

BEST-CLI – August Anniversary is the BEST!

It's been one year since the first subject was enrolled in BEST! Let's continue to make August the BEST summer month for enrollment!

From the Desktop of Matt Menard, MD

I hope that everyone has had a wonderful summer! We at BEST-CLI have spent it reaching out to sites to discuss the trial. With input from site investigators, we took time to critically assess obstacles to successful enrollment. We then went “back to the drawing board” and re-evaluated the steps that we, in the trial leadership, could take to help investigators enroll into the trial. Upon careful consideration we have suggested a number of changes to our Data Safety and Monitoring Board (DSMB). These changes were accepted by the DSMB and will be coming your way within the next month as a protocol amendment. Herein, I will review a partial list of these “coming attractions”. Please keep in mind that the purpose for these changes is to make enrollment easier while still maintaining the fidelity of the trial. These changes will only go into effect at your site after approval by your IRB. In the month of September and October we will be scheduling webinars where the protocol amendment will be discussed in detail; any questions will be answered at that time. Attendance by investigators at one of these webinars will be mandatory.

The following represent some of the major changes to the protocol:

1. The **lower age limit of the study population will be lowered** from 35 to 18 years.
2. The **term atherosclerotic will be removed from the inclusion criterion of atherosclerotic, infrainguinal PAD**. This will allow inclusion of patients whose occlusive disease may have been caused by entities other than atherosclerosis (i.e. chronic thromboembolic disease).
3. The exclusion criterion of **disease limited to fem-pop segment with TASC IIA pattern will be deleted**. The decision to enroll such patients will be left up to the investigators.
4. The **exclusion criterion of >50% common femoral artery (CFA) disease will be deleted**. Patients with any stenosis or occlusion of the CFA will be allowed. The investigators will be allowed to treat the CFA in any way they wish (open or endo) and the randomization will affect the occlusive disease distal to the CFA.
5. The **exclusion criterion of known hypercoagulable state will be deleted**. The decision to enroll such patients will be left up to the investigators.
6. The **exclusion criterion of current immunosuppressive medication will be deleted**. The decision to enroll such patients will be left up to the investigators.
7. The **exclusion criterion of known allergy to stainless steel or nitinol will be deleted**. The decision to enroll such patients will be left up to the investigators.
8. The **exclusion criterion of known non-atherosclerotic disease will be limited to active vasculitis, Buerger's disease, or acute lime ischemia**.
9. The **exclusion criterion regarding timing of previous procedures performed on the index limb will be adjusted from within 6 months to within 3 months**.
10. The **exclusion criterion regarding timing of surgical inflow procedures performed on the index limb will be adjusted from within 6 months to within 6 weeks**.

We believe that these changes will improve patient enrollment and look forward to going over these details with you during the webinars. See you soon!


Data Freeze for DSMB Meeting!

Our next DSMB Meeting is scheduled to occur on November 24, 2015, which is soon approaching. The data freeze date for this meeting has been scheduled for **Monday, September 14, 2015**. Please ensure that all data are entered by this date, and all queries are set to “answered.” If for any reason you need to have a form set to “missing,” please immediately reach out to the [BEST DM Mailbox](#), [Kathryn Odian](#), Senior Data Manager, or your individually assigned CRA. [Enter your data today!](#)

BEST July Highlights

Number of New Sites Activated: 8
Top Enroller
1238 / Univ. of Massachusetts Medical School
Sites Enrolling 1st Subject: 7

Upcoming Investigator Meetings



VASCULAR INTERVENTIONAL ADVANCES

VIVA in Las Vegas, NV
 Information Coming Soon!



VEITH in New York, NY
 Information Coming Soon!



Brigham and Women's Hospital

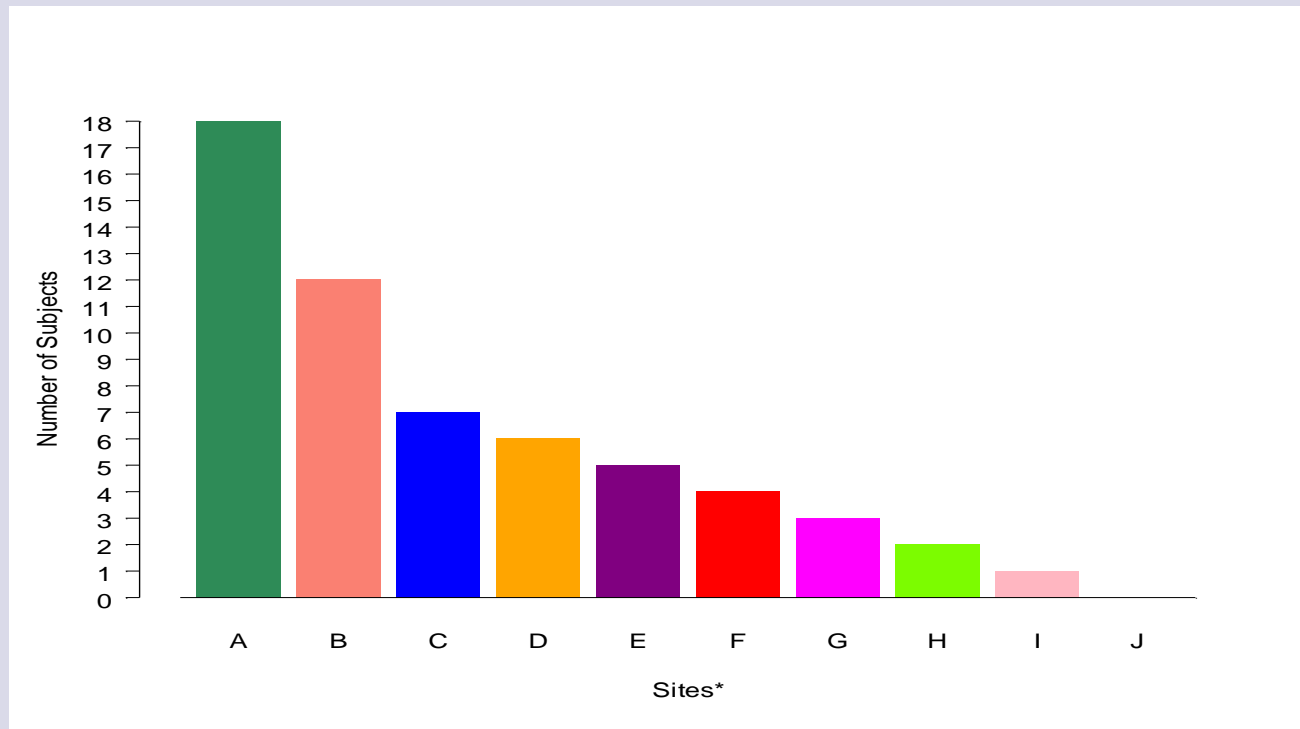


Seated, left to right: Dean Arnataoukis, MD (vascular surgery fellow), Keith Ozaki, MD; standing left to right: Louis Nguyen, MD, Samir Shah (vascular surgery fellow), Matthew Menard, MD, Yasser Motii (research coordinator). Missing in the picture are vascular surgeons Michael Belkin, Jonathan Gates, Edwin Gravereaux and Marcus Semel, interventional cardiologist Piotr Sobieszczyk and interventional radiologists Chieh Min Fan, Alisa Han, Timothy Killoran, Susan O'Horo, Dmitry Rabkin, Matthew Schenker and Michael Stecker.

The BEST-CLI team at the Brigham and Women's Hospital has been aggressively and collaboratively working towards finding suitable patients to enroll in this clinical trial. The team is home to one of the national PIs (Matthew Menard, MD) and is led by Michael Belkin of vascular surgery, Piotr Sobieszczyk of interventional cardiology and Chieh Min Fan of interventional radiology. The site CLI team is comprised of MDs from all three specialties, PAs, vascular surgery fellows and a study coordinator and meets regularly to discuss potential subjects eligible to enroll in the study. As the study has progressed, we have looked closely at the way we have screened patients, in an effort to better capture both inpatients and outpatients. To date, roughly equal numbers of inpatients and outpatients have been successfully enrolled into the trial at our site.

Participating in the BEST trial has served to strengthen the existing collaborative relationships between the three specialties that are involved. One of the keys to our success in randomizing patients into this important trial has been to ensure that each participating investigator is knowledgeable about the trial protocol and actively engaged in the effort to identify potential patients.

Enrollment Leaderboard*



Sites*

- A: 1160 - Keck MC of USC ; 1258 - Boston MC
- B: 1238 - Univ. of Massachusetts Medical School
- C: 1009 - Dartmouth Hitchcock MC; 1272 - St. Boniface General Hosp.; 1282 - Carondelet Heart & Vascular Inst.
- D: 1105 - Medical College of Wisconsin; 1288 - Kaiser Foundation Hosp.; 1314 - VA Boston Healthcare System
- E: 1005 - Brigham and Women's Hosp.; 1013 - Harbor-UCLA MC ; 1095 - Johns Hopkins Hosp.; 1108 - Michigan Heart/St Joseph Mercy Ann Arbor Hosp.; 1316 - Holy Name MC
- F: 1029 - Michael E. DeBakey VAMC ; 1055 - Mount Sinai MC; 1217 - Univ. of California Davis MC; 1260 - Greenville Memorial Hosp.; 1281 - VA Western NY Healthcare System; 1308 - The Ohio State Univ.; 1309 - Mercy Hosp. MC; 1310 - Harborview MC; 1332 - Denver VA MC
- G: 1030 - Montefiore MC; 1101 - Albany MC; 1113 - Oregon Health and Science Univ.; 1269 - Ohio Health Research Inst.; 1274 - Univ. of Oklahoma Health Sciences Ctr.; 1276 - Memorial Hermann Hosp. TMC; 1318 - Univ. of North Carolina Hosp. (Chapel Hill); 1323 - Univ. of Nebraska MC;
- H: 1010 - Emory Univ.; 1023 - Massachusetts General Hosp.; 1041 - San Francisco VAMC; 1046 - Steward St. Elizabeth's MC; 1054 - Univ. of Colorado Hosp.; 1066 - Arizona Heart Hosp.; 1076 - Northwestern Memorial Hosp.; 1104 - VA Palo Alto; 1125 - Univ. of California San Francisco MC - Parnassus; 1135 - Univ. of Pittsburgh MC; 1169 - Univ. Hosp. of Cleveland/Case Western Reserve Univ.; 1182 - Providence Heart and Vascular Inst.; 1234 - Univ. of Toledo MC; 1261 - Indiana Univ. Medical School; 1264 - Minneapolis Heart Hosp.-Abbott Northwestern Hosp.; 1271 - Southern Illinois Univ. SOM; 1275 - Medical Univ. of South Carolina; 1277 - The Univ. of Utah; 1284 - Chu de Quebec; 1290 - Loma Linda Univ. MC; 1304 - CAMC Clinical Trials Center-Univ. of West Virginia; 1311 - Dallas VA MC (affiliated w/UT SW); 1326 - The Miriam Hosp.-Brown Medical School; 1331 - Pinnacle Health System

Enrollment Leaderboard Continued

- I: 1137 - The Univ. of Vermont MC, LLC; 1151 - William Beaumont Hosp.; 1188 - Toronto General Hosp.; 1256 - Beth Israel Deaconess MC; 1257 - Univ. of Arkansas for Medical Services; 1263 - Kaiser Permanente (San Diego); 1270 - Scott and White – Temple; 1273 – Univ. of Florida (Gainesville); 1279 - North Carolina Heart and Vascular Research; 1287 - Providence Sacred Heart MC; 1294 - North Central Heart Inst.; 1305 - Univ. of Virginia (Cardio-Vascular-Radiology); 1325 - Deborah Heart and Lung Center
- J: ***

*Data frozen on 8/27/2015.

**Site names abbreviated to accommodate space.

***Full list of sites can be found on NERI Connect

FAQ – The DSMB freeze is right around the corner! How do I catch up with my data entry?

Reports are available within eCOS to help sites identify what work needs to be done in the system. When logged into BEST there is reports box on the study landing page, where these can be generated.

The Page Status Report can be a great resource to help identify pages that need to be data entered, however it can be a bit overwhelming when it's first opened as it includes a line for every CRF available for each patient at your site. To narrow this down to a list of those that need to be entered, we recommend adding filters. To do so, open the page status report and select from the dropdowns 'Page Status' and '=' the type "Expected" into the text box.

Filter By

Page Status Expected

Hit "Add" and the report below will now only list the forms at an expected status. Multiple filters can be added as needed to help narrow the list as well. For example, if I wanted a list of expected forms but wanted to exclude any for the end of study, I can add an addition filter by selecting "Visit" and "=" and entering "End of study" and hitting Add.

Filter By

Page Status = "Expected" Visit ≠ "End of study"

The report will now list all forms that are expected that are not part of the end of study visit.

Showing 1 to 100 of 1,059 entries

Country	Site #	Site Name	Subject	Visit	Page	Page Status	Deleted?
United States	1101	Albany Medical Center	1101001	30 Days Post Procedure	Visit Information	Expected	