



Randomized comparison of the clinical  
Outcome of single versus  
Multiple  
Arterial grafts



**Weill  
Cornell  
Medicine**

## July 2018

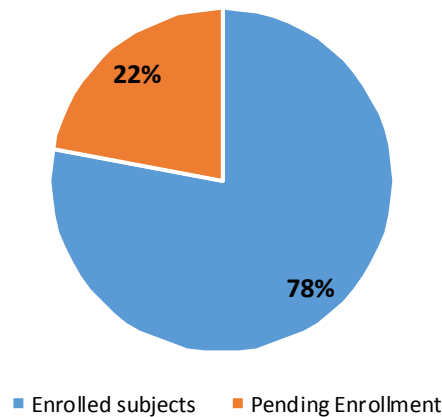
Thank you all for all your hard work and dedication to this study. We look forward to the work ahead and our collaboration on this exciting trial!

Please see [page 3](#) for important study information regarding [study crossovers](#).

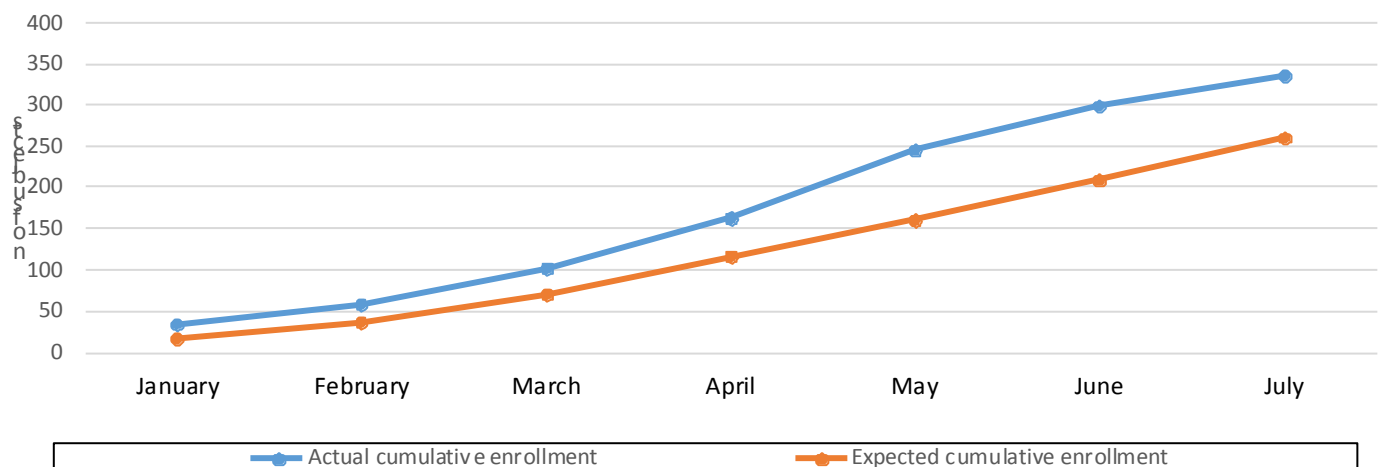
This month, we are highlighting Lennox Hill Heart and Lung on [page 6](#).

## Subject Enrollment Updates (as of July 19, 2018)

### Completion of ROMA Trial Pilot Phase

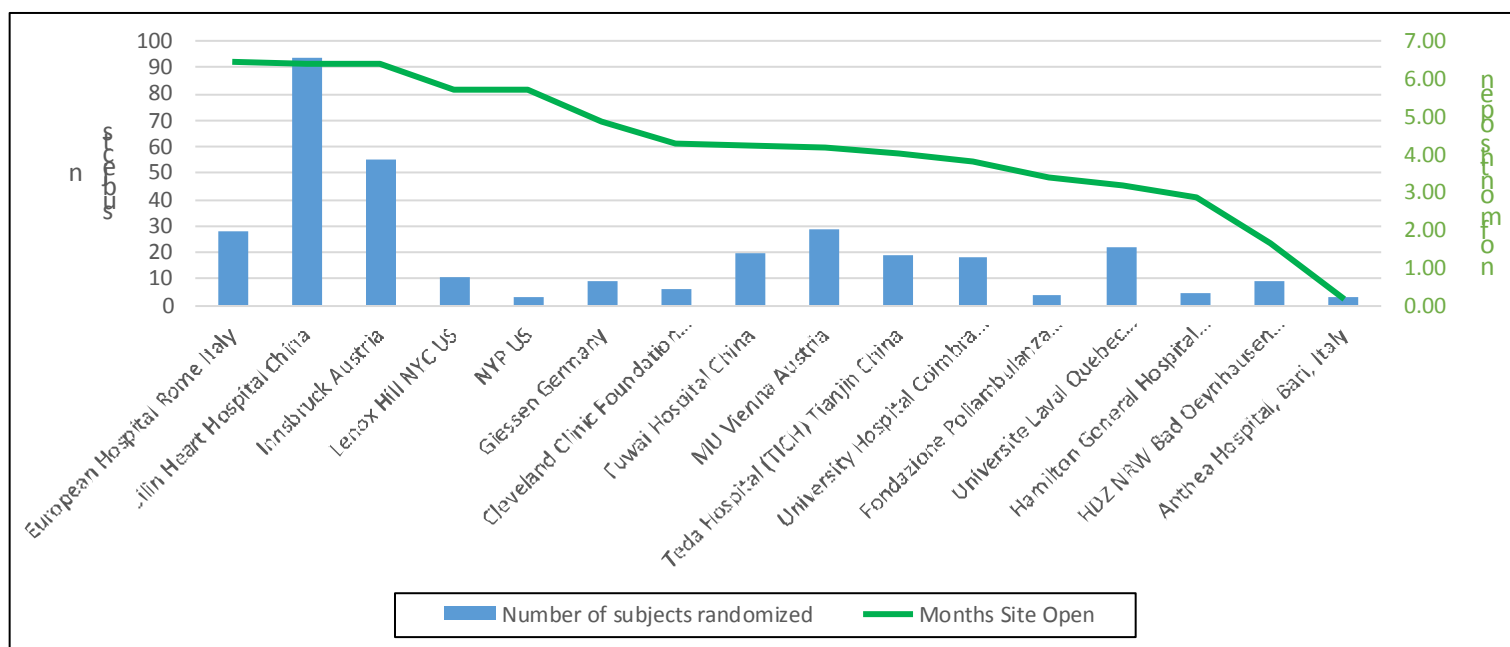


### Expected / Actual Enrollment

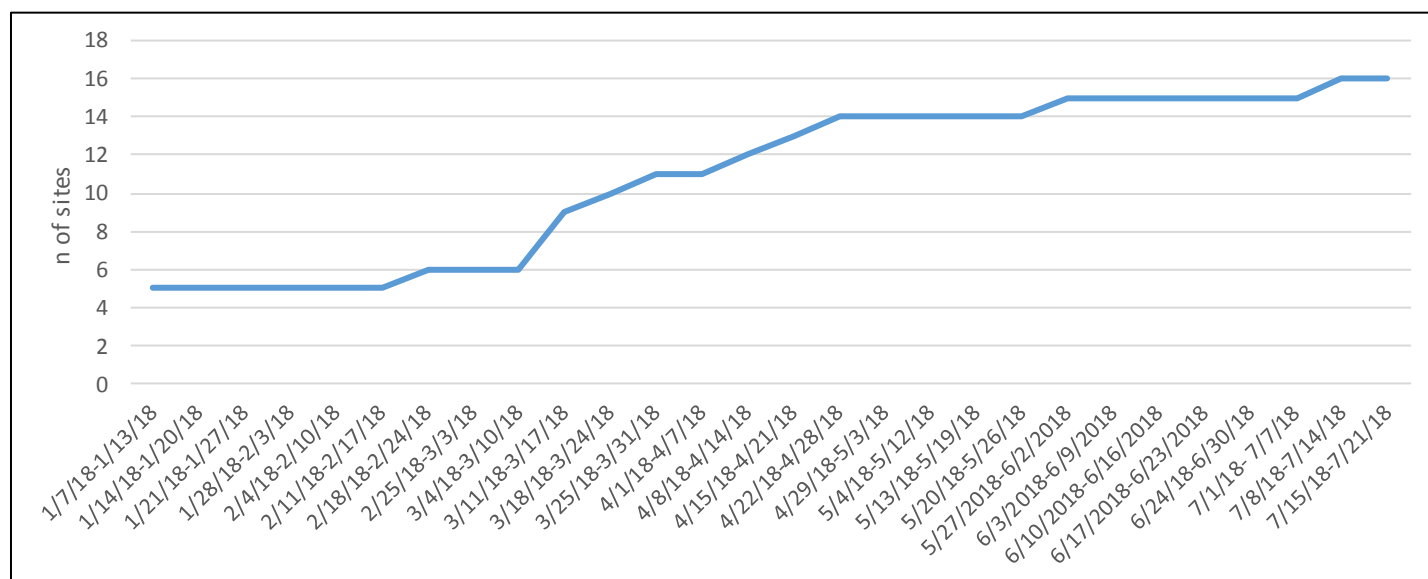


## Subject Enrollment Updates (as of July 19, 2018)

Subject Enrollment Status	Number of subjects
<b>Total Randomized</b>	335
<b>SAG</b>	165
<b>MAG</b>	170



## Cumulative Number of Open Sites



## The importance of the Xover rate for ROMA and how to minimize it

In randomized trials, Xovers from one group to the other by definition dilutes the treatment effect and works in favor of the null hypothesis. In surgical trials, the Xover rate can also express the level of comfort of the participating surgeons performing the assigned intervention or the level of complexity of the intervention.

One of the main criticisms of the ART trial was the very high rate of Xover from the BITA to SITA group (16.4%). The high number of Xover events in ART has been attributed to the limited experience of some of the ART surgeons in the systematic use of the BITA.

ROMA was designed taking into account the lessons learned for ART. As the SC of ROMA felt that there are patients, anatomic situations and surgeons for whom the radial artery, and not the right ITA, is the optimal second arterial graft, the choice of the second artery in ROMA is left to the operating surgeons to maximize efficiency and minimize the crossover rate.

It is important to note that a **Xover rate below 5% is one of the milestone that need to be met to consider the pilot phase of ROMA successful**. To date our global Xover rate is 3.2%, but there are wide variations between centers. To date, **the most important reason for Xover (60%) is related to the harvesting/quality of the second arterial conduit**.

### The suggested strategies to minimize the Xover rate in ROMA are:

1. **Select the second arterial graft that you consider most appropriate for the individual patient and local expertise**
2. **Assess conduit availability and quality before randomization (in particular for the radial artery)**
3. **Keep in mind that conduit harvesting is a crucial part of the procedure and should not be performed by the least experienced surgeon of the team**

The success of the pilot phase is obviously key for the trial. We heavily count on your surgical skill and support to make ROMA happen. Thanks for your efforts in this important study.

Mario, Steve and the ROMA Steering Committee



## Important Study Updates and Reminders

- **\*Please note\***: the study team distributed a **new set of study documents**, including an **updated protocol in June**. Please contact us if your site has not received this email: [roma@med.cornell.edu](mailto:roma@med.cornell.edu)
- In an attempt to capture all critical study information, the WCM study team is requesting that participating sites continue to email us directly when the following events occur in addition to entering into the database:
  - Protocol non-adherence to the randomized arm (crossover event)
  - Adverse events
    - For non-English speaking countries providing source documents in a different language, please provide a synopsis of the Adverse Event in addition to the source documents

***Emails can be sent directly to Dr. Gaudino, Dr. Frenes,  
and the WCM study team at [ROMA@med.cornell.edu](mailto:ROMA@med.cornell.edu).***

- Informed consent should be obtained from subjects prior to any study-related procedures occurring, including randomization into the database
- Please send your center's Pre-screening Log and Protocol Deviation Log on the 1st and 15th of each month to [ROMA@med.cornell.edu](mailto:ROMA@med.cornell.edu)

## CONTACT US

### **Weill Cornell Medicine Study Team**

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## DATABASE REMINDERS

- ⇒ Please enter ***subject initials*** only in the database when randomizing subjects.
- ⇒ Please upload a copy of a de-identified (subject full name crossed out, just leaving initial and date) ***informed consent form*** for each entered subject.
- ⇒ On the “Medication” form in the database, please mark “YES” or “NO” for each option (blank responses are considered incomplete).

## ClinvestiGator



<https://ccim.med.cornell.edu>

**Do you have a research project that  
requires an electronic database?**

**Reach out to the Clininvestigator team.  
They can work with your site to create a  
custom database.**

**Ccimsupport @med.cornell.edu**

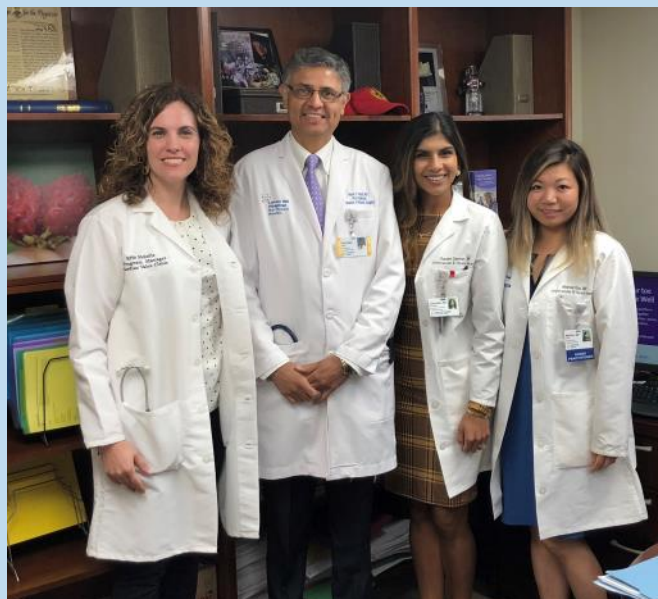


## **ROMA Participating Site Highlight: Lenox Hill Heart and Lung**

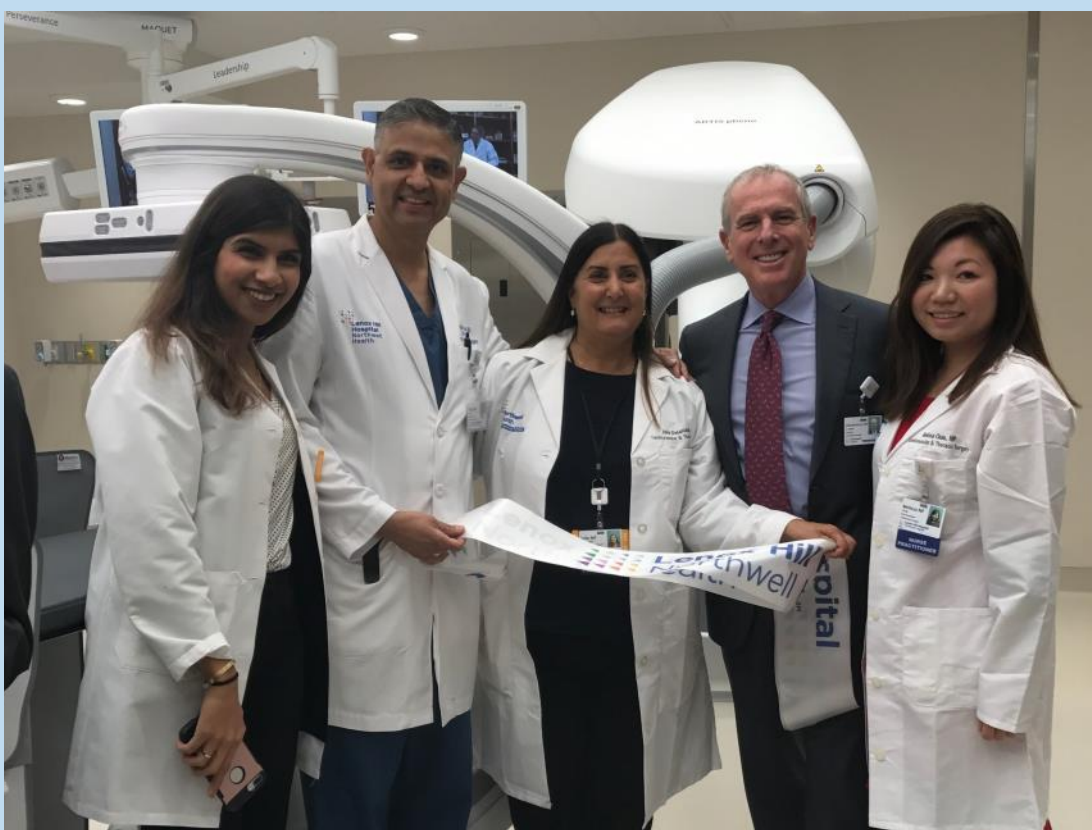
Lenox Hill Hospital has emerged as a national leader in patient care, scientific discovery, medical education, and community involvement. As a tertiary hospital of Northwell Health, one of the largest healthcare systems in the country, we proudly provide the most advanced diagnostic and therapeutic technologies to all patients. Located on Manhattan's Upper East Side, Lenox Hill Heart & Lung is a premier destination for quality cardiovascular and thoracic care and has been a staple in the community for over 150 years.

### **Part of the study team (from left to right)**

**Effe Mihelis, Director Clinical Research Programs, CTS,  
Dr. Nirav C. Patel, Chandini Daswani, NP, Melissa Chau, NP**



Lenox Hill Hospital has been a pioneer in advanced cardiac care performing many “firsts” in cardiac interventions that have transformed and defined cardiac care today. Lenox Hill was the first hospital in the nation to perform Angiocardiology, the first hospital to open a Cardiac Catheterization Lab and Cardiac Unit in New York City and the first hospital in the nation to perform Coronary Angioplasty. Continuing at the forefront of innovation, Lenox Hill pioneered the Minimally Invasive Direct Coronary Artery Bypass Surgery (MIDCAB) and performed the first Endoscopic Radial Artery Harvesting. In 2009, we performed the first Robot-Assisted closed chest beating heart double bypass operation in New York City.



**Photo taken at the grand opening of their new state-of-the-art hybrid OR suite**

**From left to right: Chandini Daswani, NP, Nirav C. Patel, MD, Julie Delianides, Supervising NP, S. Jacob Scheinerman, MD, Melissa Chau, NP.**

Dr. Nirav C. Patel, Vice Chairman of the Department of Cardiothoracic Surgery and Director of Robotic Cardiac Surgery is a world-renowned cardiac surgeon and researcher. Dr. Patel is a high volume surgeon performing MIDCAB, Robot-assisted coronary bypass grafting, and multi-artery coronary revascularization. He has demonstrated excellence in technique, patient outcomes and has published extensively in the field of cardiac surgery. More than 50% of Dr. Patel's coronary artery revascularization cases are performed using multiple artery grafts. Furthermore, multi-artery grafting is offered for both off-pump and on-pump cases. Lenox Hill Heart & Lung offers more minimally invasive surgical alternatives to conventional open heart surgery when compared to national averages. In 2017, 31% of coronary artery bypass grafting for coronary revascularization was performed with robotic- assistance. We are proud to report that the Society of Thoracic Surgeons (STS) has awarded our center as one of the top 10% of hospitals to receive an overall three-star quality rating for isolated CABG surgery.



Dr. Patel and the team at Lenox Hill Heart & Lung have been widely recognized for excellence in cardiac care and the ability to blend research into clinical practice. To support clinical expertise, we continually invest in technology and pursue research endeavors. Lenox Hill Heart & Lung has often been chosen to participate in the latest cardiac clinical trials. Our dedicated research team strives to conduct research in a thoughtful, ethical manner, following research protocols and regulatory guidelines with the utmost attention to detail. We aim to deliver only the highest quality of data in a timely fashion. Each Division within the Department of Cardiothoracic Surgery has a dedicated group of researchers focusing on various areas of cardiothoracic research.



**Nirav C. Patel, MD and Julie Delianides NP**

Under the leadership and guidance of our Chairman, Dr. S. Jacob Scheinerman, our Principal Investigators and dedicated Research Director, these study teams meet weekly to discuss all research activities including regulatory updates, screening and enrollment, recruitment strategies, community outreach and patient education.

We are honored and proud to be a participant in the ROMA trial and are dedicated to its success. Through teamwork and a commitment to excellence, we can achieve this goal. We thank Dr. Gaudino, Dr. Fremes and the entire ROMA study team for this opportunity.