

BEST-CLI – BEST Sites are Blossoming!

With just two weeks away from the first ever BEST-CLI Central Investigator’s Meeting, BEST sites SPRING into step with subject recruitment!

Central Investigator Meeting!
April 12-13, 2018
Washington D.C. – Omni Shoreham Hotel



Make your
 arrangements
 today!

Schedule of events

Thursday, April 12th 6:00-9:00pm ET (Welcome Reception and Dinner)

Friday, April 13th 7:30am–3:00pm ET (Main Meeting); 3:00-4:00pm ET (Post-Meeting Networking)

Make your travel plans ASAP*

Hotel Reservations - Email the DCC at BEST@Neriscience.com to make your hotel reservations.

Flights - Email Protravel to book your flight! Include your name as it appears on your driver’s license, date of birth, gender, cell phone #, flight seating preference, frequent flyer #/ TSA/Global entry number, if applicable, travel dates and approximate departure times in each direction.

**The BEST-CLI trial will cover the cost of 1 night stay (Thursday-Friday), round trip economy airfare, and per diem for meals/transportation; hotel reservations made after 02/Apr will not guarantee the pre-negotiated room rate.*

Site 1383/Helsinki University Hospital



Pictured above (L to R): Anders Albäck, MD PhD, Maarit Venermo, MD PhD, Katariina Noronen, MD PhD, Riikka Tulamo, MD PhD, Anita Mäkelä, RN, Tatu Kokkonen, MD, and Pekka Aho, MD PhD. Erno Peltola, MD, PhD is missing from the image.



Photograph: Matti Laine

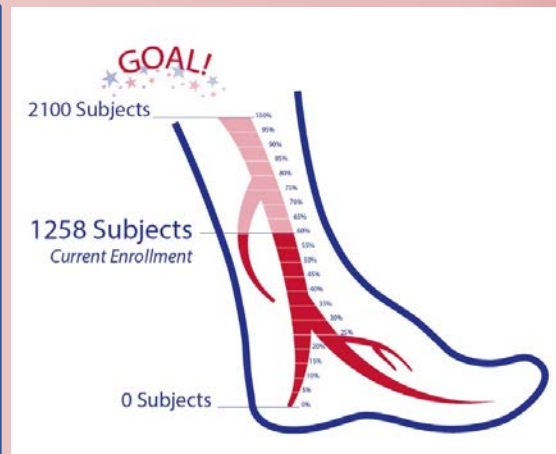
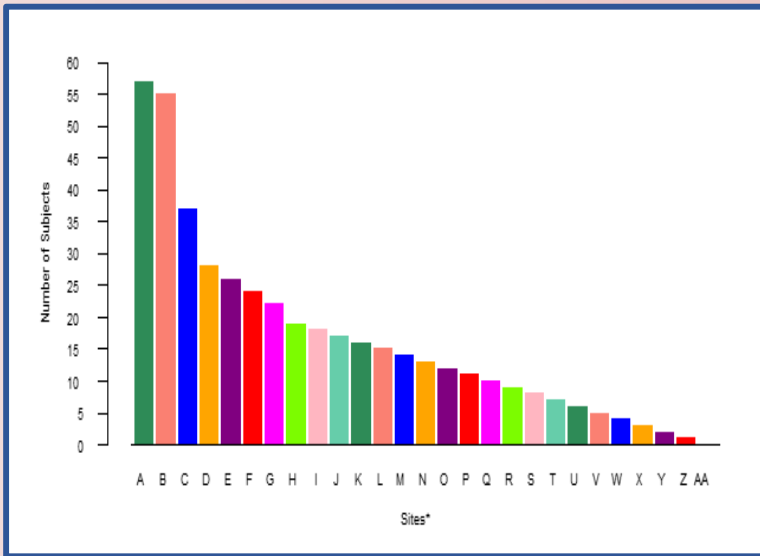


Site
 Spotlight

The Department of Vascular Surgery in Helsinki University Hospital is one of the biggest vascular surgical centers in the Nordic countries and the biggest center in Finland. Annually we perform nearly 1000 revascularizations (endovascular, surgical, or hybrid) for chronic limb threatening ischemia (CLI). We find the aims of the BEST-CLI trial to be extremely important and the whole team is fully engaged with the project.

We are very happy and proud that we had an opportunity to join the BEST-CLI trial. Our study site was opened on February and we have been able to randomize five patients so far. In our practice, we routinely perform magnetic resonance angiograms (MRA) to almost all patients with CLI, and we plan revascularizations on based on those results. In order to find patients that are suitable for the BEST-CLI trial, one investigator screens all the MRAs each day. If a patient has CLI and appears suitable for BEST-CLI trial, we interview the patient more closely to evaluate their overall suitability for the study. Beyond our physician investigators, our team includes an experienced research nurse with extensive experience on randomized controlled trials. She has demonstrated a mastery of study tasks related to randomization, CRF data entry, and completion of regulatory requirements. We are all motivated to work hard to be part of the larger team that makes this trial successful.

Enrollment Leaderboard



MARCH TOP ENROLLERS
3 subjects!
Site #1238 – UMass
2 subjects each!
Site #1276 – Memorial Hermann
Site #1277 – Univ. of Utah
Site #1367 – Englewood Hosp.
Site #1383 – Helsinki Univ.

Sites*

- A: 1160 - Keck MC of USC.
- B: 1258 - Boston MC.
- C: 1238 - Univ. of Massachusetts Medical School.
- D: 1309 - Mercy Hosp. MC/ Iowa Heart.
- E: 1154 – Yale.
- F: 1009 - Dartmouth Hitchcock MC; 1273 – U. Florida (Gainesville); 1274 – U. Oklahoma HSC
- G: 1260 - Greenville Memorial Hosp.; 1284 – Chu de Quebec
- H: 1105 - Medical College of Wisconsin.
- I: 1005 - BWH.; 1261 - Indiana Univ. Medical School
- J: 1272 - St. Boniface General Hosp.; 1281 - VA Western NY
- K: 1017 – Henry Ford Hosp.; 1041 - SFVAMC; 1288 - Kaiser Foundation Hosp. (Hawaii);
- L: 1282 - Carondelet Heart & Vascular Inst.; 1352 - San Diego VAMC;
- M: 1101 - Albany MC; 1217 – Univ. of California Davis MC; 1279 - North Carolina Heart and Vascular Research; 1367 - Englewood Hospital and Medical; 1374 - Westchester MC Health.
- N: 1104 - VA Palo Alto; 1135 - Univ. of Pittsburgh MC; 1276 - Memorial Hermann Hosp. TMC; 1318 – Univ. of North Carolina Hosp.; 1323 – Univ. of Nebraska MC.
- O: 1013 - Harbor-UCLA MC; 1095 - Johns Hopkins Hosp.; 1125 – UC, San Francisco MC; Center; 1351 – KP NCAL.
- P: 1055 - Mount Sinai MC; 1108 - Michigan Heart Hosp.; 1113 - Oregon Health and Science Univ.; 1169 - Case Western Reserve; 1256 - Beth Israel Deaconess MC; 1290 - Loma Linda Univ. MC; 1340 – Wake Forest Baptist Hosp.; 1342 – Regina Qu’Appelle; 1346 – Gundersen Health System.
- Q: 1061 - Baptist Hosp. of Miami; 1066 - Arizona Heart Hosp.; 1072 – U. Wisconsin – Madison; 1275 - Medical Univ. of South Carolina; 1305 - Univ. of Virginia; 1308 - The Ohio State Univ.; 1310 - Harborview MC; 1332 - Denver VA MC.
- R: 1010 - Emory Univ.; 1030 - Montefiore MC; 1234 – Univ. of Toledo MC; 1311 - Dallas VAMC; 1314 - VA Boston; 1344 – Michigan Vascular Center; 1348 – New Mexico Heart Institute.
- S: 1029 - Michael E. DeBakey VA MC; 1277 - The Univ. of Utah; 1306 – McGill.
- T: 1023 – Massachusetts General Hosp.; 1026 - Medstar Washington Hosp. Center; 1075 - Swedish MC; 1140 – Greater Los Angeles VA; 1156 – Minneapolis VAMC; 1173 – SUNY Upstate; 1259 - Rhode Island Hosp.; 1264 - Minneapolis Heart Hosp; 1285 – Duke Univ.; 1293 - Univ. Health System; 1359 – The Ottawa Hospital.
- U: 1003 – Alleghany General Hosp.; 1018 - Inova Fairfax; 1046 - Steward St. Elizabeth’s MC; 1134 - Univ. of Michigan; 1188 - Toronto General Hosp.; 1271 - Southern Illinois U. SOM; 1300 - Tampa General Hosp; 1337 – Loma Linda VAMC; 1345 – LAMC, Kaiser Permanente; 1349 – Queens Elizabeth II Health Science Center; 1350 - Benaroya Res. Inst. At Virginia Mason.; 1368 - Sentara Vascular Specialists; 1370 – Rutgers New Jersey MC.
- V: 1054 - Univ. of Colorado Hosp.; 1076 - Northwestern Memorial Hosp; 1263 - Kaiser Permanente (San Diego); 1316 - Holy Name MC; 1325 - Deborah Heart and Lung Center; 1326 - The Miriam Hosp.-Brown Medical School; 1331 - Pinnacle Health System; 1334 – Stanford; 1347 – Maine MC; 1357 – St. Francis Hospital; 1383 - Helsinki University Hospital (Finland).
- W: 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; 1270 - Scott and White – Temple; 1292 – Munroe Regional MC; 1304 - CAMC Clinical Trials Center.

Enrollment Leaderboard Continued

Sites Continued*

- X: 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; 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; 1354 - Durham VAMC; 1355 - Vancouver General Hospital; 1379 – Long Beach VAMC.
- Y: 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; 1365 - Tampa VAMC; 1375 - WHVA; 1377 - Decatur Memorial Hospital.
- Z: 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.; 1361 - Midwest Aortic Vascular Institute; 1362 - Mount Sinai Medical Center (Miami, FL); 1364 – Sacramento VAMC; 1369 – Milwaukee VAMC; 1376 - University of Western Ontario; 1381 - Loyola University MC; 1382 – St. Louis VA.
- AA: 1085 – Cedars Sinai; 1123 - Thomas Jefferson Univ.; 1280 - Metro Health Hosp. Wyoming Michigan; 1289 - Lenox Hill Hosp.; 1295 - Oklahoma Found. for Cardiovasc. Res.; 1296 - Sacred Heart Hosp. River Bend; 1297 - St. Joseph Hosp.; 1298 - Tufts MC; 1317- Roper Hosp.; 1319 - Hunterdon MC; 1327 - Wellmont Holston Valley MC; 1363 - University of Missouri, Columbia; 1371 - MetroHealth - Cleveland; 1373 - Baton Rouge General Medical Center.; 1388 - New Mexico VAMC; 1391 - Sunnybrook Health Sciences Ctr. (Canada)

**Data freeze 29/Mar/18 / Site names abbreviated to conserve space*

Site Management FAQ Corner Source Document Collection

Source documents are where data are **FIRST** recorded (i.e. original records, certified copies of original records, clinical findings, or other records of clinical investigation)

Source documents should be the first observation of data, support reported clinical data and kept in the subject’s research records

Key Points

- If it is not documented, it did not happen!
- A good source document identifies subject, date of assessment, follows ALCOA* and signed & dated by staff member completing assessment.
- A source document is NOT a photocopy of the CRF pages

***Source data should be “ALCOA”:**

- **A – Attributable** - make clear who has documented the data
- **L – Legible** - Clearly readable, and signatures identifiable
- **C – Contemporaneous** - Documented in real time with the flow of events. If data cannot be entered at the correct time, chronology should be recorded. Acceptable amount of delay should be defined and justified.
- **O – Original** - Original, first record made by the appropriate person. If not original, should be exact copy and include notation that it is a copy. The Investigator should have the original source documents.
- **A – Accurate** - An accurate, consistent, and real representation of facts; piece of a whole and complete picture.

Next Round of Site Payments!

The data freeze for the next round of site payments occurred on **March 31th** and payments are currently being processed. Sites should expect to receive payments via electronic transfers or physical check by mid-May.

Have site payment question?
Please send them to
BEST@neriscience.com.

Data Freeze for June DSMB Meeting!

The data freeze date for the 19/June/18 DSMB meeting is scheduled for **Monday, 09/Apr/18**. Make sure that all data are entered by this date, and all queries are set to “answered.”

Need a form set to missing? Have a question about data entry?
Contact your data manager at
BEST-DM Mailbox.



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