

BEST-CLI - BEST New Year's Resolutions

Be the BEST in 2015 by making a resolution at your site today! Whether it's taking steps to activate your site or to randomize more subjects, we are confident sites have the drive to make their resolutions last!

How to Discuss Enrollment in BEST-CLI with a Potential Patient

From the Desktop of Alik Farber, MD

Getting a patient to agree to participate in a clinical trial can be challenging. After all, most patients who come to see us hold the belief that we have all the answers and many expect that the solutions we offer are "tried and true". Therefore, by proposing participation in a randomized trial a physician suggests to the patient that the solution to their problem is not clear and this can be very unsettling. Patients may be frustrated with the fact that there is equipoise in the way their condition is managed or may feel uncomfortable with the randomization process.

Despite these potential obstacles, adequate enrollment is crucial to the success of any trial.

What then, is the best approach to randomizing a patient with critical limb ischemia (CLI) into BEST-CLI? The following suggestions may be helpful to the investigator in obtaining a patient's consent to participate in the trial:

- *Explain the concept of revascularization.* The patient needs to understand that treatment of CLI entails delivering more blood to the affected leg in order to avoid amputation. In some ways, this concept transcends the fact that there are multiple ways to achieve this goal.
- *Explain that there are different strategies for revascularizing the leg (endovascular and open).* The patient needs to appreciate that in North America there is great variability as to which CLI treatment strategy is offered to each patient. Furthermore, it is the treating physician who chooses which therapy to offer the patient and it is very rare for the patient to be given the opportunity to make this decision. Finally, both endovascular and open strategies have their risks and benefits and this is precisely why both are currently being studied and compared within BEST-CLI.
- *Underscore the significance of BEST-CLI.* Explain that the National Institutes of Health has invested an enormous amount of effort to conduct this largest-ever trial in the field of CLI, and your center, along with the top 120 vascular centers of excellence in North America, is participating.
- *Clarify what participation in BEST-CLI entails.* Make sure that the patient understands that no matter whether they are randomized to endovascular or open revascularization they will still be getting a "standard of care" treatment, that the trial is overseen by a multidisciplinary CLI Team at the site as well as an independent safety review board, and that their participation will help countless future patients with CLI, as well as their own physician and other physicians who treat CLI. Also make sure that they understand that part of trial participation involves returning for scheduled follow-up visits over the next several years. This schedule of visits is similar to follow-up for CLI patients who are not participating in the trial.

Despite challenges that are inherent in recruitment of patients into a clinical trial, it is incumbent on us as investigators to enroll patients into BEST-CLI. As stated by Michael Jaff, one of the most respected experts in the field of CLI, "*BEST-CLI... is the most important, impactful, patient-centered clinical trial of our professional lifetime....*" We, as investigators, need to assertively embrace this opportunity to provide the answer to this significant inquiry for the sake of our patients, our field and the medical community as a whole.

Michigan Heart/St. Joseph Mercy Hospital



From left to right: Mansoor Qureshi, MD; Autumn Howe, RN; Michael Heidenreich, MD; Brian Halloran, MD (Vascular Surgery PI); Herbert Aronow, MD (Contact & CVM PI); Kristy Wippler, RN (Primary RC); Abdulhameed Aziz, MD; not pictured, Chinmaya Shelgikar, MD; Walter Whitehouse, MD; Cyril Ruwende, MD

"The Michigan Heart/St. Joseph Mercy Hospital BEST-CLI team has been successful because of the collaborative efforts of our Investigators. Our Vascular Surgeons and Interventional Cardiologists meet regularly and have established a team approach for the treatment of Peripheral Vascular Disease. Investigators are highly involved in referring patients into the study, and consulting each other for clinical equipoise. Our research department has a central phone number, for ease of physician referrals. Our research department also benefits from an auto-paging system. This system notifies the Research Coordinator, through the electronic medical record, when a peripheral vascular procedure is ordered. We are pleased to be a part of the BEST-CLI trial."



BEST Enrollment Expectation:

At least 1 subject per site per month
2100 subjects by August 31, 2016

Johns Hopkins Hospital



From left to right: Kristine Orion, MD, James Black, MD, Mahmoud Malas, MD, Ying Wei Lum, MD, Umair Qazi, MD, Bryan Ehlert, MD, Bruce Perler, MD, Maggie Arnold, MD, Tom Reifsnyder, MD

"Our Vascular Surgery group is a very busy practice that spans over 2 hospitals. Initially, it was slightly challenging to recruit patients because of our referral pattern in receiving patients who have had multiple interventions at other institutions (in the preceding 6 months) or patients with multiple other co-morbidities. However, our entire team has been very vigilant and conscientious about not "waiting for the perfect patient" and we have had some recent success in recruiting patients to the trial. We constantly discuss candidacy for BEST trial inclusion at our conferences. Our vascular fellows and physician assistants are also very well informed about the importance of conducting this trial successfully."

BEST December Highlights

- Number of New Sites Activated: 20**
- Top Enroller: 1108 Michigan Heart/St Joseph Mercy Ann Arbor Hospital**
- Sites Enrolling 1st Subject: 11**

Enrollment Leaderboard*

Site # / Name	# Rand
1258 / Boston Medical Center	6
1108 / Michigan Heart/St Joseph Mercy Ann Arbor Hospital	4
1160 / Keck Medical Center of USC	4
1260 / Greenville Memorial Hospital	3
1316 / Holy Name Medical Center	3
1005 / Brigham and Women's Hospital	2
1009 / Dartmouth Hitchcock Medical Center	2
1013 / Harbor-UCLA Medical Center	2
1095 / Johns Hopkins Hospital	2
1281 / VA Western NY Healthcare System	2
1331 / Pinnacle Health System	2
1182 / Providence Heart and Vascular Institute	1
1238 / University of Massachusetts Medical School	1
1256 / Beth Israel Deaconess Medical Center	1
1263 / Kaiser Permanente (San Diego)	1
1288 / Kaiser Foundation Hospital	1
1310 / Harborview Medical Center (affiliated w/University of Washington)	1
1311 / Dallas VA Medical Center (affiliated w/UT SW)	1
1318 / University of North Carolina Hospitals (Chapel Hill)	1
1282 / Carondelet Heart &Vascular Institute	1
Total	40

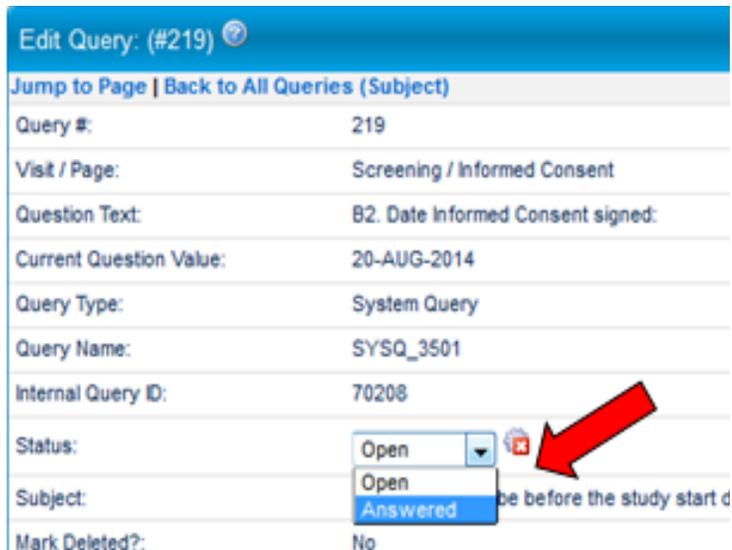
*Full site listing available on NERI connect.

Frequently Asked Question:

Q: What do I do if a measurement was not done and I don't have a result to report on the eCRF in eCOS?

A: If you don't have a result to enter, you should leave the field blank. This will create a query saying the field cannot be empty. To resolve this, simply answer the query saying the measurement was not obtained and the data manager will close it out for you.

For more detailed instructions on how to answer queries, please refer to Chapter 7 of the MOO.



The screenshot shows the 'Edit Query' interface for query #219. The query is titled 'B2. Date Informed Consent signed:' and is a 'System Query' with the name 'SYSQ_3501'. The current value is '20-AUG-2014'. The 'Status' dropdown menu is open, showing 'Open' and 'Answered' options. A red arrow points to the 'Answered' option, which is highlighted. The 'Subject' field is partially visible as 'be before the study start d'.

Calling all Screen Failures! Make it a New Year's resolution to ensure screen failure information is documented on your bi-weekly screening logs before submitting to the DCC.