BEST-CLI – Beat the heat, enroll your BEST (subjects that is!)

May the fourth be with you this July to enroll more subjects! BEST-CLI teams are blasting away with increased recruitment efforts!

From the Desktop of Alik Farber, MD

We recently caught up with Rick Powell, Professor and Chief of Vascular Surgery at Dartmouth Hitchcock Medical Center and a founding member of the BEST-CLI Leadership Team, to ask him about BEST-CLI.

You have been a big part of the BEST-CLI trial effort to date. In addition to being a Co-Investigator at Dartmouth Hitchcock Medical Center, what other roles do you serve in the trial?

RP: I currently serve on the Executive Committee and the Ancillary Studies Committee. I also chair the Surgical Interventional Management Committee (SIMC) which is our credentialing committee.

What is your view of the goals and potential impact of this trial in the context of your own practice and CLI treatment, in general, in North America?

RP: The trial will answer important questions regarding the potential treatment options in the care of patients with critical limb ischemia. Each day we see patients with CLI and have very little data to support our treatment decisions. This trial will have a huge impact on the care of this currently underserved patient population.

After a slow start, Dartmouth has been quite successful in enrolling patients over the recent months. What do you think made the difference in your more recent success? Have the investigators on your CLI team been able to put aside their own biases in determining the eligibility of patients for both open surgery and endovascular therapy?

RP: It is critically important for there to be an advocate for the trial who keeps BEST-CLI front and center in the co-investigators minds during busy, clinically demanding days. Phil Goodney at our site has done a great job of reminding all of us at Dartmouth to try and enroll every CLI patient into BEST. It is not easy to put aside your individual biases until you realize that there are individuals in your own group with biases opposite to those that you hold. It then becomes clear that there is equipoise in how these patients should be treated.

Through your work on the BEST-CLI trial, what have you learned about multi-disciplinary practice at other sites?

RP: As the chair of our credentialing committee I have talked with many of the investigators throughout the country. Each site must determine which approach to patient flow will work best for them. The trial is an ideal mechanism for different specialties to come together to share ideas regarding CLI care that, in the end, will only improve the care of the patient.

You are a big clinical trialist – how does the BEST-CLI trial compare to other trials you have been involved with?

RP: I have served as the PI for numerous gene and cell therapy trials for CLI. CLI trials are difficult to run because of the frail and heterogeneous patient population. The size and scope of BEST-CLI is impressive and I think the fact that the specialties that care for these patients have come together to work on developing and implementing this trial, demonstrates that we can work together. In the vascular disease world this will be a landmark trial that is similar in impact to the early carotid endarterectomy trials and the recently completed CREST trial.

Funded by: NIH National Heart, Lung, and Blood Institute

Site Spotlight

UMASS Medical School

1st row: Kate Small NP, Jess Simons MD, Donna D'Agostino NP, Marcel Droz PA, Shauneen Valliere NP SC, Jan Beschle NP, Devon Robichaud NP. 2nd row: Andres Schanzer MD, Louis Messina MD, Elias Arous MD, William Robinson MD, Joan Dowd NP, Colleen Hanesian CWON, Francesco Aiello MD, Lorraine Loretz DPM, NP, Danielle Doucet MD. Missing: Mollynda McArthur RC, Mohammad Akhter MD, Daniel Fisher MD

"The UMASS Memorial multidisciplinary BEST-CLI team under the leadership of Andres Schanzer MD has been successful in enrolling and treating subjects in the trial due to the focus of faculty and residents in identifying potential subjects in both the inpatient and outpatient settings. We have noticed that recruitment of inpatients has generally been more successful than outpatients with 2/3rds of our subjects recruited from the inpatient setting.

We attribute this difference to faculty, residents and study coordinators having more time to discuss the study and why it is important. Patients also have more time to carefully read the informed consent form and have their questions answered.

Unlike many of our studies, we feel strongly that this study requires the patient's attending surgeon or interventionalist to first present the study to the patient and be available for follow up discussion should it be necessary."

Request for Screening Logs!

Screening Logs are due bi-weekly to the DCC. The next round of screening logs is due

August 7th

Click here to submit yours!

Be sure to document all screen failures on your screening logs.

Mid Study Update Complete!

At the DSMB meeting held on 01/June/2015, the DSMB requested that sites identify patients that have bilateral disease. An additional section has therefore been added to the end of the Vascular Physical Assessment page (see page 4 for details).

To learn more about this Mid Study Update, check out DM Memo #4, posted on NERI Connect.

BEST June Highlights

Number of New Sites Activated: 10

Top Enroller: 1238 / University of Massachusetts Medical School

Sites Enrolling 1st Subject: 5

Got Questions?

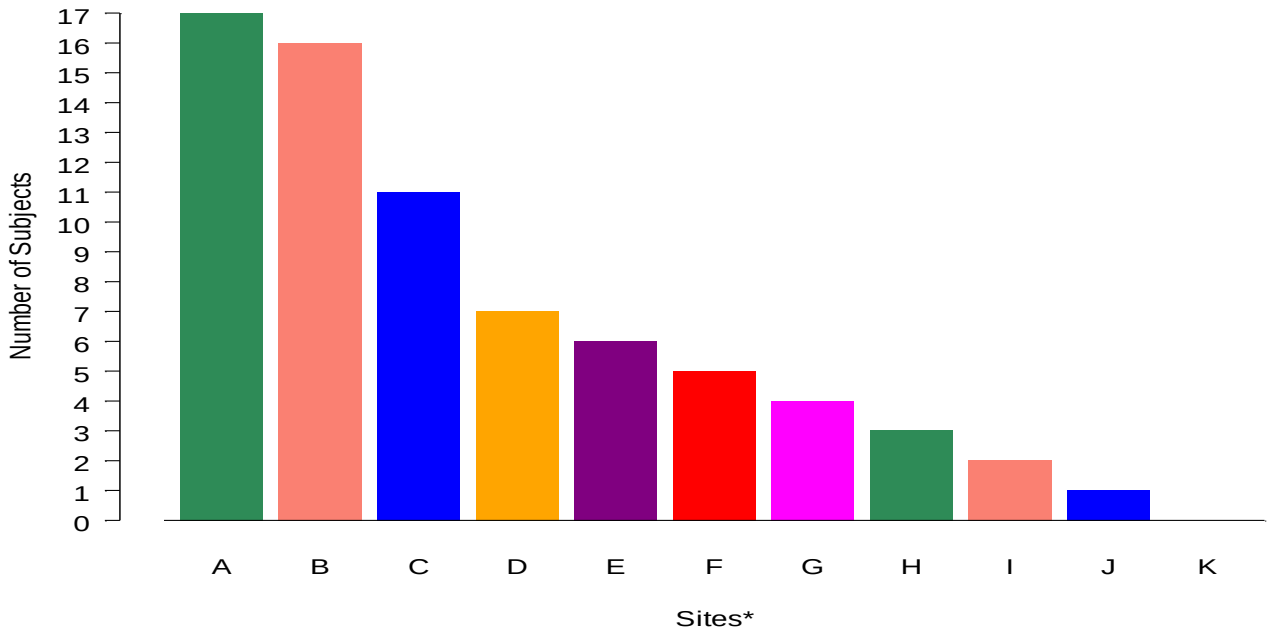
Wonder whether that potential subject with SFA disease is eligible?

- The toll free number to reach a member of the Clinical team is 1-844-BEST-120 (1-844-237-8120) available 24 hours a day.
- You can also reach out to your CRA who to forward your questions to the Clinical team. The email address to reach the BEST-CLI DCC team is best@neriscience.com.

Queries are complete but still showing as a "Q" even though the query is resolved?

- This is a question for our data management team! Kathryn Odian, Senior Data Manager, can be reached at kodian@neriscience.com or 617-972-3363 or DM-Best@neriscience.com.

Enrollment Leaderboard



Sites*

A: 1258 - Boston MC

B: 1160 - Keck MC of USC

C: 1238 - Univ. of Massachusetts Medical School

D: 1009 - Dartmouth Hitchcock MC

E: 1105 - Medical College of Wisconsin; 1282 - Carondelet Heart & Vascular Inst.; 1314 - VA Boston

F: 1005 - Brigham and Women's Hosp.; 1013 - Harbor-UCLA MC ; 1108 - Michigan Heart/St Joseph Mercy Ann Arbor Hosp.; 1272 - St. Boniface General Hosp.; 1288 - Kaiser Foundation Hosp.; 1316 - Holy Name MC

G: 1029 - Michael E. DeBakey VAMC; 1055 - Mount Sinai MC; 1095 - Johns Hopkins Hosp.; 1217 - Univ. of California Davis MC; 1260 - Greenville Memorial Hosp.; 1281 - VA Western NY; 1309 - Mercy Hosp. MC; 1310 - Harborview MC; 1332 - Denver VA MC

H: 1113 - Oregon Health and Science Univ.; 1276 - Memorial Hermann Hosp. TMC;1318 - Univ. of North Carolina Hosp. (Chapel Hill)

I: 1041 - San Francisco VAMC; 1046 - Steward St. Elizabeth's MC; 1054 - Univ. of Colorado Hosp.; 1066 - Arizona Heart Hosp.; 1076 - Northwestern Memorial Hosp.; 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.; 1261 - Indiana Univ. Medical School; 1269 - Ohio Health Research Inst.; 1271 - Southern Illinois Univ. SOM; 1277 - The Univ. of Utah; 1304 - CAMC Clinical Trials Center-Univ. of West Virginia; 1311 - Dallas VAMC; 1323 - Univ. of Nebraska MC; 1326 - The Miriam Hosp.-Brown Medical School; 1331 - Pinnacle Health System

J: 1003 - Allegheny General Hosp.; 1007 - Cleveland Clinic Foundation; 1010 - Emory Univ.; 1023 – Massachusetts General Hosp.; 1030 - Montefiore MC; 1034 - Ochsner MC-Clinic Foundation; 1072 - Univ. of Wisconsin – Madison; 1104 - VA Palo Alto; 1137 - The Univ. of Vermont MC, LLC; 1151 - William Beaumont Hosp.; 1188 - Toronto General Hosp.; 1234 - Univ. of Toledo MC; 1256 - Beth Israel Deaconess MC; 1257 - Univ. of Arkansas for Medical Services; 1263 - Kaiser Permanente (San Diego); 1264 - Minneapolis Heart Hosp.-Abbott Northwestern Hosp.;

Enrollment Leaderboard Continued

J: 1270 - Scott and White – Temple; 1273 – Univ. of Florida (Gainesville); 1274 - Univ. of Oklahoma Health Sciences Ctr.; 1275 - Medical Univ. of South Carolina; 1279 - North Carolina Heart and Vascular Research; 1284 – Chu de Quebec; 1287 - Providence Sacred Heart MC; 1290 - Loma Linda Univ. MC; 1294 - North Central Heart Inst.; 1305 - Univ. of Virginia (Cardio-Vascular-Radiology); 1308 - The Ohio State Univ.; 1325 - Deborah Heart and Lung Center

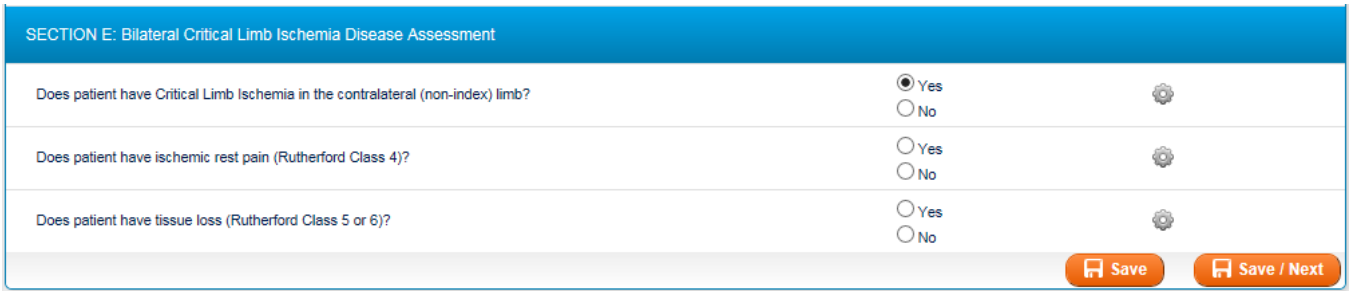
K: 1008 – Columbia Univ. MC; 1019 - Jewish General Hosp.; 1024 – Mayo Clinic (Rochester); 1026 - Medstar Washington Hosp. Center; 1059 - The Univ. of Alabama at Birmingham; 1061 - Baptist Hosp. of Miami; 1075 - Swedish MC; 1085 – Cedars Sinai; 1101 - Albany MC; 1116 - Rush Univ. MC; 1121 – Temple Univ.; 1123 – Thomas Jefferson Univ.; 1126 - Univ. of Chicago Medicine; 1131 – Univ. of Maryland; 1134 - Univ. of Michigan Health System; 1154 – Yale; 1229 - Penn State Milton S. Hershey MC; 1259 - Rhode Island Hosp.; 1280 - Metro Health Hosp.; 1283 – Univ. of Oklahoma College of Medicine at Tulsa; 1285 – Duke; 1289 - Lenox Hill Hosp.; 1293 - Univ. Health System: LSU Health Sciences; 1295 - Oklahoma Foundation for Cardiovascular Research; 1296 - Sacred Heart Hosp. River Bend; 1297 – St. Joseph Hosp.; 1298 – Tufts MC; 1299 - Univ. of Tennessee MC; 1301 – UCSD-Sulpizio Cardiovascular Center; 1302 - UCLA-Gonda Vascular Surgery; 1306 – McGill; 1315 - George Washington Univ. Hosp.; 1317 - Roper Hosp.; 1319 - Hunterdon MC; 1320 - Portland VA MC; 1327 - Wellmont Holston Valley MC; 1330 - The Heart Center of Lake County; 1334 – Stanford; 1336 - Staten Island Univ. Hosp.; 1337 – Loma Linda VAMC; 1339 – Cadence Health (Chicago); 1340 – Wake Forest Baptist Hosp.; 1341 – Meriter Wisconsin Heart; 1344 – Michigan Vascular Center; 1345 – Los Angeles MC, Kaiser Permanente; 1346 – Gunderson Health System

*Site names abbreviated to accommodate space.

FAQ – Subjects with Bilateral Disease

Q: What information has changed on the Vascular Physical Assessment page?

A: Upon initial entry there will be one new question asking if the subjects had disease in the contralateral (non-index) leg. If this question is answered yes (as pictured below), two additional questions will appear regarding the Rutherford Classification as shown in the screen shot below.



This update was made retrospectively, so it did result in an open query for currently enrolled subjects. Please review the medical record or consult with the PI as needed in order to complete questions for these subjects.

Quick tip for closing missing data queries! If you enter the missing data directly on the page first, eCOS will recognize that the query is no longer valid and automatically close it. There will be no need to update it to answered and provide a comment.

A corresponding worksheet can be found on NERI Connect: https://connect.neriscience.com.