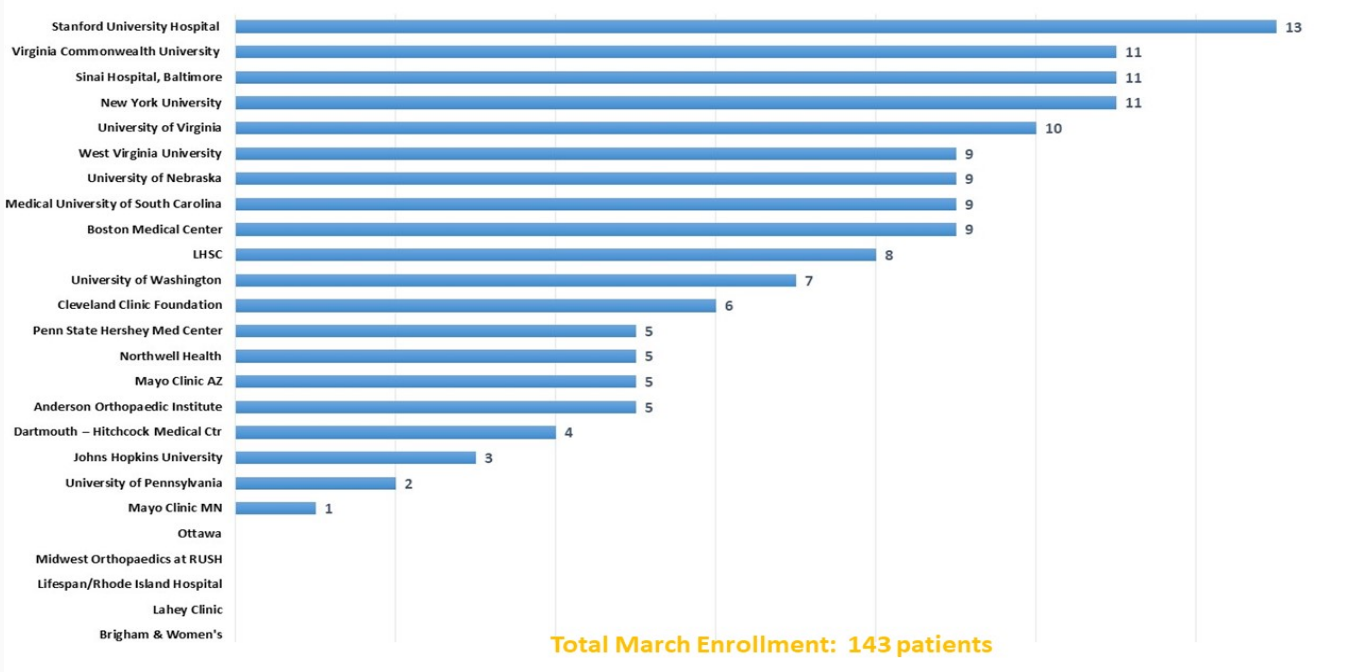
PEPPER

Pulmonary Embolism Prevention after hiP and kneE Replacement



PEPPER COLLEAGUES, WE MISS YOU!!

And so we are elated to hear that the majority of you have begun to 'Go Live' with the next phase of PEPPER recruitment, with the sites that remain not far behind!

With this news in mind, please know that we in the Clinical Coordinating Center have also been hard at work, excited to present the following updates to your PEPPER trialing experience:

The PEPPER Newsletter is back!!

Every month the usual updates on enrollment will begin to be paired with other study metrics of similar importance to trial outcomes. This gives more sites a chance to highlight their strengths, all the while learning from others to refine areas of weakness. We'll be showcasing your tips and tricks in the newsletters to come!

NEW COVID-19 Questionnaire

COVID-19 may present important changes to patient perceptions of procedural urgency and safety. The PEPPER team would also like to know if prior exposures, symptomatic or not, affect one's risk for DVT or PE. This brief, but optional questionnaire will soon begin to be administered centrally; *There are no additional work requirements at the level of the site.*

Testing STATIX 2.0

We continue to partner with our content development experts at Statix, to deliver refinements that make sense for the end user. We look forward to showing you what they've been up to, and rolling out a training strategy as soon as they are ready!

Calling all ASAC data requests: Do we have YOUR site's PEPPER proposal yet?

- ✓ This is for requests for use of PEPPER data for ancillary science that does **not** compromise PEPPER's primary and secondary outcomes
- ✓ Data set includes demographics, comorbidities, surgical variables, HOOS/KOOS metrics and PRO's at each follow-up
- ✓ Reach out if you'd like a copy of the ASAC submission form

RedCap e-Consenting is coming!

An updated consent form will be used to facilitate all methods of consent: ***in-person***, ***by phone*** and ***e-Consent!***

- ✓ Includes an optional checkbox for contact about future research

E-Consent version will be loaded directly into RedCap

- ✓ An email link directly to a scrollable consent form during the education process
- ✓ 'Real time' counter-signing and dating immediately unlocks the Baseline Survey & Contact Form processes

Et Voila'! Fit for COVID and beyond! Missed clinic visits abated; transportation issues solved!

HOW'S YOUR CHECKLIST GOING?

E-Consenting Logistics?

Will your site situation call for in-person, all virtual, or hybrid recruiting?

✓ On-Site vs. Off-Site division of labor: well-anticipated, mapped out, coordinated and communicated across all relevant team mates?

✓ Ensuring visible access to the PEPPER consent form: what if your patient doesn't have an email account? Internet-savvy, but stymied by poor connectivity in the hospital or at home? Is someone on campus willing and able to provide paper copies of the consent form? Bumper tablets prior to/during the consenting phone call?

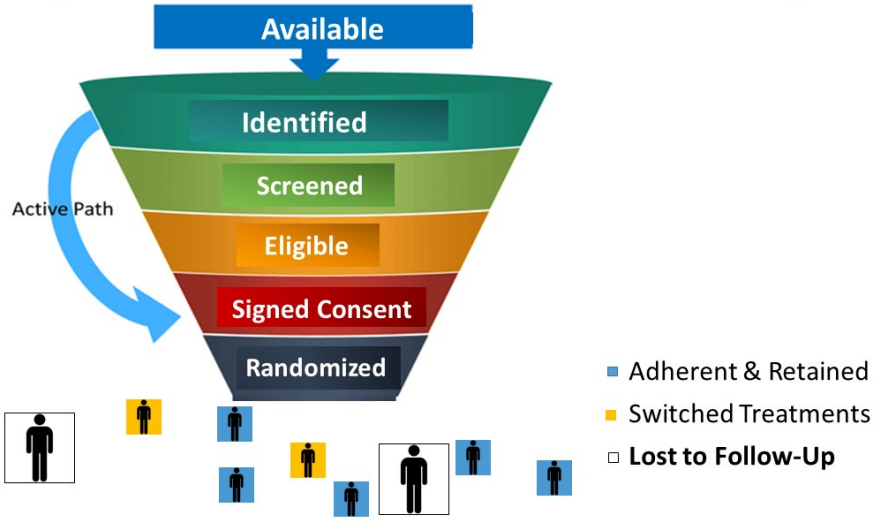
Any INR Monitoring changes?

Some sites are reporting changes to the way INR monitoring is handled at their site. Any changes to the following should be reported to the Clinical Coordinating team, before attempting to 'go live' with PEPPER recruiting. Thank you!

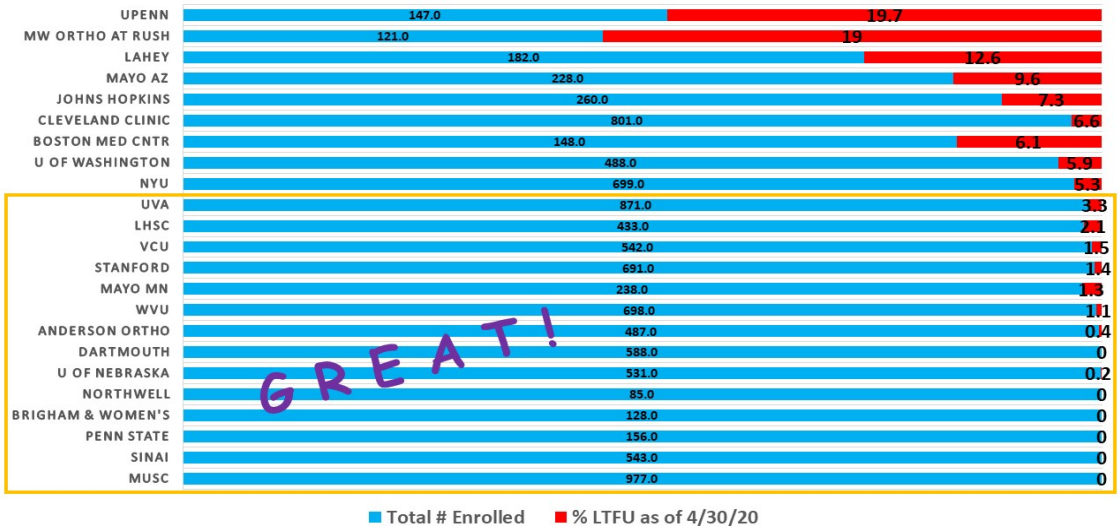
- ✓ Any changes to the general availability or usual 4-week duration of monitoring typically provided by outpatient clinics, home health agencies, or visiting nurses working in your area?
- ✓ Any LSI's, Surgeons, Physician Assistants or Pharmacists temporarily reticent to prescribe or adhere to a Coumadin prescription, due to exposure concerns?

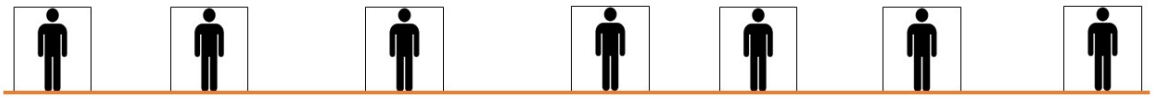
Catch up on Lost-to Follow-Up

'What's Up' with Lost to Follow-Up?



Sites at top in red, We Need Your Help!





How Important is it?

Very Important. It can severely threaten the validity of any trial's outcomes. For example, what if these patients are different from those who remained in the study?

- ✓Patients who return to full function quickly, and feel no need to return to the clinic or Statix survey phone calls

  OR

- ✓Patients who don't return, because they've had a particularly bad outcome (worsening pain or function, a complication, or death)

In either case, missing data can affect accurate estimates of benefit and harm. This is why we ask that you treat 'Lost to Follow-Up' tasks as an incumbent part of any enrollment occurring at your site. No matter what your % LTFU currently is…know that another LTFU dataset is imminent. *Do not relax your grip, friends!*

Having a hard time catching up?

We get it. Despite your best efforts, not everyone will be 'found'. However, if your LTFU is above 5%, we ask that you please revisit past efforts to ensure due diligence and double-down where you see gaps to explore. Reach out if you need help.

Are you really good at resolving 'Lost to Follow-Ups'?

Please reach out to your Coordinating team. We'd be honored to put you in touch with a site refining this skillset! Working together, we can nail this.

Your CAC is coming - Stay Tuned!

Our mailing address is:
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