

BEST-CLI – Here’s to the BEST year yet!

From Matt Menard: ONE OF A KIND BEST-CLI TRIAL INVESTIGATOR MEETING!

We are extremely excited to be hosting our first ever stand-alone BEST CLI Trial Investigator Meeting. **The meeting will take place this April 12-13, 2018 in Washington, DC, at the terrific Omni Shoreham Hotel. A reception dinner on the evening of Thursday, April 12, with some compelling don’t miss content, will precede a full program from 7:30 AM – 3:00 PM on Friday, April 13.** Hotel, round-trip economy airfare, and per diem (against receipts per NIH guidelines) for two Investigators and one Coordinator from each site will be covered.

Our goal is to take advantage of this truly unique opportunity to bring together so many people dedicated to CLI, and structure a standout meeting that will both help advance the care of this challenging disease and bring BEST-CLI further forward toward its important completion. We anticipate over 400 trial investigators, coordinators and faculty will attend.

We recognize the rare opportunity this meeting represents – a roomful of folks, keenly interested in CLI, without distraction. Compelling speakers, leaders from the NIH, CMS and FDA, and dynamic discussions. Our aim is to update and inspire, but also to provide a forum where we can all expand our thinking on CLI, including a look to the future beyond BEST.

There is tremendous energy in the PAD world these days (I had a hearty chuckle when several cardiology colleagues recently whined that PAD is taking over the AHA – no longer a forgotten stepsister to CAD and stroke are we). From the tantalizing dawn of real medical therapy, to the hunt for far-better measures of post-revasc perfusion, to the ongoing efforts to decipher the predictive impact of specific anatomic patterns, to recognizing and challenging the disconnect between guidelines (and trial results) and practice. We promise some of this, and possibly a fiery debate or two, as well as a special breakout session for coordinators.

We timed the meeting to allow participants to make return Friday flights home (even to the west coast), so as not to miss another weekend away. As an added draw for those who might want to bring family, the meeting will fall during the official Cherry Blossom Festival. (April 13th also happens to be the birthday of Thomas Jefferson, an early supporter of BEST).

We understand the demands on everyone’s time, and greatly appreciate each site’s commitment to participate. We believe this will be a timely, important and highly enjoyable event. We will be in communication with further details.

Matthew Menard

From the Desktop of Dr. Kenneth Rosenfield: vCLI On the Horizon...

The BEST-CLI Trial will define treatment of CLI for the next decade and beyond. We all recognize that, even with the incredible efforts of each investigator to randomize every patient, many patients will not qualify. What happens to these non-randomized patients? Are their treatment modalities and outcomes similar to those who are randomized? This question is of great interest to our investigators, and the answers may provide some context to help our vascular community interpret the results of the trial. To further expand the reach of BEST-CLI, accumulate more data about the patients who are *not* randomized, and to provide a “real world” dataset about current treatment of CLI, the **vCLI Registry** has been created. The vCLI Registry is intended to be an important component of the overall “BEST-CLI PROGRAM.” It is being spearheaded and seed-funded by VIVA Physicians, in collaboration with Duke Clinical Research Institute (DCRI), with the support of BEST-CLI leadership and NIH. Several corporate sponsors have also committed to support this data collection effort. We anticipate rolling out the registry within the next several months. It will utilize similar case report forms as those within the randomized trial, to enable optimal benchmarking. Investigators who are actively enrolling and randomizing patients will be offered the opportunity to participate in vCLI. From the vantage point of clinical sites, the combination of the BEST-CLI and the vCLI Registry will offer an amazing opportunity to get the full picture of treatment and outcomes for all patients with CLI within the institution. Stay tuned to hear more about vCLI!

Kenneth Rosenfield



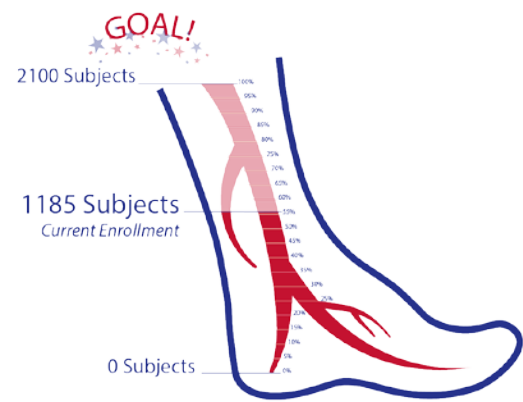
Site 1374 / Westchester Medical Center



Pictured above (L to R): Igor A. Laskowski, MD, PhD, Sateesh Babu, MD, Romeo Mateo, MD, Francis Carroll, MD, Arun Goyal, MD, Joseph Fulton, MD, John Kwon, MD, Jayesh Modi, MD

Our practice, Westchester Heart and Vascular is located north of New York City and has eight vascular surgeons on two campuses: Westchester Medical Center in Valhalla and Mid-Hudson Regional Hospital in Poughkeepsie.

We were late to join BEST CLI trial and we only started enrolling patients in May of this year. Since then we have been fortunate to include 8 subjects in the study. In our approach we try to stay very much focused on identifying potential trial candidates and once considered we explain to them the benefits of the study early in their treatment. Given that our practice is spread over multiple locations across great geographic distance, the main task of patient enrollment lays with individual physicians rather than study coordinator. The coordinator however is invaluable in maintaining the patient database and ensures compliance with all study and regulatory requirements. We hold regular research meetings, during which we discuss research projects; we also have a physician champion who is tasked with personally supporting practice members to assure ongoing involvement of all doctors in patient screening and enrollment. We find BEST CLI to be one of the most important studies in recent years and we continue to be fully committed to its success.



**January Top Enrollers
2 subjects each!**

- 1160 / Keck MC**
- 1169 / Case Western**
- 1281 / VA Western NY**
- 1318 / U. North Carolina**
- 1374 / Westchester MC**

**Adverse Event Reporting
Stop and Think!**

What was the reason or cause for the hospitalization or procedure?

The reported adverse event **term** must be a sign, symptom, or disease. Avoid reporting procedures, actions, and outcomes as they are not considered adverse events.

Only **ONE** event can have an outcome of death. If a subject has multiple AEs at the time of death, the AEs not the direct cause of death will be considered resolved as of the death date. If the cause of death is unknown, the event term should be "unknown cause of death."

Complete applicable eCRFs:

- Hospitalization/ED encounter
- CLI Intervention/Procedure (Re-intervention)
- Amputation Details

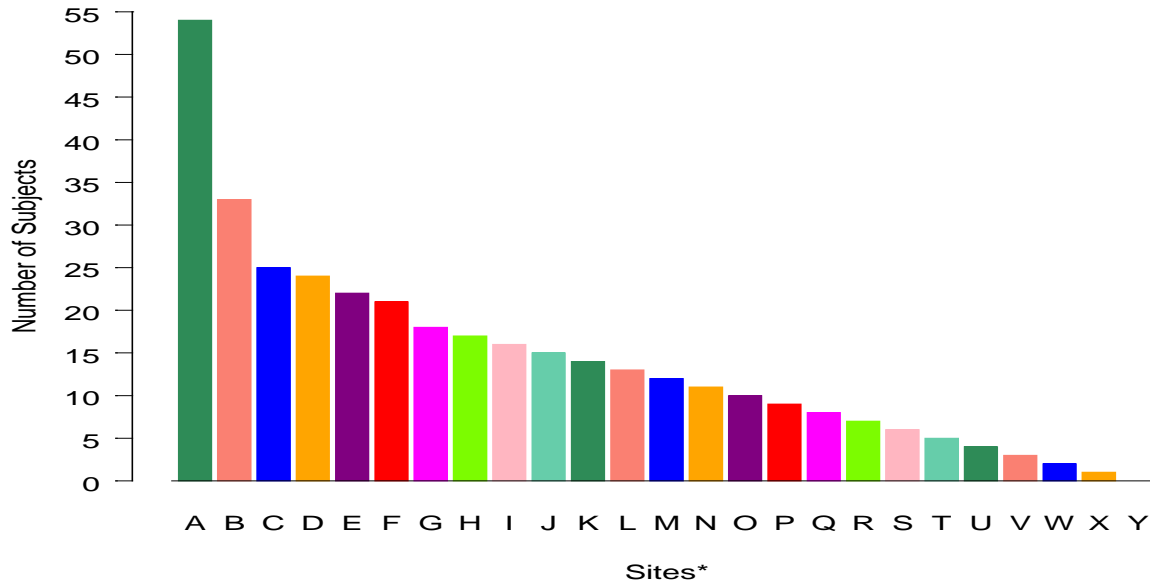
Medication Reporting Corner!

A review of the subjects current medications should take place and be reported at each visit. Please complete eCRFs for the medications subjects are taking belonging to the following classes only:

Anticoagulants	Antihypertensives	Diabetes meds - oral & injectable
Antiplatelets	Cholesterol-lowering agents (including statins)	

Reminder: Total daily dose: this is the total amount of medication taken in one day. A BID dose of 500 mg should be reported as 1000 mg. For eCRF completion, the total daily dose is 1000 and dosage units is mg. (Reference Chapter 5 of the Manual of Operations (MOO)).

Enrollment Leaderboard



Sites*

- A: 1160 - Keck MC of USC; 1258 - Boston MC.
- B: 1238 - Univ. of Massachusetts Medical School.
- C: 1154 – Yale; 1309 - Mercy Hosp. MC/ Iowa Heart.
- D: 1273 – Univ. of Florida (Gainesville); 1274 – Univ. of Oklahoma Health Sciences Ctr.
- E: 1009 - Dartmouth Hitchcock MC.
- F: 1260 - Greenville Memorial Hosp.; 1284 – Chu de Quebec.
- G: 1105 - Medical College of Wisconsin.
- H: 1005 - BWH.; 1261 - Indiana Univ. Medical School; 1272 - St. Boniface General Hosp.;
- I: 1041 - SFVAMC; 1281 - VA Western NY Healthcare System; 1288 - Kaiser Foundation Hosp.(Hawaii).
- J: 1017 – Henry Ford Hosp; 1282 - Carondelet Heart & Vascular Institute.
- K: 1101 - Albany MC; 1352 - San Diego VAMC.
- L: 1104 - VA Palo Alto; 1217 – UC Davis MC; 1279 - North Carolina Heart and Vascular Research.
- M: 1013 - Harbor-UCLA MC; 1125 – Univ. of California San Francisco MC; 1276 - Memorial Hermann Hosp. TMC; 1318 – Univ. of North Carolina Hosp.; 1323 – Univ. of Nebraska MC; 1351 – KP NCAL.; 1367 - Englewood Hospital and Medical Center; 1374 - Westchester MC Health.
- N: 1055 - Mount Sinai MC; 1095 - Johns Hopkins Hosp.; 1108 - Michigan Heart Hosp.; 1113 - Oregon Health and Science Univ ; 1135 - Univ. of Pittsburgh MC; 1256 - Beth Israel Deaconess MC; 1290 - Loma Linda Univ. MC; 1342 – Regina Qu’Appelle; 1346 – Gundersen Health System.
- O: 1066 - Arizona Heart Hosp.; 1275 - Medical Univ. of South Carolina; 1308 - The Ohio State Univ.; 1310 - Harborview MC; 1332 - Denver VA MC;
- P: 1030 - Montefiore M; 1061 - Baptist Hosp. of Miami; 1305 - Univ. of Virginia; 1311 - Dallas VAMC 1314 - VA Boston Healthcare System; 1340 – Wake Forest Baptist Hosp;
- Q: 1010 - Emory Univ; 1029 - Michael E. DeBakey VA MC; 1234 – Univ. of Toledo MC; 1306 – McGill.
- R: 1072 - Univ. of Wisconsin – Madison; 1075 - Swedish MC; 1140 – Greater Los Angeles VA; 1169 - Case Western Reserve; 1173 – SUNY Upstate; 1259 - Rhode Island Hosp.; 1277 - Univ. of Utah; 1293 - LSU; 1344 – Michigan Vascular Center; 1348 – New Mexico Heart Inst.; 1359 – Ottawa Hospital.

Enrollment Leaderboard Continued

Sites*	
S:	1003 – Alleghany General Hosp.; 1018 - Inova Fairfax Medical Campus; 1023 – Massachusetts General Hosp.; 1026 - Medstar Washington Hosp. Center; 1046 - Steward St. Elizabeth's MC; 1156 – Minneapolis VAMC; 1188 - Toronto General Hosp.; 1264 - Minneapolis Heart Hosp.; 1285 – Duke Univ.; 1337 – Loma Linda VA MC; 1345 – LAMC, Kaiser Permanente; 1349 – Queens Elizabeth II Health Science Center.; 1368 - Sentara Vascular Specialists; 1370 – Rutgers New Jersey Medical Center.
T:	1054 - Univ. of Colorado Hosp; 1076 - Northwestern Memorial Hosp.; 1134 - Univ. of Michigan Health System; 1263 - Kaiser Permanente (San Diego); 1271 - Southern Illinois Univ. SOM; 1300 - Tampa General Hosp; 1316 - Holy Name MC; 1325 - Deborah Heart and Lung Center; 1331 - Pinnacle Health System; 1334 – Stanford; 1347 – Maine MC; 1350 - Benaroya Res. Inst. At Virginia Mason.
U:	1059 - The Univ. of Alabama; 1137 - The Univ. of Vermont MC, LLC; 1182 - Providence Heart and Vascular Institute; 1229 - Penn State Milton S. Hershey MC; 1292 – Munroe Regional MC; 1304 - CAMC Clinical Trials Center; 1326 - The Miriam Hosp./Brown Medical School.
V:	1007 – Cleveland Clinic Foundation; 1008 – Columbia Univ. MC; 1019 - Jewish General Hosp.; 1024 – Mayo Clinic (Rochester); 1034 – Ochsner MC/Clinic Foundation; 1226 – St. Paul’s Hospital (U. Saskatchewan); 1269 - Ohio Health Research Institute; 1270 - Scott and White – Temple; 1278 – Univ. of California Irvine; 1283 – Univ. of Oklahoma College of Medicine (Tulsa); 1294 - North Central Heart Institute; 1307 – Univ. of Rochester; 1320 - Portland VA MC; 1341 – Meriter Wisconsin Heart; 1355 - Vancouver General Hospital; 1357 – St. Francis Hospital; 1379 – Long Beach VAMC.
W:	1257 - Univ. of Arkansas for Medical Services; 1287 - Providence Sacred Heart MC; 1301 – UCSD - Sulpizio Cardiovascular Center; 1302 – UCLA - Gonda Vascular Surgery; 1336 - Staten Island Univ. Hosp.; 1339 – Cadence Health (Chicago); 1356 - South Shore Hosp.; C; 1365 - Tampa VAMC; 1375 - West Haven VA (WHVA).; 1377 - Decatur Memorial Hospital.;
X:	1116 - Rush Univ. MC; 1121 – Temple Univ.; 1126 - Univ. of Chicago Medicine; 1131 – Univ. of Maryland; 1151 - William Beaumont Hosp.; 1299 - Univ. of Tennessee MC; 1315 - George Washington Univ. Hosp.; 1354 - Durham VAMC; 1361 - Midwest Aortic Vascular Institute; 1362 - Mount Sinai Medical Center (Miami, FL); 1364 – Sacramento VAMC; 1369 – Milwaukee VAMC; 1376 – Univ. of Western Ontario.
Y:	1327 - Wellmont Holston Valley MC; 1358 - Vascular Health Partners, CCP; 1373 - Baton Rouge General MC; 1381 - Loyola University Medical Center; 1382 – St. Louis VA; 1388 - New Mexico VA.
*Data frozen on 28/Jan/2018	
**Site names abbreviated to conserve space	

Thank you!!



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Visit our **website!**