



**R**andomized comparison of the clinical  
**O**utcome of single versus  
**M**ultiple  
**A**rterial grafts



**Weill  
Cornell  
Medicine**

## ROMA TRIAL Newsletter - MARCH 2021

### Current Subjects Enrolled

2 4 6 0

### ***In this issue:***

Participating Site Updates \_\_\_\_\_ Page 2

Enrollment Status \_\_\_\_\_ Page 3

Meet the ROMA Team \_\_\_\_\_ Page 6

## ROMA QOL—Health Related Quality of Life (HRQOL) in ROMA subjects

While both operative and postoperative outcomes have improved after CABG, we do not yet know whether CABG improves health related quality of life, physical functioning, or mental health symptoms.

The objective of ROMA:QOL is to understand how CABG surgeries impact quality of life and symptom burden over time. At the end of this study, we will have longitudinal evidence as to which CABG surgical technique (MAG vs. SAG) is optimal for improving the most common distressing symptoms and QOL in order to better inform patients of the risks and benefits of surgery



*ROMA: QOL PIs*

*Dr. Ruth Masterson Creber and Dr. Mario Gaudino*

Subjects consenting to QOL complete questionnaires at baseline, the first postoperative visit, and at 6, 12, 24, 36, 48, and 60 months. They can be collected either electronically, by telephone, or in-person, based on patient preference.

The QOL study is currently enrolling at 13 centers within the trial. The first subject was enrolled at the University of Ottawa Heart Institute on December 4, 2020. Thank you for working together with our team to make ROMA a success and now to help bring our Quality of Life (QOL) study to life! Participation to the ROMA QOL study is open to all active sites. If you would like to open the study, please contact the team: [roma@med.cornell.edu](mailto:roma@med.cornell.edu).

# Please Welcome Our New ROMA Sites!



Newly activated sites



Sites activated prior to May 2020

Country	Participating Center
Germany	Duisburg Heart Center
Croatia	University Hospital Dubrava
Germany	Essen University
Germany	Frankfurt University
Germany	Krankenhaus der Barmherzigen Brüder Trier
US	University of Nebraska Medical Center
Portugal	Centro Hospitalar Universitário São João
Germany	Düsseldorf University
Canada	Toronto General Hospital
Spain	Hospital Univeritario Del Vinalopo
Germany	Jena University Hospital
Canada	Royal Victoria Hospital
Spain	Hospital Clinic de Barcelona
Canada	University Hospital of Montreal
Canada	St. Boniface General Hospital
Poland	Medical University of Silesia
Czech Republic	General University Hospital
Brazil	Federal University of Sao Paulo



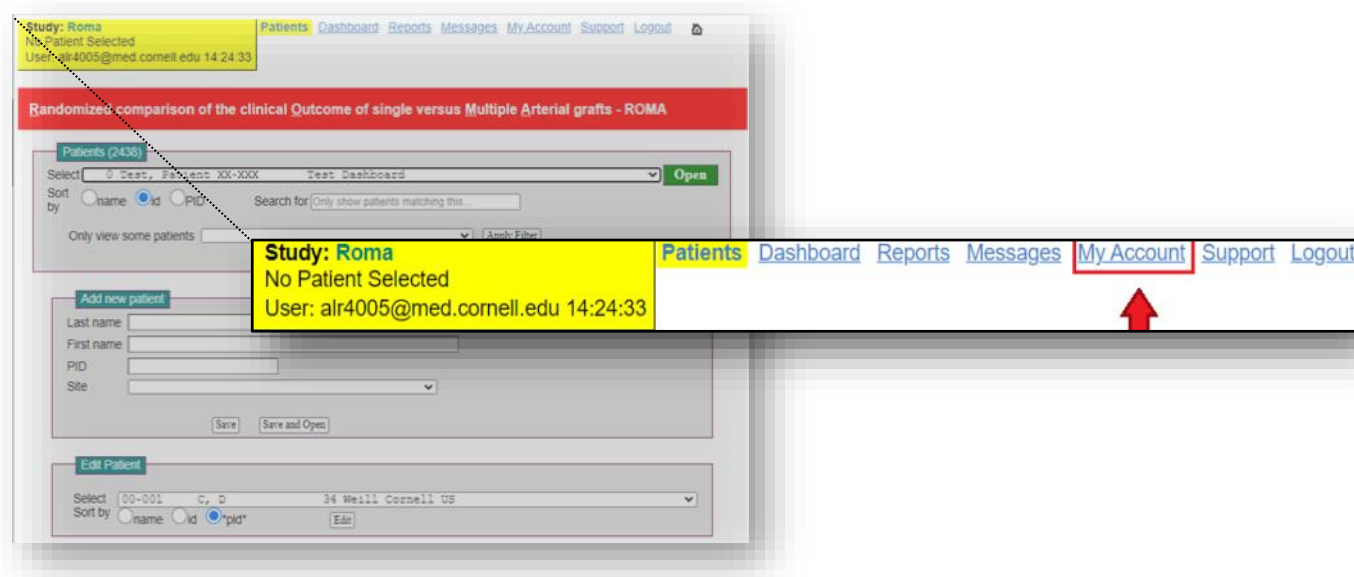
# Clininvestigator Database—ACTION REQUIRED

## Updating User Information

We have received a number of requests for assistance with password retrieval. In response we now collect alternative contact information including a secondary email.

Please update your user settings to provide secondary email using the below guidance:

1. Log onto your Clininvestigator at <https://ccim.weill.cornell.edu>
2. Select “My Account” from your shortcut tab, as shown below



3. Add a Secondary email then Save

A screenshot of the 'Your account' form in the Clininvestigator application. The form is titled 'Your account (Login name: alr4005@med.cornell.edu)'. It contains several input fields for user information: First name (Annette), Last name (Rios), Last 4 digits of SSN, Address, Address 2, City, State, ZIP, Home phone, Work phone, and Mobile phone. There are also fields for Primary email (alr4005@med.cornell.edu) and Secondary email. A note states: 'Make sure your email is current. You will need it if you let your password expire and then try to login!'. Below the email fields is a link to 'Change password and security information'. At the bottom are 'Save' and 'Cancel' buttons. A red asterisk indicates required fields.

## Clininvestigator Database—QOL Enrollment

Upon enrollment to the ROMA main trial, please follow the below to ensure you record if the subject also enrolled on the QOL study. Completion of all of these steps will ensure that your subject is confirmed as enrolled on the QOL study and help guide the coordinating center when calculating enrollment.

### How to record a subject's consent on ROMA QOL:

1. Complete the Eligibility / Randomization form as normal. This step must be performed first.
2. A ROMA QOL consent/email/language Form will automatically appear under the Eligibility/Randomization form.

Randomized comparison of the clinical Outcome of single versus Multiple

Baseline (Date of surgery: 2018-03-01)

Form	Status	Action
Eligibility / Randomization	Incomplete	<a href="#">View</a> <a href="#">Edit</a>
<b>QOL: Quality of Life - consent / email / language</b>	Incomplete	<a href="#">View</a> <a href="#">Edit</a> ✓
Preoperative	Incomplete	<a href="#">View</a> <a href="#">Edit</a>
Intraoperative data	Incomplete	<a href="#">View</a> <a href="#">Edit</a>
Medication	Incomplete	<a href="#">View</a> <a href="#">Edit</a>

3. Click to enter this form and select **YES** or **NO** based on the subject's response and complete the remainder of the form.

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

Quality of Life - consent / email / language (Baseline)

Collection Date: 12/18/2020 Last change: 01/26/2021 10:29 (EST) edited by: tra2002@med.comell.edu - new changes

Questions

Did the participant consent to the QOL study?

☐ Yes

☐ No

Save Cancel

**Both forms must be entered at the time of enrollment.**

**Please don't hesitate to reach out with any questions.**



## Meet the Weill Cornell Medicine ROMA Team!

Silvia Senese



Marlene Alvarez



Annette  
Rios



Trisha  
Ali-Shaw

## Meet the Weill Cornell Medicine ROMA Team!

The ROMA Coordinating Center at Weill Cornell Medicine (WCM) has been involved with the study since its inception in 2016. Trisha, Silvia, Annette, and Marlene are the 4-person team who are working to assure that the ROMA study runs smoothly. Given the great number of subsites and subjects, working on this trial is a challenging yet gratifying task with new adventures occurring every day.



The ROMA team is a part of the Joint Clinical Trials office at Weill Cornell Medical College. The Medical College quickly became a national leader in medical instruction and has followed an educational philosophy that emphasizes the importance of combining a foundation in the medical sciences with clinical training in patient care. WCM doctors and scientists have been engaged in world-class clinical care and cutting-edge research that connect patients to the latest treatment innovations and prevention strategies. Weill Cornell Medicine's powerful network of collaborators extends to its parent university Cornell University; to Qatar, Tanzania, Haiti, Brazil, Austria and Turkey.

## Meet the Weill Cornell Medicine ROMA Team!



The ROMA team's office is located in the heart of Midtown Manhattan. For the past year, the team has readjusted to working remotely due to the COVID pandemic, but they have been able to keep up the momentum and remain in close contact with all of our ROMA sites.

The team is extremely proud of the ROMA study and all of the amazing accomplishments over the past few years, under the exceptional guidance and leadership of Dr. Gaudino and Dr. Fremes. They all truly enjoy working with the diverse subsites and have made many friends along the way. Trisha, Silvia, Annette, and Marlene look forward to continued work with all participating centers and the many future ROMA successes to come.



## ANNOUNCEMENTS

### 2021 ROMA Investigators Meeting

Friday, April 30<sup>th</sup>, 2021

Join us to speak with our esteemed PIs and receive overall study updates, enrollment, and case report form completion rates, and hear about long-term plans for the ROMA trial. We will also be speaking about ROMA: Quality of Life (QOL). It is being held during the **101<sup>st</sup> AATS Annual Meeting**.

**See it here first!**

**The use of the radial artery for coronary artery bypass grafting improves long-term outcomes: And now what?**

Mario Gaudino, MD, MSCE,<sup>a</sup> Paul Kurlansky, MD,<sup>b</sup> and Stephen Froles, MD<sup>c</sup>

*An Editorial Comment by our Principal Investigators will be published in the Invited Expert Opinion section of the upcoming April 2021 Journal of Thoracic and Cardiovascular Surgery*

## REMINDERS

### Reimbursement

As the fiscal year comes to a close we encourage you to submit invoices to help cover study expenses.

**Please reach out to us for details to initiate!**

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### Stay Vigilant ...

Continue to document reported instances of COVID-19 infections within the population using special CRF.

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### Future analysis

Please submit proposals for potential sub-analysis to Dr. Gaudino and Dr. Froles as soon as possible.

**WE WANT TO HEAR FROM YOU!**

Send us suggestions to best suit your needs.

## CONTACT US

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