

## BEST-CLI – Keep MARCHing on to enroll more!

*BEST sites are starting to bloom with subjects this season!* Let's leave winter behind us and spring ahead to reach our enrollment goal!

### University of North Carolina, Chapel Hill



Back row (left to right): Dr. Mark Farber, Dr. William Marston, Dr. Jason Crowner, Dr. Raghuvier Vallabhaneni; Front row (left to right): Nicolle Lemire, Dr. Vik Jain, Dr. Kate McGinagle, Ana Kouri, Rebekah Roten, Kathy Mallard

The BEST-CLI team at the University of North Carolina is led by Dr. Vallabhaneni along with four other Vascular Surgeons, Drs. William Marston, Mark Farber, Kate McGinagle, and Jason Crowner, and our two research coordinators, Nicolle Lemire and Ana Kouri. Our team also works alongside several nurses, PAs, fellows, residents, and vascular technicians to efficiently identify and assess possible candidates in our broad patient population.

Our team specializes in the treatment of critical limb ischemia and, as the state hospital of North Carolina, our patient population includes the indigent and complex candidates that are unable to be treated elsewhere. We treat greater than 95% of peripheral arterial disease in our hospital and feel that this trial is especially important in determining the best revascularization option for these diseased patients. Our Wound and Limb Preservation Center is nationally recognized and has been a great referral source for trial patients. The Peripheral Vascular Lab is one of the oldest in the region and is also an integral part to the screening process. Together, the study team and, in particular, the research coordinators have helped make enrollment easy and seamless from a practitioners' standpoint.

Over the past several months our enrollment has increased through encouraged involvement of our fellows and residents in the screening of patients and consults for CLI. We hold weekly conferences to discuss this patient population and our overall progress and updates to the study. We feel that BEST-CLI trial is extremely important and essential in defining optimal therapy for future CLI patients.

## Data Freeze for DSMB Meeting!

Our next DSMB Meeting is scheduled to occur on June 21, 2016, which is fast approaching. The data freeze date for this meeting has been scheduled for **Monday, April 25, 2016**. 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 Odian](#), Senior Data Manager, or your individually assigned CRA. [Enter your data today!](#)

## Next Round of Site Payments!

The data freeze for the next round of site payments is scheduled for **March 31st**. Be sure you enter your data and respond to queries in eCOS to ensure proper payment!

## Data Management FAQ Corner

**Q: What is the best strategy for closing queries?**

**A:** It is recommended that if any changes are to be made to the eCRF, that these are saved **PRIOR** to updating the query status and providing a response. If the conditions of the query are met, the status and details will automatically update, meaning less work for YOU at the site!

For example, on the Hospitalization/ED Encounter eCRF, let's say you didn't know the discharge date because the patient was still in the hospital at the time of data entry. A "date cannot be empty" query will be triggered. Once you know the date of discharge, simply adding it to the eCRF and saving the form will automatically update and close the query! The EDC automatically adds a default message to the action/comments box so you don't have to!

## Request for Screening Logs!

Screening Logs are due bi-weekly to the DCC. The next round of screening logs is due **March 18<sup>th</sup>**. Be sure to document all screen failures on your screening logs. If you are not sure how to fill out the log, please contact us at [BEST@neriscience.com](mailto:BEST@neriscience.com) or reach out to your assigned CRA.

**VA Palo Alto Health Care System**

**Site Spotlight**

Front row (left to right): Jane Paris, RNP, Wanda O’Kelly, RVT, Dr. Wei Zhou, Dr. George Lee, Phyllis McGrath, CNS, Brittney Baughman, MS  
 Back Row (left to right): Dr. Oliver Aalami, Dr. Patrick Thompson, Dr. Andy Lee, Theresa Alexander, Missing: Dona Bahmani and Juanito (Jay) Alanes, RVT

Dr. Zhou is the BEST-CLI Contact PI and Drs. G Lee, Aalami, Raj Shah are sub-investigators at the Palo Alto VA. Dona Bahmani and Daniella Baughman are study coordinators. We make great effort to recruit every patient with a wound that is in need of intervention to the BEST-CLI trial. Every member of our clinical team is acutely aware of the BEST-CLI trial, and each member of the CLI team helps to recruit patients, including our nursing staff (Phyllis McGrath, CNS, and Jane Paris, RNP), trainees (Drs. A Lee and Thompson), and ultrasonographers (Jay Alanes, Wanda O’Kelly, and Theresa Alexander)

**BEST February Highlights**

# of Sites Activated under Protocol Amendment: 116

Top Enroller: 1260/Greenville Memorial Hospital

# of First Time Enrollers: 4

**499 Subjects Randomized as of 3/11/2016!**

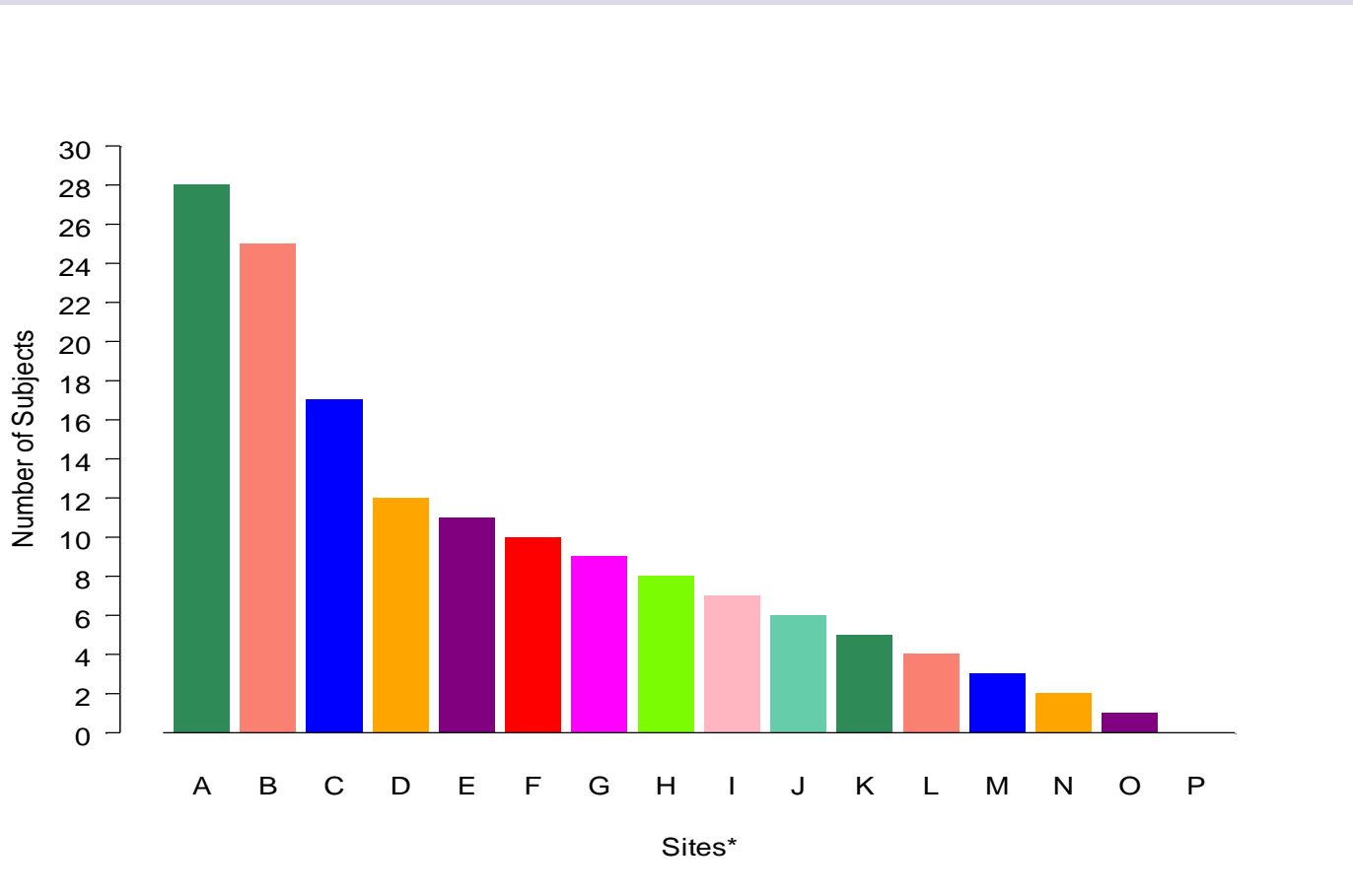
**Site #1261, Indiana U. Medical School randomized our 490th Subject!**

**Site #1260, Greenville Memorial Hospital randomized 5 subjects this month!**

**Tweet us @BEST\_CLI**

**www.facebook.com/BESTCLI**

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



## Enrollment Leaderboard Continued

M: 1003 – Alleghany General Hosp.; 1026 - Medstar Washington Hosp. Center; 1046 - Steward St. Elizabeth's MC; 1061 - Baptist Hosp. of Miami; 1072 - Univ. of Wisconsin – Madison; 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; 1305 - Univ. of Virginia; 1323 – Univ. of Nebraska MC; 1326 - The Miriam Hosp.-Brown Medical School; 1334 – Stanford; 1347 – Maine MC

N: 1007 – Cleveland Clinic Foundation; 1017 – Henry Ford Hosp.; 1134 - Univ. of Michigan Health System; 1135 - Univ. of Pittsburgh MC; 1257 - Univ. of Arkansas for Medical Services; 1270 - Scott and White – Temple; 1285 – Duke Univ.; 1287 - Providence Sacred Heart MC; 1293 - Univ. Health System: LSU Health Sciences; 1300 - Tampa General Hosp.; 1331 - Pinnacle Health System; 1341 – Meriter Wisconsin Heart; 1345 – Los Angeles MC, Kaiser Permanente

O: \*\*\*

P: \*\*\*

\*Data frozen on 3/08/2016.

\*\*Site names abbreviated to accommodate space.

## Randomization How To's

Randomizing a subject in eCOS? Once all of the necessary screening pages have been entered (General Information, Informed Consent, Inclusion Criteria, Exclusion Criteria, Vein Mapping, and Randomization) and the subject is determined to be eligible, the subject can be randomized. Randomization is done as a special **Subject Status change**.

After data entering the Randomization page, click the subject ID number on the gray toolbar to go to the Subject Grid screen and select the blue “Randomized?” hyperlink (Figure 1). Review the confirmation screen (Figure 2) and click “GO.”

If randomization is successful, eCOS will bring you to the Information page (Figure 3) for that subject and the status will be listed as “Randomized.” To view the randomization treatment arm you will have to click on the “View Unblinding Information” button.

**IMPORTANT:** Randomization is contingent upon the subject meeting study eligibility requirements and screening data entry being complete. Please contact study staff for assistance if you receive an error message or have difficulty during the randomization process.

Figure 1. Randomized? hyperlink

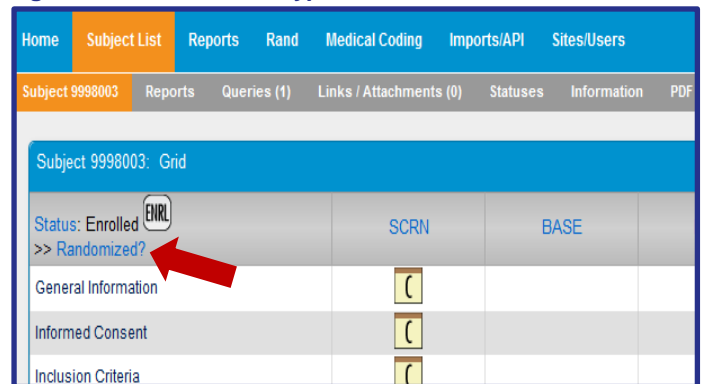


Figure 2. Confirmation Screen

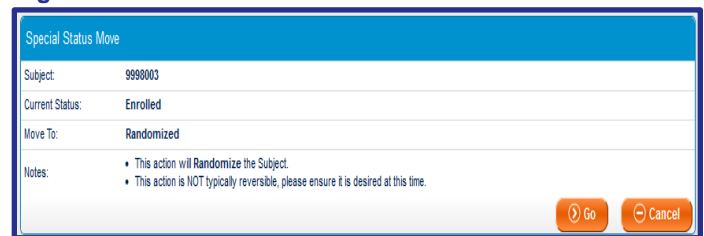


Figure 3. Information Page

