



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



**Weill
Cornell
Medicine**

Dear ROMA Study Teams,

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!

This month, we are highlighting European Hospital in Italy starting on page 5.

Study Updates

- As a result of all of the efforts of our collaborating sites, as of May 21, 2018, **211** subjects have been randomized!
- The Weill Cornell Medicine (WCM) study team has created an email address: **ROMA@med.cornell.edu**. This can be used for all ROMA-related correspondence.
- In an attempt to capture all critical study information, the WCM study team is requesting that participating sites 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

Emails can be sent directly to Dr. Gaudino, Dr. Frenes, and the WCM study team at ROMA@med.cornell.edu. Please see page 4 for study team contact information.

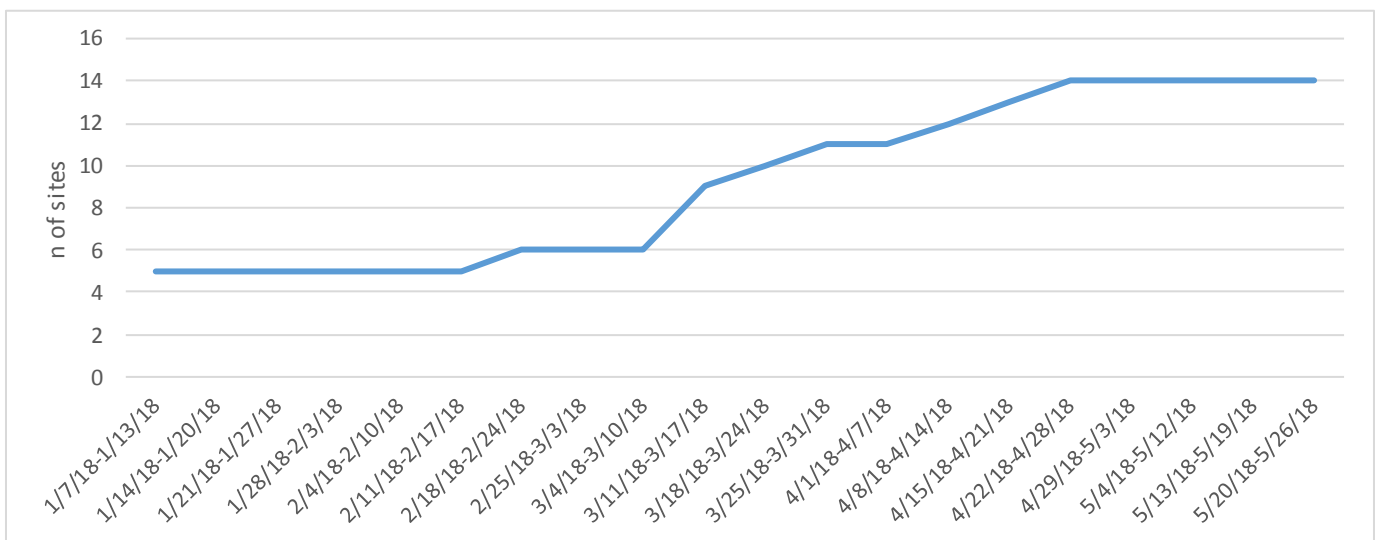
- We have a few documents for your review. You can find them by scrolling to the end of the newsletter:
 - Page 8: Updated list of source documents requested for adverse events.
 - Page 9: Study memo to clarify the initial post-operative follow-up window

ENROLLMENT SUMMARY

As of May 21, 2018

Subject Enrollment Status	N
Total Randomized	211
SAG	104
MAG	107

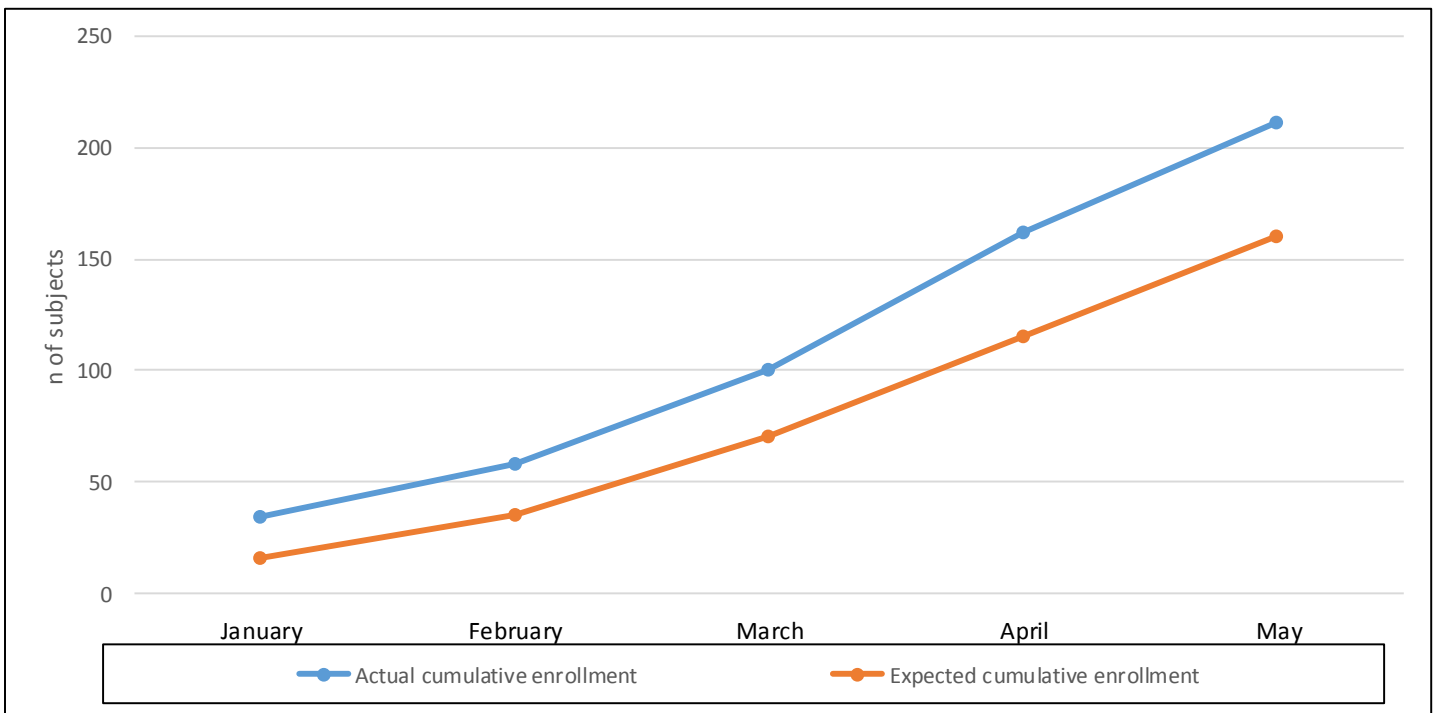
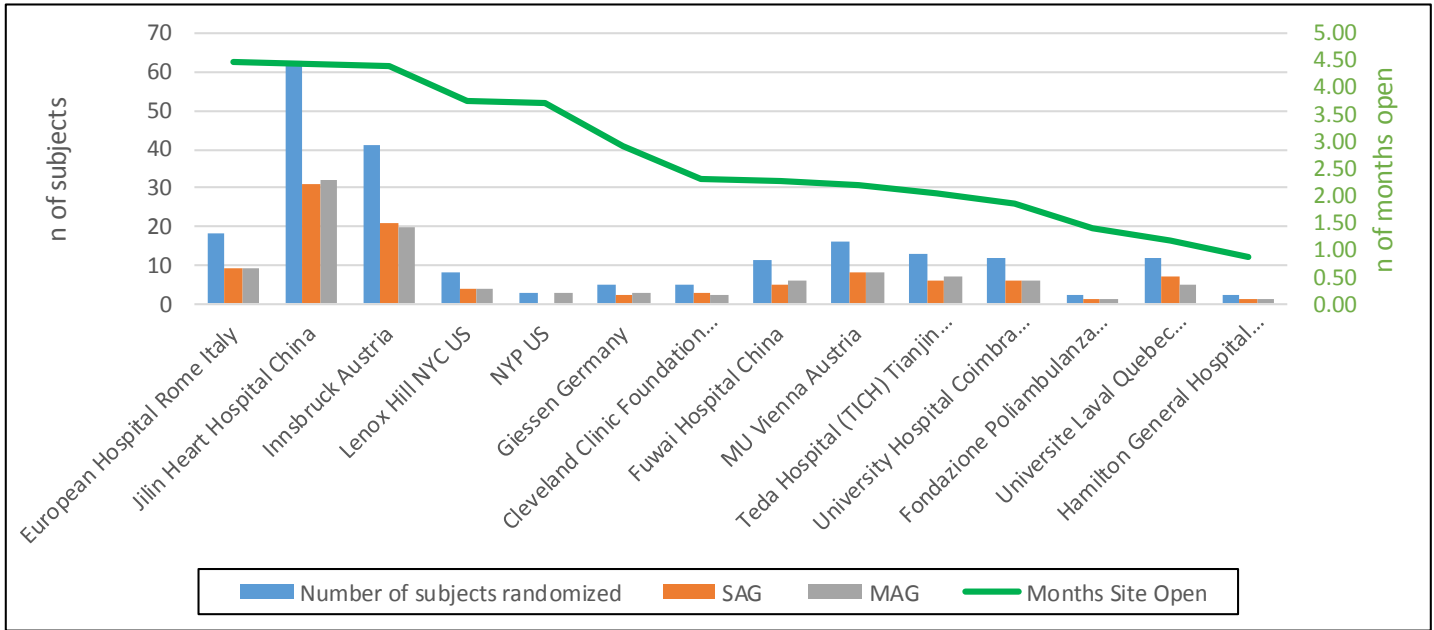
Cumulative Number of Open Sites as of May 21, 2018



ENROLLMENT SUMMARY

As of May 21, 2018

Subject Enrollment Updates



CONTACT US

Weill Cornell Medicine Study Team

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Important Study Reminders

- ◆ **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

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

ClinvestiGator



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).



ROMA Participating Site Highlight: European Hospital

Roma Embraces the ROMA Trial

Italy is often known over the world for its historical and cultural immense heritage, or because of its food and fashion excellences, but it is as well one of the places where heart surgery was pioneered even before the invention of the heart-lung machine.

The epidemiology of heart surgery pathology in Italy has been evolving in parallel to the other so called “First World” countries, with a decreasing prevalence of rheumatic and congenital diseases and a steep increase in degenerative and atheromasic problems.

The European Hospital Heart Surgery Unit is situated in Italy’s Capital City, Rome, and was founded in 1990 at the time of the opening of the Tor Vergata University of Medicine, and lately becoming an independent division offering a public service for the majority of cardiac diseases.

Since April 2006, the European Hospital Heart Surgery Unit has been under the direction of Prof. Ruggero De Paulis who has continued and promoted an environment of intense clinical and research activity . With more than 8 thousands open heart surgery and hundreds of internationally peer reviewed publications it is one of the leading



European Hospital Heart Surgeons

Upper Row, left to right: Francesco Irace, Lorenzo Guerrieri-Wolf, Luca Weltert

Lower Row, left to right: Andrea Salica, Salvatore D'Aleo, Ruggero De Paulis (Department Head), Ilaria Chirichilli, Alessandro Bellisario

In this hospital the first world's first aortic root graft was developed, today known as the Valsalva™ graft, specifically designed to address all types of aortic root surgery, from Bentalls to both types of valve sparing operation, the remodeling and the reimplantation procedures . This graft is now utilized worldwide routinely in many aortic root surgeries and has also been an invaluable research instrument . It has stimulated several studies on the role of the sinuses of Valsalva in regulating the dynamics of the aortic valve, and in modulating aortic and coronary flows. It has been instrumental in optimizing the reconstruction of a perfect root anatomy.

The vision of the Hospital is synergic to that of the cardiologists and cardiac surgeons in building a Comprehensive Excellence Heart Center for the adult, with special focus on aorta (from root to ascending to arch), and aortic valve (with pioneering reconstruction and minimally invasive replacement techniques as well as trans-catheter approaches), on mitral valve (with high success in repair rate, either performed via sternotomy or left mini-thoracotomy with endoclamping) and of course on coronary artery revascularization. Regarding coronary artery revascularization, both off-pump (80%) and on-pump (20%) surgery are routinely performed and whenever possible a no-touch-aortic approach is preferred, either by in situ full arterial revascularization or composite Y grafts with mammary arteries and/or veins, and systematic Transit Time Flow Measurement.

In 2005 a seminal paper (1) was published on coronary revascularization highlighting the different results between single vs. double internal thoracic arteries as well as the differences when these conduits were used in a pedicled or a skeletonized fashion. Given the background, it was easy to fully embrace enthusiastically the proposal to be part of the ROMA trial so masterfully designed by our friends and colleagues at Weill Cornell Medicine/New York Presbyterian Hospital. The craving to find the definitive answer to the long lasting debate on the superiority of the arterial graft is shared with all participants to this trial as patients continue to be enrolled. .

Our full attention on recruitment and follow up continues, as we are honored to be part of this trial and curiously of being part of this crucial scientific answer.

Greetings from our full team!

1. The effect of bilateral internal thoracic artery harvesting on superficial and deep sternal infection: The role of skeletonization. De Paulis R, de Notaris S, Scaffa R, Nardella S, Zeitani J, Del Giudice C, De Peppo AP, Tomai F, Chiariello L.J Thorac Cardiovasc Surg. 2005 Mar;129(3):536-43.

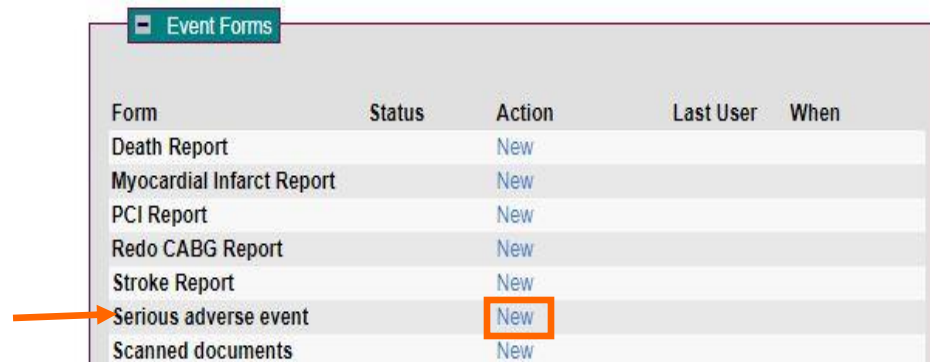


Required Source Documentation to Support Adverse Events

Please use this list as a reference for required source documentation when reporting adverse events.

Death	<ol style="list-style-type: none"> 1. Chart, consultation and discharge reports 2. Clinical/nursing notes 3. Autopsy report (if applicable)
Repeat revascularization (PCI or CABG)	<ol style="list-style-type: none"> 1. Pre-procedure ECG 2. Post-Procedure ECG 3. Laboratory reports (cardiac enzymes) 4. Cath report 5. Operative report 6. Chart, consultation and discharge reports 7. Autopsy report (if applicable)
Myocardial Infarction	<ol style="list-style-type: none"> 1. Chart, consultation and discharge reports 2. Laboratory reports (cardiac enzymes), ECGs 3. Angiogram 4. Echocardiogram 5. Clinical/nursing notes 6. Autopsy report (if applicable)
Stroke	<ol style="list-style-type: none"> 1. Chart, consultation and discharge reports 2. Imaging (CT and/or MRI head scan) report(s) 3. Clinical/nursing notes 4. Autopsy report (if applicable)
Surgical site infection	<ol style="list-style-type: none"> 1. Chart, consultation and discharge reports 2. Laboratory report(s) 3. Imaging/x-ray report(s) 4. Surgical notes 5. Clinical/nursing notes

Upload the requested documents in the ROMA Database (<https://ccim.med.cornell.edu>) using the form 'scanned documents' under the section 'Event Forms'.





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Study Clarification Memo

Protocol Title:	Randomized comparison of the clinical Outcome of single versus Multiple Arterial grafts: The ROMA Trial.
Weill Cornell IRB #:	1703018094
Prepared by:	Weill Cornell Medicine, Joint Clinical Trials Office, Investigator-Initiated and Multicenter Protocol Operations Team
Date prepared:	27 April 2018

This memo serves as clarification of protocol section 5.8, Follow-up.

The current protocol version 10.2 reads, “Patients will be seen in clinic 6-12 weeks postoperatively as per individual institutional routine.”

This should read, **“Patients will be seen in clinic 2-12 weeks postoperatively OR as per individual institutional routine.”**

This will be corrected with a forthcoming protocol amendment.

(Signed version on next page)

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Mario
PI Signature: Gaudino

 Digitally signed by Mario Gaudino
DN: cn=Mario Gaudino, o=Cornell
University, ou=Dept. CT Surgery,
email=m.g0004@med.cornell.edu, c=US
Date: 2018.04.27 17:27:49 -0400

Date: 4/27/18