answer is b. We can never control how accurately a patient fills out their survey, so in essence this is no different than any other PEPPER participant. However, this also may be a case for "No Contact". If the patient is unwilling or unable to complete the surveys, we can still keep her in the study and simply perform a 6 month medical record review once she hits the REDCap LTFU database.
