

BEST-CLI Summer 2016 Newsletter – Issue 16

From the Desktop of Alik Farber...

As BEST-CLI is approaching the milestone of being 1/3 enrolled I wanted to share the current demographics of the participating sites and investigators. As National Co-Principal Investigators, Matt, Kenny and I have taken great effort to make sure that the sites and investigators represent well the physicians who currently treat patients with advanced peripheral arterial disease in North America.

Of the 132 sites that were originally activated 121 sites are currently open for enrollment. The geographic distribution of sites is balanced. 24.0% are in the American Northeast, 20.7% are in the Midwest, 24.0% are in the South and 25.6% are in the West. We have 7 active sites in Canada.

With regard to site investigators, 129 are interventional cardiologists (IC), 129 are interventional radiologists (IR), 7 are interventional vascular medicine specialists (VM) and 610 are vascular surgeons (VS). We have taken great effort to engage everyone who regularly treats critical limb ischemia and to that end 75.2% of our sites are multidisciplinary. Of these multidisciplinary site, 16.5% of have VS, IC and IR investigators, 20.7% of sites have VS and IR, 32.2% of sites have VS and IC, 24.8% of sites have VS alone and finally 5.8% of sites have VM in combination with other specialties.

BEST-CLI is a gargantuan multidisciplinary endeavor that is slowly but surely moving closer to its eagerly awaited finish line. At this finish line is the scientific version of a “pot of gold” which will lead to the establishment of an evidence-based standard of care for the treatment of patients with advanced peripheral arterial disease. On behalf of the BEST-CLI leadership we thank you, **The BEST Nation**, for your effort and support. Please keep up your screening and enrollment!

BEST Spring Highlights

TOP ENROLLER:

Site 1160, Keck Medical Center of USC

OF PATIENTS ENROLLED:

32 Patients



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As a reminder:

All PI's must login to eCOS to electronically sign off on all 'COMPLETED' and 'MONITORED' pages.
Please do this on a monthly basis!

...On the question of cardiac and neurovascular assessment...

Dear BEST-CLI Colleagues,

Over the next week, all investigators will be receiving a brief survey to complete regarding cardiovascular and neurovascular testing in your patients with CLI. Our NIH Data Safety and Monitoring Board (DSMB) is concerned about “ascertainment bias”...that is:

- a) Are there differences in physician approach or institutional practice when looking for adverse cardiac events or stroke?
- b) How might those differences influence reporting of outcomes in BEST-CLI – particularly for MI and stroke?

We would like to ask each of you to take a few minutes to complete this survey. We know how busy you are, but this is an important issue and we are being asked to provide this for our DSMB. Parenthetically, it will be really interesting to know the range of practices across our sites with regards to cardiovascular testing pre and post-revascularization for both open and endo. One potential benefit of this effort might be the development of a more standardized approach to cardiovascular testing before and after interventions for CLI.

PLEASE NOTE, your responses to this survey will be confidential.
Please keep your eye out for the survey. We are aiming for 100% participation!

Thank you in advance!

Next Round of Site Payments!

The data freeze for the next round of site payments is scheduled for **June 30, 2016**.
Be sure to enter your data and respond to queries in eCOS to ensure proper payment!

Clinical Endpoints Committee Reminder:

As a reminder the Clinical Endpoints committee is reviewing all strokes, MIs and first major re-interventions for subjects randomized into the trial. These events should all be reported within eCOS. According to the protocol definition a “major re-intervention” is defined as new bypass graft, jump/interposition graft revision, surgical thrombectomy with or without surgical patch angioplasty and thrombectomy of an occluded graft or arterial segment using pharmacologic or mechanical thrombolysis. These major re-interventions are components of the primary endpoint.

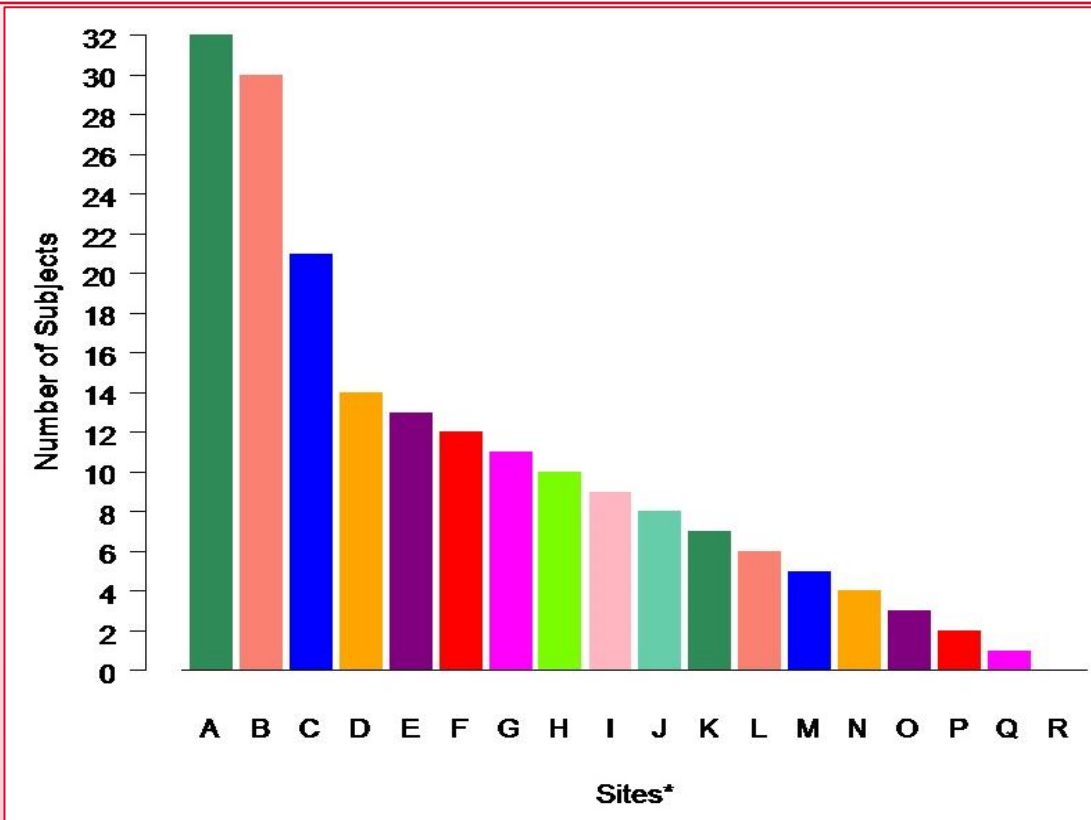
- Your site will receive an email notification requesting source documents once the event has been reported and confirmed eligible for adjudication.
- Questions on how to report a stroke, MI or major re-intervention? Reach out to your assigned CRA or BEST@neriscience.com

Please Note:

All visits/visit windows are calculated based on the **date of RANDOMIZATION** (not procedure) EXCEPT for the 30 day post-procedure visit.

The 30 day visit is calculated on the Index Procedure Date.

Enrollment Leaderboard*



Sites*

- A: 1160 - Keck MC of USC
- B: 1258 - Boston MC
- C: 1238 - Univ. of Massachusetts Medical School
- D: 1260 - Greenville Memorial Hosp.; 1274 – Univ. of Oklahoma Health Sciences Ctr.
- E: 1261 - Indiana Univ. Medical School
- F: 1009 - Dartmouth Hitchcock MC; 1282 - Carondelet Heart & Vascular Institute;
- G: 1101 - Albany MC; 1104 - VA Palo Alto; 1288 - Kaiser Foundation Hosp.(Hawaii)
- H: 1005 - Brigham and Women's Hosp.; 1154 – Yale; 1272 - St. Boniface General Hosp.; 1284 – Chu de Quebec
- I: 1013 - Harbor-UCLA MC; 1030 - Montefiore MC; 1273 – Univ. of Florida (Gainesville)
- J: 1105 - Medical College of Wisconsin; 1256 - Beth Israel Deaconess MC; 1310 - Harborview MC; 1318 – Univ. of North Carolina Hosp.
- K: 1041 - San Francisco Veterans Affairs MC; 1055 - Mount Sinai MC; 1095 - Johns Hopkins Hosp.; 1217 – Univ. of California Davis MC; 1306 – McGill; 1309 - Mercy Hosp. MC; 1332 - Denver VA MC
- L: 1029 - Michael E. DeBakey VA MC; 1061 - Baptist Hosp. of Miami; 1108 - Michigan Heart Hosp.; 1113 - Oregon Health and Science Univ.; 1169 - Case Western Reserve; 1276 - Memorial Hermann Hosp. TMC; 1281 - VA Western NY Healthcare System; 1308 - The Ohio State Univ.; 1311 - Dallas VA MC; 1314 - VA Boston Healthcare System; 1346 – Gundersen Health System
- M: 1023 – Massachusetts General Hosp.; 1066 - Arizona Heart Hosp.; 1135 - Univ. of Pittsburgh MC; 1173 – SUNY Upstate; 1259 - Rhode Island Hosp.; 1264 - Minneapolis Heart Hosp; 1275 - Medical Univ. of South Carolina; 1277 - The Univ. of Utah; 1290 - Loma Linda Univ. MC; 1305 - Univ. of Virginia; 1316 - Holy Name MC; 1342 – Regina Qu’Appelle
- N: 1003 – Alleghany General Hosp.; 1010 - Emory Univ.; 1054 - Univ. of Colorado Hosp.; 1072 - Univ. of Wisconsin – Madison; 1140 – Greater Los Angeles VA; 1182 - Providence Heart and Vascular Institute; 1188 - Toronto General Hosp.; 1234 – Univ. of Toledo MC; 1304 - CAMC Clinical Trials Center; 1326 - The Miriam Hosp.-Brown Medical School; 1340 – Wake Forest Baptist Hosp.; 1344 – Michigan Vascular Center

Enrollment Leaderboard Continued*

- O: 1008 – Columbia Univ. MC; 1026 - Medstar Washington Hosp. Center; 1046 - Steward St. Elizabeth's MC; 1075 - Swedish MC; 1076 - Northwestern Memorial Hosp.; 1125 – Univ. of California San Francisco MC; 1137 - The Univ. of Vermont MC, LLC; 1269 - Ohio Health Research Institute; 1271 - Southern Illinois Univ. SOM; 1293 - Univ. Health System: LSU Health Sciences; 1300 - Tampa General Hosp.; 1323 – Univ. of Nebraska MC; 1325 - Deborah Heart and Lung Center; 1334 – Stanford; 1345 – Los Angeles MC, Kaiser Permanente; 1347 – Maine MC; 1349 – Queens Elizabeth II Health Science Center
- P: 1007 – Cleveland Clinic Foundation; 1017 – Henry Ford Hosp.; 1019 - Jewish General Hosp.; 1024 – Mayo Clinic (Rochester); 1034 – Ochsner MC/Clinic Foundation; 1134 - Univ. of Michigan Health System; 1257 - Univ. of Arkansas for Medical Services; 1270 - Scott and White – Temple; 1285 – Duke Univ.; 1287 - Providence Sacred Heart MC; 1294 - North Central Heart Institute; 1301 – UCSD-Sulpizio Cardiovascular Center; 1331 - Pinnacle Health System; 1337 – Loma Linda VA MC; 1341 – Meriter Wisconsin Heart
- Q: 1116 - Rush Univ. MC; 1126 - Univ. of Chicago Medicine; 1131 – Univ. of Maryland; 1151 - William Beaumont Hosp.; 1229 - Penn State Milton S. Hershey MC; 1263 - Kaiser Permanente (San Diego); 1279 - North Carolina Heart and Vascular Research; 1283 – Univ. of Oklahoma College of Medicine; 1299 - Univ. of Tennessee MC; 1302 - UCLA-Gonda Vascular Surgery; 1307 – Univ. of Rochester; 1315 - George Washington Univ. Hosp.; 1320 - Portland VA MC; 1336 - Staten Island Univ. Hosp.; 1339 – Cadence Health (Chicago); 1348 – New Mexico Heart Institute
- R: 1018 - Inova Fairfax Medical Campus; 1059 - The Univ. of Alabama; 1085 – Cedars Sinai; 1121 – Temple Univ.; 1278 – Univ. of California Irvine; 1327 - Wellmont Holston Valley MC; 1350 - Benaroya Res. Inst. At Virginia Mason

*Data frozen on 6/3/2016.

**Site names abbreviated to accommodate space.

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

Thank you!!