



Randomized comparison of the clinical

Outcome of single versus

Multiple

Arterial grafts



**Weill
Cornell
Medicine**

ROMA Trial Newsletter

June 2018

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 Medical University Vienna starting on [page 5](#).

Study Updates

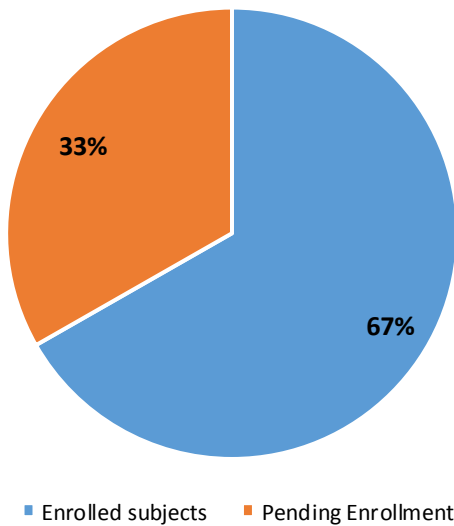
- As a result of all of the efforts of our collaborating sites, as of June 21, 2018 **287** subjects have been randomized!
- ***Please note***: the study team recently distributed a **new set of study documents**, including an **updated protocol**. Please contact us if your site has not received this email: 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. Please see [page 4](#) for study team contact information.

ENROLLMENT SUMMARY

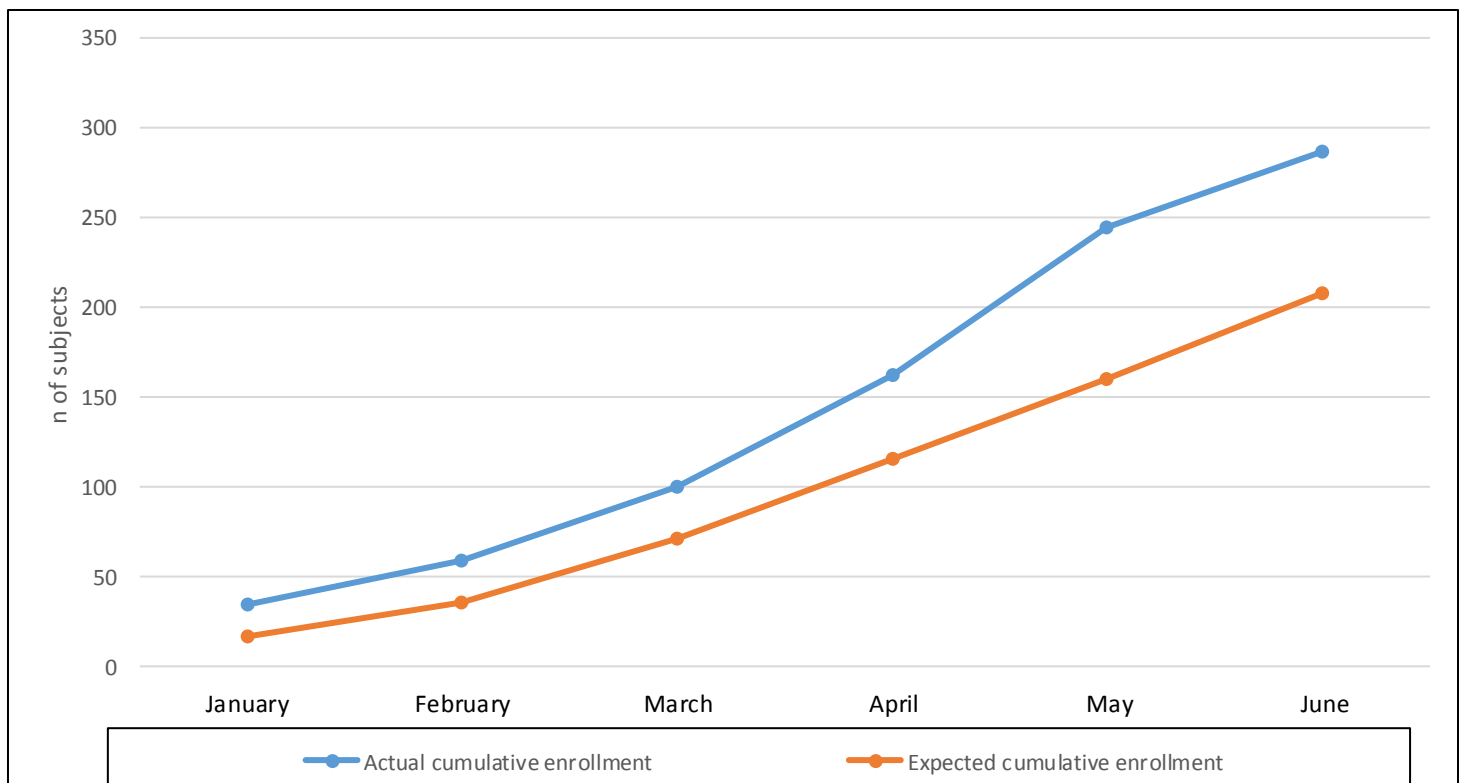
As of June 21, 2018

Completion of ROMA Trial Pilot Phase



Subject Enrollment Status	Number of subjects
Randomized	287
SAG	140
MAG	147

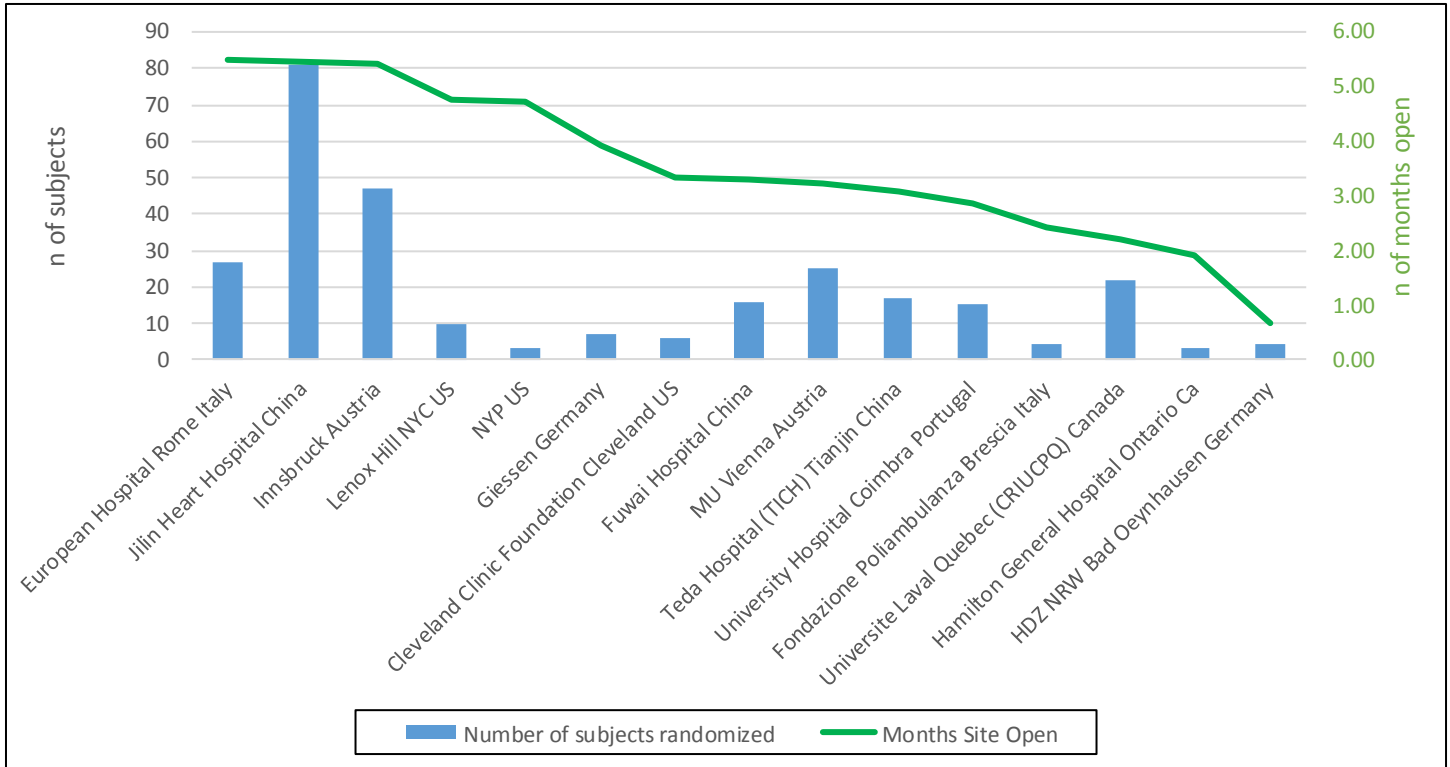
Expected / Actual Enrollment as of June 21, 2018



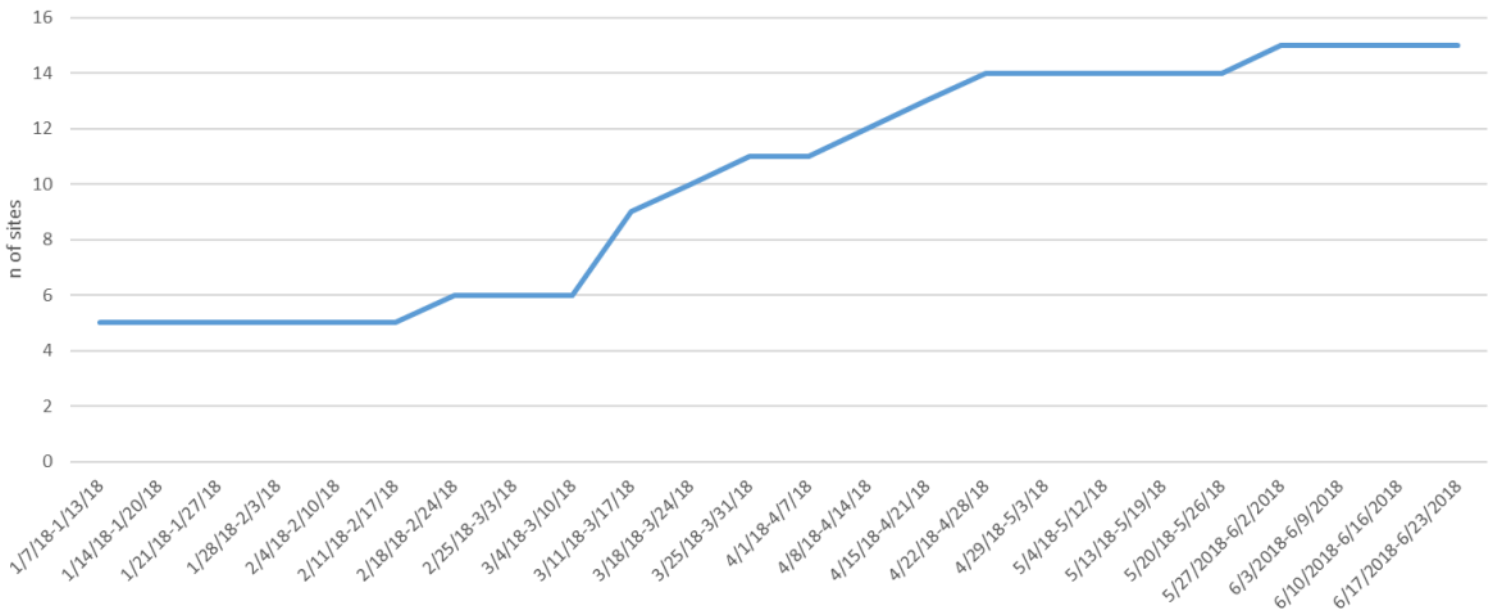
ENROLLMENT SUMMARY

As of June 21, 2018

Subject Enrollment Updates



Cumulative Number of Open Sites as of June 21, 2018



CONTACT US

Weill Cornell Medicine Study Team

Mario FL Gaudino, MD, FEBCTS
Principal Investigator
mfg9004@med.cornell.edu

Stephen E. Fremes, MD, FRCSC
Principal Investigator
Stephen.Fremes@sunnybrook.ca

General, Regulatory, and Data Inquiries

ROMA@med.cornell.edu

Trisha Ali-Shaw
Multicenter Program
Manager
tra2002@med.cornell.edu

Silvia Senese
Program Specialist
sis2018@med.cornell.edu

Kyle Calder
Program Specialist
kyc2003@med.cornell.edu

ClinvestiGator Database Technical
Assistance:
Ccimsupport @med.cornell.edu

Contract & Budget Inquiries:
JCTOcontracts
@med.cornell.edu

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).



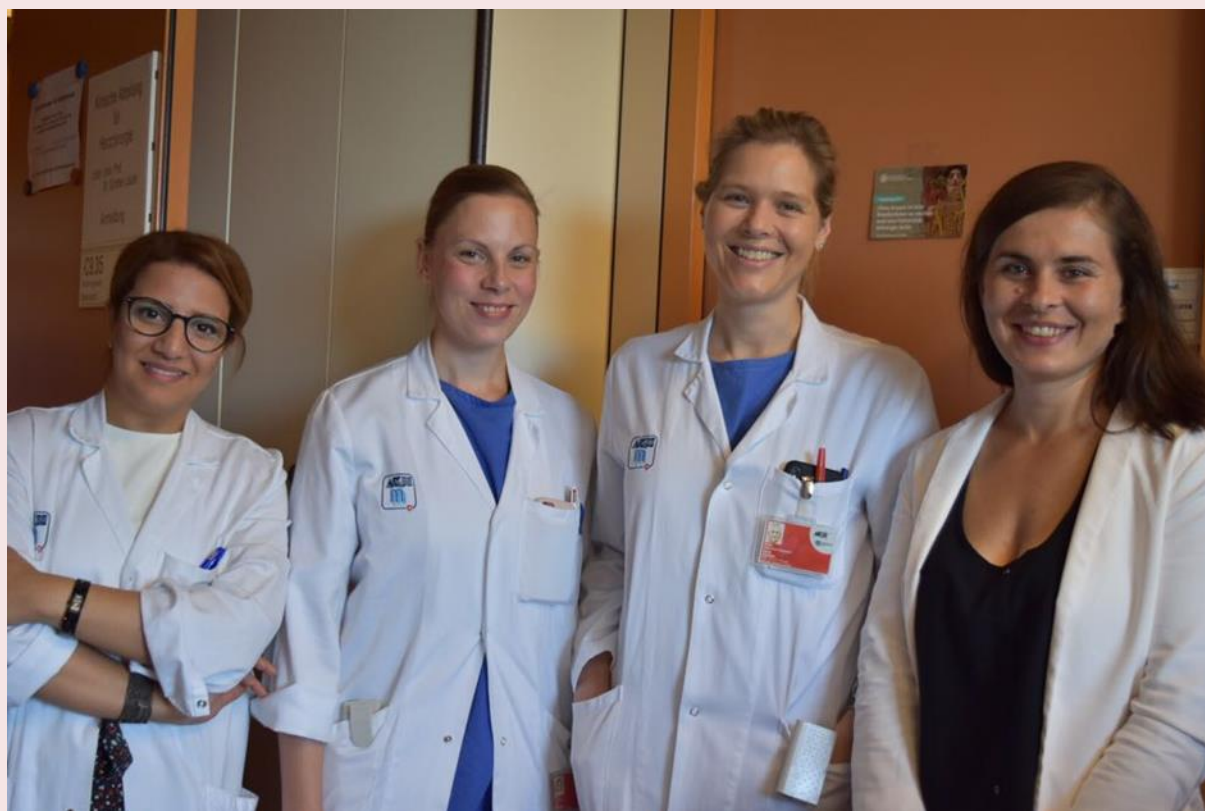
ROMA Participating Site Highlight: Medical University Vienna



The Medical University Vienna (MedUni Vienna) is one of the largest medical education and research facilities in Europe. Its primary teaching hospital, Vienna General Hospital, is one of the biggest hospitals in Europe and serves >650,000 patients annually.

The Department of Cardiac Surgery at Medical University Vienna performs approximately 300 isolated CABG procedures per year. Although the majority of procedures are carried out with LIMA + SVGs, the proportion of patients receiving 2 or more arterial grafts has increased over the past years with 35-40 % of patients currently routinely receiving 2 or more arterial grafts. That percentage increases to 60% in patients <70 years of age, with both the RIMA and radial artery routinely used as a second arterial conduit.

Our center is currently participating in multiple clinical trials focused on improving outcomes after CABG surgery: the VEST III Trial, which evaluates the outcomes of externally stented saphenous vein grafts; the DuraGraft Registry Study; and the TiCAB Trial (Ticagrelor in CABG), a surgical multicenter trial evaluating ticagrelor compared with aspirin after CABG. Results of the TiCAB Trial are expected for this year. The Coronary Surgery Program is led by Dr. S. Sandner.



The ROMA Trial study team is led by Dr. Sandner and includes cardiac surgery fellow Dr. Julia Riebandt, study coordinator Shiva Shabanian, and research assistant Dijana Barbaric.

A note from Dr. Sandner:

Dear Colleagues,



I would like to congratulate Mario and Steve on successfully getting the ROMA Trial underway to address one of the foremost issues in coronary surgery.

I would also like to congratulate all participating centers on the outstanding recruitment effort that is outperforming expectations. We are excited and proud to be part of this effort.

Sincerely,

Sigrid E. Sandner, MD