

## BEST-CLI – Let’s Kick off the BEST Summer Yet!

*Summertime means enrollment time so jump into June to recruitment more subjects!*  
The heat is on for BEST-CLI teams to meet their enrollment goals in BEST. You can do it!

### From the Desktop of Alik Farber MD:

#### What’s in an Investigators Meeting?

An Investigators Meeting in any trial is an opportunity for trial leadership and site investigators to interact with each other. Its purpose is to update investigators about trial progress and discuss any issues related to trial management. Last Friday, at the Society for Vascular Surgery (SVS) Vascular Annual Meeting (VAM), we held a **BEST-CLI Investigators Meeting**. Even though the time of the meeting competed with two other presentations, we had a robust turn out. Over 60 individual site investigators showed up in support of the trial.

After a brief overview of the protocol and an update on current enrollment status, we delved into the **challenges** that our investigators face with every patient they consider for enrollment. These challenges include:

1. Getting started/”Hassle Factor”
2. Increasing awareness of BEST-CLI at sites
3. Engaging investigators to participate in the trial
4. Establishing flow of screening and randomization procedures
5. Identifying patients likely to meet inclusion/exclusion criteria
6. Overcoming treatment bias
7. Discussing the trial with prospective patients and families

We had the privilege of having **eight BEST-CLI site investigators** provide their perspective on these obstacles and the solutions they devised at their particular sites. The following individuals provided their insight:

- Peter Schneider, *Kaiser Foundation Hospital, Hawaii*
- Chris Owens, *San Francisco VA*
- CJ Lee, *Medical College of Wisconsin*
- Phil Goodney, *Dartmouth-Hitchcock Medical Center*
- Erica Mitchell, *Oregon Health and Science University*
- Shonda Banegas, *Carondelet Heart & Vascular Institute*
- Randy Guzman, *St. Boniface General Hospital*
- Vince Rowe, *Keck Medical Center of USC*

It was enlightening to hear these investigators, who are **high enrollers in the trial**, speak about how they wrestled with the difficulties that BEST-CLI, as any other randomized clinical trial of this magnitude, presents to enrollment. These investigators teach us that, as difficult as it can be, **enrollment in BEST-CLI is possible!**

At the end of the meeting **Michael Conte**, BEST-CLI Executive Committee Co-Chair and SVS Research Council Chair, provided his support and views on the relevance of BEST-CLI, offering compelling reasons as to why the vascular community needs to get behind this trial. The closing remarks were provided by **Professor Andrew Bradbury**, the architect of the BASIL trial and current PI of BASIL II. He encouraged all attendees to continue to work hard to enroll patients, noting that BEST-CLI and BASIL II, together, will provide a wealth of information on how to best manage patients with CLI in the current era.

## Mid Study Update Complete!

To make data entry more efficient and reduce system-generated queries, updates were made to the eCRFs in eClinicalOS (eCOS). A Visit Windows Report (highlighted on page 3) was also created to help sites plan subject visits.

To learn more the Mid Study Update, check out DM Memo #3, posted on [NERI Connect](#).

## Next Round of Site Payments!

The data freeze for the next round of site payments is scheduled for **July 10th**. Be sure you enter your data and respond to queries in eCOS to be paid!

### Kaiser Foundation Hospital, Hawaii



From left to right: Eric Hayman PA-C, Alex Kang RN, Peter Schneider MD, Nicolas Nelken MD, Amy Stone Murai APRN, Michael Caps MD

“Aloha! The Kaiser Permanente, Hawaii Vascular Surgery and Research Team treats a diverse and multi-cultural patient population from every part of the world. Our team consists of Vascular Surgeons, PA-Cs, APRNs and RNs to evaluate, treat and monitor the progress of our patients. Our BEST-CLI team has been successful recruiting and enrolling subjects into the study through careful screening of patients that are seen by the Vascular Surgery Team. We work together to ensure every patient has an opportunity to participate in the study. Coordination of study related visits are carefully monitored and administered by the team. The safety of our subjects and the quality of our research is paramount.”

Site Spotlights

## BEST SVS VAM Presentation Now Available on [NERI Connect](#)!

### VA Boston Healthcare Systems



From Left to Right: Scott Kinlay, MBBS PhD, Sara T. Jones PhD, Mariah Bundy, James McPhee MD, Summer Mattera PA, Shannon Arehart APRN, Michelle Martin MD  
Not pictured: Joseph Raffetto MD, Naren Gupta MD, Ducksoo Kim MD, Sarah White APRN

“The VA Boston Healthcare Systems has a highly collaborative, multi-disciplinary, BEST-CLI team under the leadership of Scott Kinlay, MBBS, PhD and James McPhee, MD. The team consists of physicians, PAs, APRNs, and research personnel from Interventional Cardiology and Radiology, and Vascular Surgery. Patients are referred through the Vascular Medicine and Vascular Surgery clinics, and we collaborate with the Podiatry clinics to identify CLI cases.

At our site, all CLI patients are considered for the trial, and we have a weekly meeting to discuss potential cases. These meetings include the research personnel, NPs and physicians. Patients are approached by clinicians and research personnel to discuss the trial and find out whether they are interested in participating.

The BEST-CLI trial has had a major impact on increasing the increasing dialogue between specialties. Randomization adds excitement to the patient’s management as we all wait to see which arm the subjects fall into! The patients are also excited!

Overall our participation in the trial has had a lot of positive effects. We feel like we are all contributing to a trial that will help assess the best way to treat CLI.”

## Visit Window Report – New!

Thanks to Caitlin Kielhorn, Study Coordinator at the Denver VAMC, for suggesting the idea!

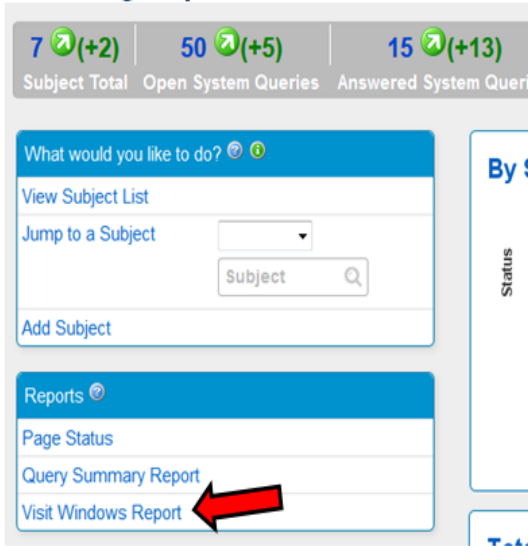
Be sure to check this out! The Visit Window Report is now available to all eCOS users with access to the BEST study data. This report will show the target date for when each post-procedure visit should occur for every randomized subject as well as the acceptable visit window (Start Date to End Date). Users may access this report from the quick links on the home screen or under “Reports” on the blue menu bar (shown below). Note: the visit windows for a subject will only appear on this report AFTER the randomization date has been entered on the Randomization Date page. Also, the 30 Days Post Procedure visit is based off of the procedure date entered on the Index Procedure Summary page and will need to be manually recalculated for any subjects who do not have an index procedure within 30 days of randomization.

### Other key features of the report:

- There is an option to export to Excel at the far right-hand side of the report
- Can be viewed on subject level by clicking on subject-specific reports on the gray menu bar from subject grid
- Use the “search” feature to look for visit statuses that are “due” (window is open) or “overdue” (window has closed- indicated in red)
- Keep in mind- If the Visit Information page is marked as “no visit,” the report will still show the visit as “overdue” since no visit date was entered
- When the visit is completed the visit date will appear under the “Target Date”

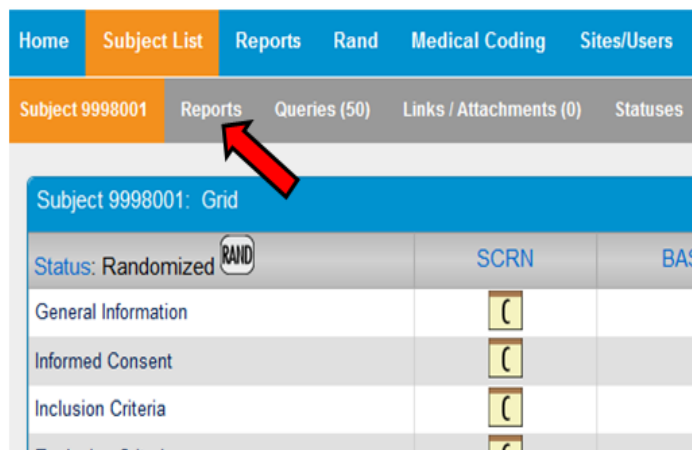
Please reach out the senior data manager, Michelle Grenache at [mgrenache@neriscience.com](mailto:mgrenache@neriscience.com) or 617-972-3189 with any questions!

### Accessing Report From the Home Screen:



The screenshot shows the eCOS home screen with three summary cards at the top: '7 (+2)', '50 (+5)', and '15 (+13)'. Below these are sections for 'What would you like to do?' and 'Reports'. In the 'Reports' section, the 'Visit Windows Report' link is highlighted with a red arrow.

### Accessing Report on Subject Level:

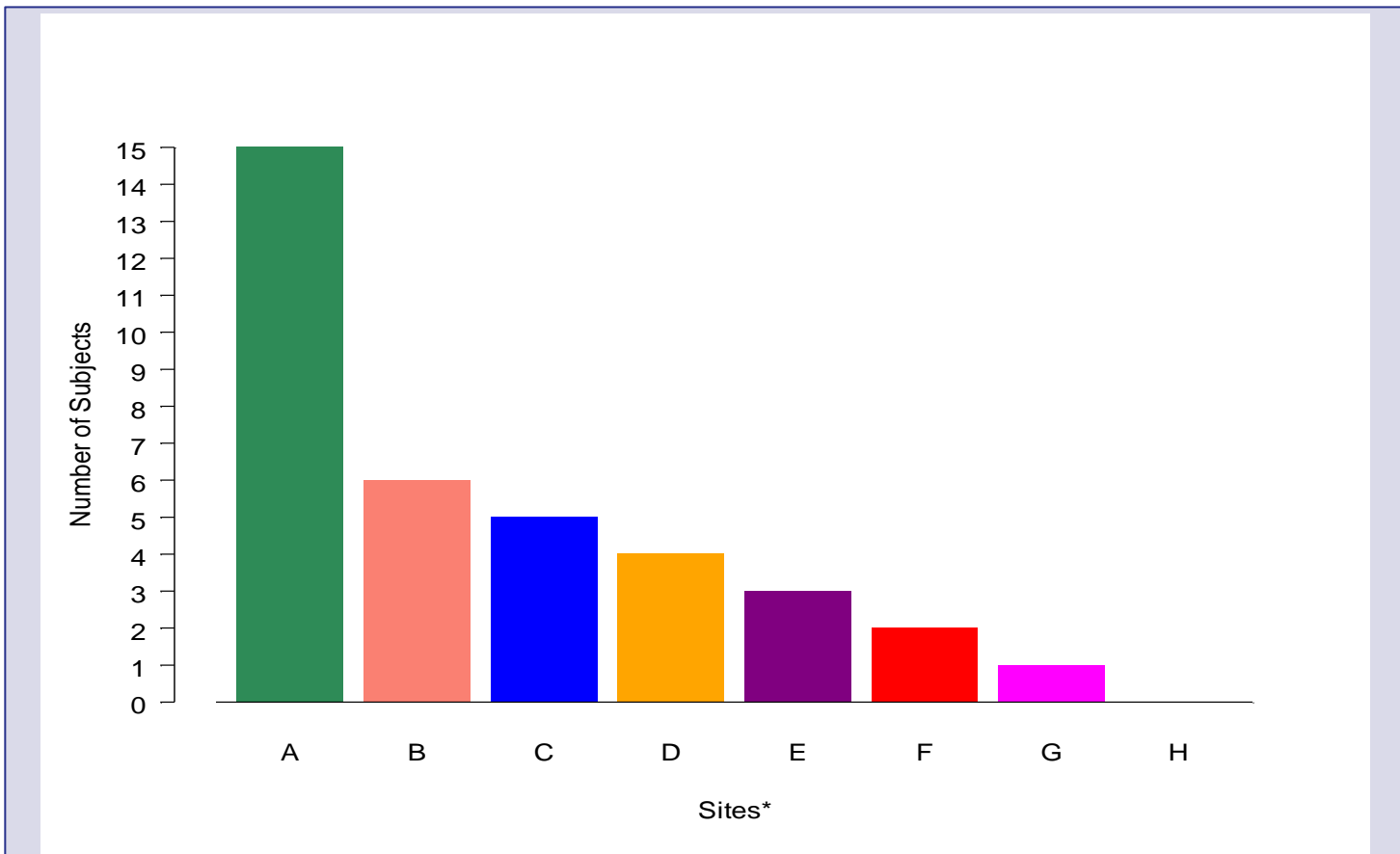


The screenshot shows the subject level menu for 'Subject 9998001'. The 'Reports' option is highlighted with a red arrow. Below the menu, a grid for 'Subject 9998001: Grid' is visible, showing various report categories like 'General Information', 'Informed Consent', and 'Inclusion Criteria'.

### Visit Windows Report:

Site #	Site Name	Subject	A2. Randomization Date	Date of Index Procedure	30 Days Post Procedure					3 Months			
					Visit	Start Date	Target Date	End Date	Status	Visit	Start Date	Target Date	End Date
9998	Test Site	9998001	01-APR-2015	15-APR-2015	30 Days Post Procedure	08-MAY-2015	15-MAY-2015	29-MAY-2015	Overdue	3 Months	31-MAY-2015	30-JUN-2015	30-JUL-2015
9998	Test Site	9998002	15-JUN-2015	15-JUN-2015	30 Days Post Procedure	08-JUL-2015	15-JUL-2015	29-JUL-2015		3 Months	14-AUG-2015	13-SEP-2015	13-OCT-2015

## Enrollment Leaderboard



**Sites\***

- A: 1160 - Keck Medical Center of USC ; 1258 – Boston Medical Center
- B: 1009 - Dartmouth Hitchcock MC; 1105 - Medical College of Wisconsin; 1238 – UMass Medical School
- C: 1108 - Michigan Heart/St Joseph Mercy Ann Arbor Hosp.; 1282 - Carondelet Heart & Vascular Inst.; 1288 - Kaiser Foundation Hosp.; 1314 - VA Boston Healthcare System; 1316 - Holy Name MC
- D: 1005 - Brigham and Women's Hosp.; 1013 - Harbor-UCLA MC ; 1029 - Michael E. DeBakey VAMC ; 1055 - Mount Sinai MC; 1095 - Johns Hopkins Hosp.; 1217 - Univ. of California Davis MC; 1260 - Greenville Memorial Hosp.; 1272 - Southern Illinois Univ. SOM; 1281 - VA Western NY Healthcare System; 1309 - Mercy Hosp. MC; 1310 - Harborview MC
- E: 1113 - Oregon Health and Science Univ.; 1276 - Memorial Hermann Hosp. TMC; 1318 - Univ. of North Carolina Hosp. (Chapel Hill); 1332 - Denver VA MC
- F: 1041 - San Francisco VAMC); 1046 - Steward St. Elizabeth's MC; 1076 - Northwestern Memorial Hosp.; 1169 - Univ. Hosp. of Cleveland/Case Western Reserve Univ.; 1182 - Providence Heart and Vascular Inst.; 1261 - Indiana Univ. Medical School; 1269 - Ohio Health Research Inst.; 1271 - Southern Illinois Univ. SOM; 1277 - The Univ. of Utah; 1304 - CAMC Clinical Trials Center-Univ. of West Virginia; 1311 - Dallas VA MC); 1323 - Univ. of Nebraska MC; 1331 - Pinnacle Health System
- G: 1003 - Allegheny General Hosp.; 1007 - Cleveland Clinic Foundation; 1010 - Emory Univ.; 1030 - Montefiore MC; 1034 - Ochsner MC-Clinic Foundation; 1054 - Univ. of Colorado Hosp.; 1066 - Arizona Heart Hosp.; 1072 - Univ. of Wisconsin – Madison; 1104 - VA Palo Alto; 1125 - Univ. of California San Francisco MC – Parnassus; 1135 - Univ. of Pittsburgh MC; 1137 - The Univ. of Vermont MC, LLC; 1151 - William Beaumont Hosp.; 1256 - Beth Israel Deaconess MC; 1257 - Univ. of Arkansas for Medical Services; 1263 - Kaiser Permanente (San Diego); 1264 - Minneapolis Heart Hosp.-Abbott Northwestern Hosp.; 1270 - Scott and White – Temple; 1279 - North Carolina Heart and Vascular Research; 1287 - Providence Sacred Heart MC; 1290 - Loma Linda Univ. MC; 1294 - North Central Heart Institute; 1305 - Univ. of Virginia; 1308 - The Ohio State Univ.; 1325 - Deborah Heart and Lung Center; 1326 - The Miriam Hosp.-Brown Medical School

## Enrollment Leaderboard Continued

### Sites Continued\*

H: 1008 – Columbia Univ. MC; 1019 - Jewish General Hosp.; 1023 – Massachusetts General Hosp.; 1026 - Medstar Washington Hosp. Center; 1059 - The Univ. of Alabama at Birmingham; 1061 - Baptist Hosp. of Miami; 1075 - Swedish MC; 1101 - Albany MC; 1116 - Rush Univ. MC; 1123 - Thomas Jefferson Univ.; 1126 - Univ. of Chicago Medicine; 1134 - Univ. of Michigan Health System; 1154 – Yale  
 1229 - Penn State Milton S. Hershey MC; 1234 - Univ. of Toledo MC; 1259 - Rhode Island Hosp.; 1273 – Univ. of Florida (Gainesville); 1274 - Univ. of Oklahoma Health Sciences Ctr.; 1275 - Medical Univ. of South Carolina; 1280 - Metro Health Hosp. Wyoming, Michigan; 1284 – Chu de Quebec; 1285 – Duke; 1289 - Lenox Hill Hosp.; 1293 - Univ. Health System: LSU Health Sciences; 1295 - Oklahoma Foundation for Cardiovascular Research; 1296 - Sacred Heart Hosp. River Bend; 1298 – Tufts MC; 1299 - Univ. of Tennessee MC; 1302 - UCLA-Gonda Vascular Surgery; 1306 – McGill (formerly known as Royal Victoria); 1315 - George Washington Univ. Hosp.; 1317 - Roper Hosp.; 1319 - Hunterdon MC; 1320 - Portland VA MC; 1327 - Wellmont Holston Valley MC; 1330 - The Heart Center of Lake County; 1334 – Stanford; 1336 - Staten Island Univ. Hosp.; 1341 – Meriter Wisconsin Heart; 1346 – Gunderson Health System

### BEST May Highlights

**Number of New Sites Activated: 2**  
**Top Enrollers: #1029/Michael E. DeBakey VAMC and #1314/ VA Boston Healthcare Systems**  
**Sites Enrolling 1<sup>st</sup> Subject: 9**

### Request for Screening Logs!

Screening Logs are due bi-weekly to the DCC. The next round of screening logs is due

**July 3rd**

**[Click here to submit yours!](#)**

Be sure to document all screen failures on your screening logs.

**REMINDER**  
**Excel Version of**  
**Screen Failure**  
**Log Available on**  
**NERI Connect!**



### DSMB Memo on NERI Connect!

The BEST-CLI DSMB completed its second meeting on Monday, June 01, 2015. A DSMB memo, which was a result from the meeting, has been posted to [NERI Connect](#).

Please follow your institutional guidelines when it comes to notifying your IRBs of this information.

### Staff Changes at Your Site?

**Here are 3 easy steps to take...**

1. Notify your IRB
2. Provide updated regulatory documents to NERI including:
  - Statement of Investigator for any changes in investigators
  - Delegation of Authority log
  - CV and medical license
  - Financial disclosure form
  - Attestation form for any changes in investigators
3. LASTLY, please send updated CONTACT INFORMATION to NERI at [best@neriscience.com](mailto:best@neriscience.com). Thank you!