

BEST-CLI – FALLing for BEST!

From the Desktop of Niteesh K. Choudhry, MD, PhD (PI of the Cost Effectiveness-Core)

The clinical impact of PAD and CLI are widely recognized. Less well appreciated, but equally important, are the acute economic effects that this disease is now imposing. By the turn of the century, Medicare spending on PAD was already more than \$4 billion. As of this year, annual estimates of PAD spending exceed \$25 billion in the U.S. alone. These changes reflect not only the rising prevalence of PAD and CLI but also technological advances in care. In specific, the introduction and evolution of endovascular procedures have significantly increased treatment options. The rapidly rising use of less invasive treatment modalities have been driven by the desire of patients and physicians to minimize procedural risks and it is gratifying that less invasive also generally means less expensive in the short-run. That said, because of potential concerns about inferior durability, from an economic perspective, the lower procedural costs associated with less invasive procedures for CLI may have come at the expense of the added costs associated with the greater need for re-intervention.

In this context, the imperative of the BEST trial is to not only rigorously evaluate the optimal approach for minimizing the morbidity and mortality imposed by CLI but also to identify how these treatment options affect health spending. To do this, with your help, we are prospectively measuring resource consumption and health-related quality of life. We will use this information to measure the short-term cost-effectiveness of the interventions being evaluated and to project these estimates over the longer-term using state-of-the-art discrete event simulation techniques.

A clinical trial that prospectively measures economic outcomes in parallel with clinical events, unfortunately, remains a rarity and the methodology we are using in BEST will serve as a model for future trials in vascular medicine. More importantly, by measuring the benefits and risks of different approaches for managing CLI as well as their associated costs, BEST will provide patients, health care providers and policy makers with a complete set of data on which the base decisions about high-value care.

Niteesh K. Choudhry, MD, PhD
Professor, Harvard Medical School

BEST Fall Highlights

TOP ENROLLERS

July

**1017/Henry Ford and
1238/UMass**

August

1309/Iowa Heart

September

1258/BMC

Join BEST on Social Media



Tweet us **@BEST_CLI**



Join our [Linkedin](#) group!

Be at your BEST with these important updates!

Data Freeze for DSMB Meeting!

Our next DSMB Meeting is scheduled to occur on **Tuesday, January 10th**, which is fast approaching. The data freeze date for this meeting has been scheduled for **Tuesday, November 1st**. 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 Mayo](#), Senior Data Manager, or your individually assigned CRA.

Next Round of Site Payments!

The data freeze for the next round of site payments occurred on **September 30th** and is currently being processed. Sites should expect to receive payments via electronic transfers or physical check by mid-November.

Have questions regarding site payments? Please send them to BEST@neriscience.com.

Ascertainment Bias Survey

Calling all investigators to complete a survey on ascertainment bias as requested by our DSMB. Be on the lookout for an email COMING SOON with a link to the survey.

Upcoming Investigator Meeting

Thursday, November 17th, 4:00-5:30PM ET
New York Hilton Midtown: New York Suite,
4th Floor
1335 Avenue of the Americas, New York,
NY 10019

To **RSVP** for the Investigator’s Meeting, please respond to BEST@neriscience.com






Please Note:

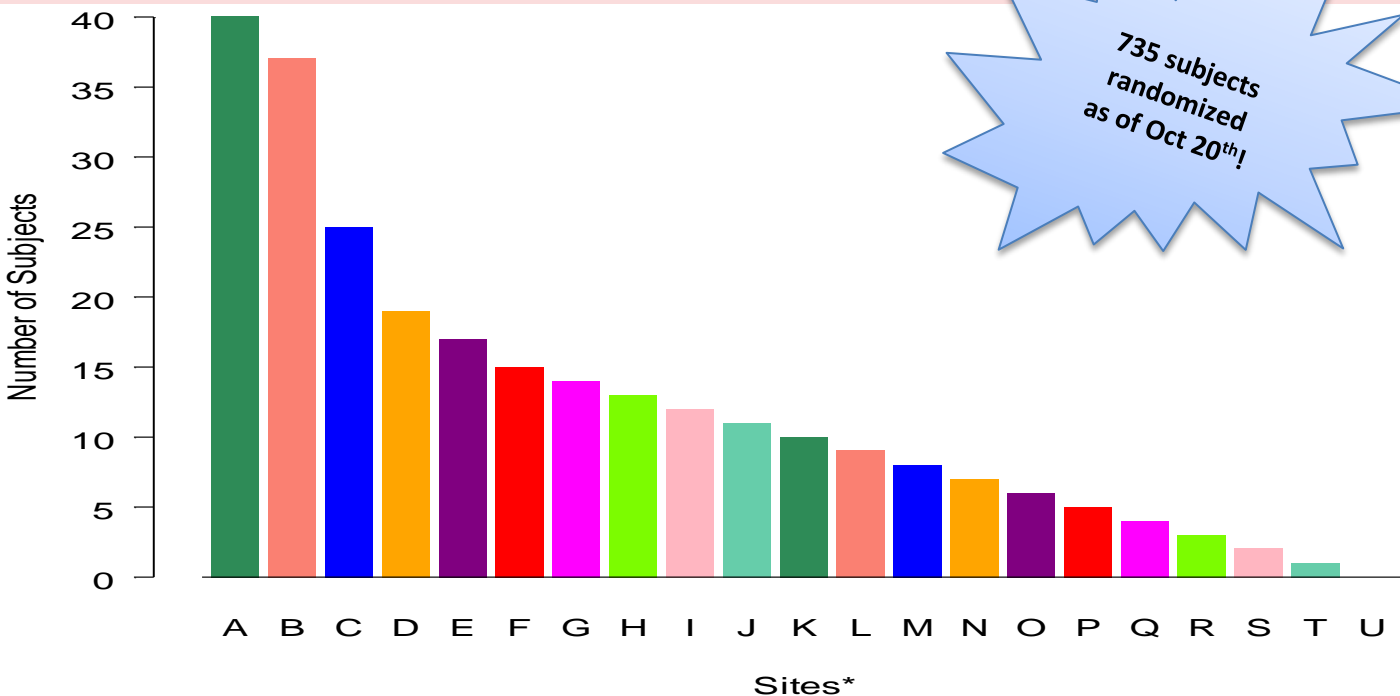
All visits/visit windows are calculated based on the **date of RANDOMIZATION** (not procedure) EXCEPT for the 30 day post-procedure visit.

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

Data Management FAQ Corner:

- **What do the query colors symbolize?**
 - The queries are color coded to help provide a quick visual cue of the query status. Queries that are at an ‘Open’ status will have a red starburst symbol , and the field will be highlighted in red. Once the status has been updated to ‘Answer’ the starburst will change to blue  and the field will no longer be highlighted. **Please note, this will only occur when the status dropdown is updated to ‘answered’.** When the query is marked as ‘closed’ the starburst will update to green . It can be helpful to do a quick visual inspection of eCRFs to ensure all queries were appropriately responded to.

Enrollment Leaderboard*



Sites*

- A: 1258 - Boston MC
- B: 1160 - Keck MC of USC
- C: 1238 - Univ. of Massachusetts Medical School
- D: 1260 - Greenville Memorial Hosp.
- E: 1274 - Univ. of Oklahoma Health Sciences Ctr.
- F: 1009 - Dartmouth Hitchcock MC; 1282 - Carondelet Heart & Vascular Institute
- G: 1284 - Chu de Quebec
- H: 1101 - Albany MC; 1261 - Indiana Univ. Medical School; 1309 - Mercy Hosp. MC
- I: 1005 - Brigham and Women's Hosp.; 1154 - Yale; 1272 - St. Boniface General Hosp.; 1273 - Univ. of Florida (Gainesville); 1288 - Kaiser Foundation Hosp.(Hawaii)
- J: 1013 - Harbor-UCLA MC; 1104 - VA Palo Alto
- K: 1105 - Medical College of Wisconsin
- L: 1017 - Henry Ford Hosp.; 1030 - Montefiore MC; 1055 - Mount Sinai MC; 1135 - Univ. of Pittsburgh MC; 1332 - Denver VA MC; 1342 - Regina Qu'Appelle
- M: 1095 - Johns Hopkins Hosp.; 1113 - Oregon Health and Science Univ.; 1217 - Univ. of California Davis MC; 1256 - BIDMC; 1276 - Memorial Hermann Hosp. TMC; 1310 - Harborview MC; 1318 - Univ. of NC Hosp.
- N: 1041 - San Francisco Veterans Affairs MC; 1061 - Baptist Hosp. of Miami; 1108 - Michigan Heart Hosp.; 1281 - VA Western NY Healthcare System; 1306 - McGill; 1311 - Dallas VA MC; 1346 - Gundersen Health System
- O: 1023 - Massachusetts General Hosp.; 1029 - Michael E. DeBakey VA MC; 1066 - Arizona Heart Hosp.; 1169 - Case Western Reserve; 1259 - Rhode Island Hosp.; 1308 - The Ohio State Univ.; 1314 - VA Boston Healthcare System; 1340 - Wake Forest Baptist Hosp.
- P: 1010 - Emory Univ.; 1046 - Steward St. Elizabeth's MC; 1054 - Univ. of Colorado Hosp.; 1072 - Univ. of Wisconsin - Madison; 1075 - Swedish MC; 1173 - SUNY Upstate; 1188 - Toronto General Hosp.; 1234 - Univ. of Toledo MC; 1264 - Minneapolis Heart Hosp; 1275 - Medical Univ. of South Carolina; 1277 - The Univ. of Utah; 1285 - Duke Univ.; 1290 - Loma Linda Univ. MC; 1293 - Univ. Health System: LSU Health Sciences; 1305 - Univ. of Virginia; 1316 - Holy Name MC; 1337 - Loma Linda VA MC; 1344 - Michigan Vascular Center
- Q: 1003 - Alleghany General Hosp.; 1026 - Medstar Washington Hosp. Center; 1140 - Greater Los Angeles VA; 1182 - Providence Heart and Vascular Institute; 1271 - Southern Illinois Univ. SOM; 1300 - Tampa General Hosp.; 1304 - CAMC Clinical Trials Center; 1323 - Univ. of Nebraska MC; 1325 - Deborah Heart and Lung Center; 1326 - The Miriam Hosp.-Brown Medical School; 1345 - Los Angeles MC, Kaiser Permanente; 1347 - Maine MC

*Enrollment Leaderboard Continued**

- R: 1007 – Cleveland Clinic Foundation; 1008 – Columbia Univ. MC; 1076 - Northwestern Memorial Hosp.; 1125 – Univ. of California San Francisco MC; 1134 - Univ. of Michigan Health System; 1137 - The Univ. of Vermont MC, LLC; 1269 - Ohio Health Research Institute; 1331 - Pinnacle Health System; 1334 – Stanford; 1341 – Meriter Wisconsin Heart; 1349 – Queens Elizabeth II Health Science Center; 1367 - Englewood Hospital and Medical Center
- S: 1019 - Jewish General Hosp.; 1024 – Mayo Clinic (Rochester); 1034 – Ochsner MC/Clinic Foundation; 1229 - Penn State Milton S. Hershey MC; 1257 - Univ. of Arkansas for Medical Services; 1270 - Scott and White – Temple; 1287 - Providence Sacred Heart MC; 1294 - North Central Heart Institute; 1301 – UCSD-Sulpizio Cardiovascular Center; 1307 – Univ. of Rochester; 1336 - Staten Island Univ. Hosp.; 1350 - Benaroya Res. Inst. At Virginia Mason
- T: 1059 - The Univ. of Alabama; 1116 - Rush Univ. MC; 1121 – Temple Univ.; 1126 - Univ. of Chicago Medicine; 1131 – Univ. of Maryland; 1151 - William Beaumont Hosp.; 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; 1315 - George Washington Univ. Hosp.; 1320 - Portland VA MC; 1339 – Cadence Health (Chicago); 1348 – New Mexico Heart Institute; 1351 - Kaiser Permanente, San Francisco; 1352 - San Diego VAMC;
- U: 1018 - Inova Fairfax Medical Campus; 1085 – Cedars Sinai; 1226 – St. Paul's Hospital (U. Saskatchewan); 1278 – Univ. of California Irvine; 1292 – Munroe Regional MC; 1327 - Wellmont Holston Valley MC; 1355 - Vancouver General Hospital; 1358 - Vascular Health Partners, CCP; 1359 – The Ottawa Hospital; 1360 - Midwest Cardiovascular Research Foundation; 1361 - Midwest Aortic Vascular Institute (MAVI); 1362 - Mount Sinai Medical Center (Miami, FL)

*Data frozen on 10/20/2016.

**Site names abbreviated to accommodate space.

Thank you!!