ROMA

Randomized comparison of the clinical

Outcome of single versus

Multiple

Arterial grafts

Weill Cornell Medicine

March 2019

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

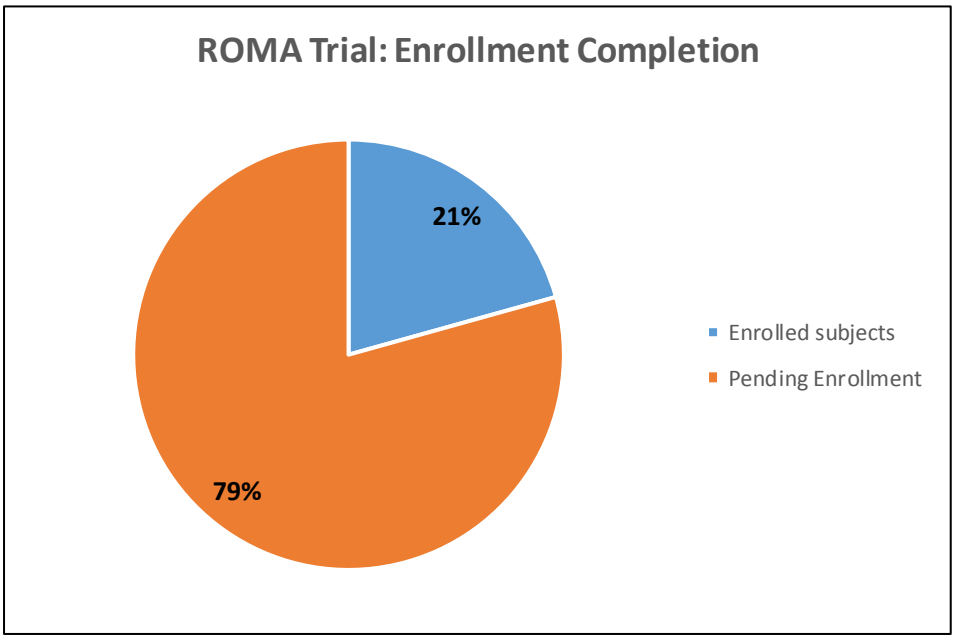
A few exciting items to announce!

- We have hit our 900th subject randomization!
- The Canadian Institutes of Health Research (CIHR) Grant was awarded earlier this year. We are currently in the process of working out budget details and more information is forthcoming.
- The Steering Committee is in the process of submitting a National Institutes of Health (NIH) grant this spring.
- The ROMA Investigator Meeting at the AATS Annual Meeting (Toronto, Canada) will be on **Sunday May 5th from 6:00pm-7:30pm**. The meeting will be held in the Manitoba room at the Fairmont York Royal Hotel. We look forward to seeing you there!

Please keep reading for more updates to subject enrollment, a reminder about adverse event reporting, and our highlighted center of the month,

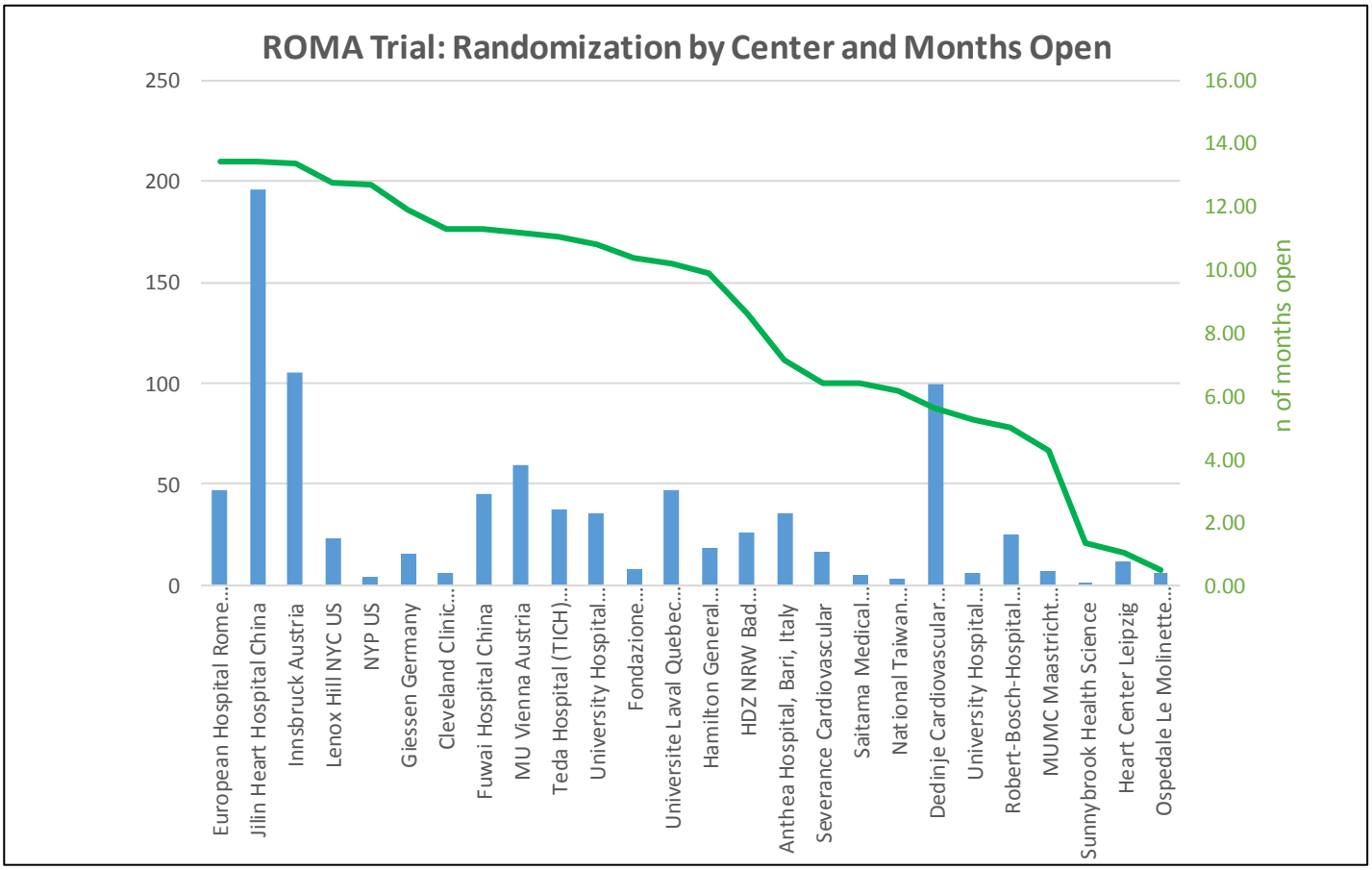
Institute for Cardiovascular Diseases "Dedinje": Belgrade, Republic of Serbia

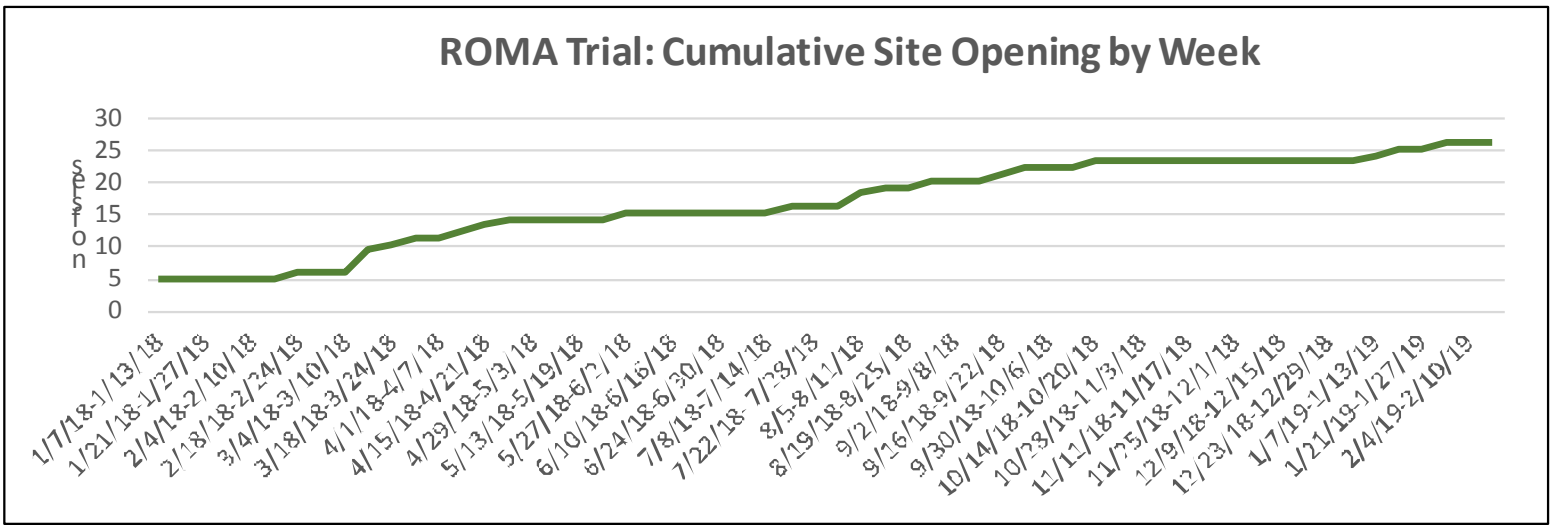
Subject Enrollment Updates



Subject Enrollment Status	number of subjects
Randomized	900
SAG	447
MAG	453

Subject Enrollment Updates





Important Study Updates and Reminders

- Please make all efforts to the **send the pre-screening and protocol deviation log on the 1st and 15th of each month.** This information is critical to the success of the trial.
- 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

    You MUST complete an AE CRF in the database once an event occurs. This triggers the notification to the study team. If you only fill out event forms, we will NOT be notified.

    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. Fremes, and the WCM study team at ROMA@med.cornell.edu.

Informed Consent Process and Documentation

- Informed consent should be obtained from subjects prior to any study-related procedures.
- Consent documents must be signed in the subject's native language or a language of complete fluency.
- Informed consent documents must be properly redacted. **This means that the subject's full name should not appear, but the first and last initials should be retained as well as date for verification purposes.** This is being enforced and sites will be notified for consistent consent issues.

ROMA

What is an Adverse Event?

An adverse event is any untoward medical occurrence in a participant, which does not necessarily have a causal relationship with the trial intervention. These events should be reported to Weill Cornell Medicine via email and in the trial database, Clinvestigator. You must provide medical documentation in your native language as well as a synopsis of the event in English. On the next page, you will find a list of source documents requested for common adverse events on this trial .

Notably, events that are part of the primary safety outcome of this trial are:

- **Myocardial Infarction**
- **Stroke**
- **Death, from any cause**

We ask that these particular events are reported as soon as possible for adjudication.

Source documentation requested to support Adverse Events

Common Events

Death	1. Chart, consultation and discharge reports 2. Clinical/nursing notes 3. Autopsy report (if applicable)
Repeat revascularization (PCI or CABG)	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	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	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	1. Chart, consultation and discharge reports 2. Laboratory report(s) 3. Imaging/x-ray report(s) 4. Surgical notes 5. Clinical/nursing notes
Pericarditis	1. Chart, consultation and discharge reports 2. Echocardiogram 3. ECG

ROMA Participating Site Highlight:

Institute for Cardiovascular Diseases “Dedinje”: Belgrade, Republic of Serbia

Institute for Cardiovascular Diseases "Dedinje" in Belgrade, Republic of Serbia is the largest highly specialized institution for Cardiovascular diseases in Southeastern Europe. Dedinje is dedicated to a high quality of patient care, continues education of healthcare practitioners and trainees, and performs clinical research with the highest ethical and scientific standards. The Institute is composed of several clinical units including Basic Cardiology, Interventional Cardiology, Cardiac and Vascular Surgery, as well as Anesthesiology and Intensive Care Unit. Since its founding in 1973. the staff of the Institutes has performed more than 50,000 open heart operations, 45,000 vascular operations and 200,000 cardiac catheterizations.

Left to right: Milan Milojevic, Principal Investigator, Petar Milacic, Ivana Petrovic

The Institute has a capacity of 200 inpatients beds, including 36 beds in the ICU. It is home to a team of 593 employees working under the leadership of experienced physicians and prominent scientists. Today, the cardiac surgery program performs more than 2,200 open heart procedures in 5 operation rooms, vascular surgery more than 1,700 in 2 operation rooms, and our experts in interventional cardiology and electrophysiology performs more than 2,700 procedures annually in 4 cath lab rooms.

Continuous training of our healthcare practitioners in centers of excellence worldwide significantly adds to the improvement of patient safety and care in daily practice. Moreover, the Department of Continuing Medical Education provides comprehensive weekly activities for our employees and other healthcare institutions. This specific education is designed to increase medical knowledge and skills, build team spirit among colleagues and ultimately change practice behavior, methods or procedures in cardiovascular medicine. Notably, we are trying to continually include not only in education but also in decision-making and procedures well-known experts from the field, who share their practical knowledge and assist in the management of patients with complex needs.

The collaboration that has been established with the Weill Cornell Medicine is of great importance for our Institution. It is a privilege to participate in the ROMA project together with the other colleagues from the leading centers worldwide. Coronary artery disease (CAD) is the number-one cause of death for both men and women with a tremendous social and economic burden in our region. Strategies aimed at improving the outcome of patients who have CAD are therefore one of the ultimate goals for our mission and the general health care system in Serbia. The results of the ROMA could bring a fantastic step forward in treatment-decision making, improved long-term survival, and quality of life in patients who require myocardial revascularization. Therefore, sincerely, we are delighted to support this brilliant initiative fully.

ClinvestiGator

https://ccim.med.cornell.edu

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).

CONTACT US

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ClinvestiGator

The result of over 30 years of experience in clinical research and medical informatics !

ClinvestiGator has been developed based upon over 30 years of experience in clinical research and medical informatics. The ClinvestiGator team of informatics system experts, includes computer scientists, programmers, methodological, statistical and research experts and exceptional user support. Unlike other off-the-shelf packages, ClinvestiGator provides the ability to customize the system to individual researcher needs, and the team develops and adapts the ClinvestiGator data management system as required to meet the objectives for a specific study or registry. Because we have performed our own research over the last three decades, the ClinvestiGator team understands what is required to automate the research process to improve study workflow and to analyze study data.

ClinvestiGator is a Web-Based System for Data Collection

- The researcher defines what data, fields and forms need to be included
- The ClinvestiGator team creates the web-based version of these forms as part of the database
- Data can be entered by diverse users including research staff and patients
- Data from other sources can be imported into *ClinvestiGator*

ClinvestiGator Facilitates Study Coordination

- Investigators can easily manage flow of study protocol
- Patients can be followed over time
- Patient status at any point in time can be easily determined
- Time sensitive "To Do" list maintained by system
- Information easily communicated among members of study team
- Staff work load and productivity can easily be tracked

ClinvestiGator is a Powerful Tool for Real-Time Reporting and Analysis

- Reports can identify populations or outcomes of interest
- Reports can be run in real time to analyze variables of interest
- Reports can be run to determine overall study status
- Reports can be run to export data