



Randomized comparison of the clinical

Outcome of single versus

Multiple **A**rterial grafts



**Weill
Cornell
Medicine**

ROMA TRIAL Newsletter - March 2021

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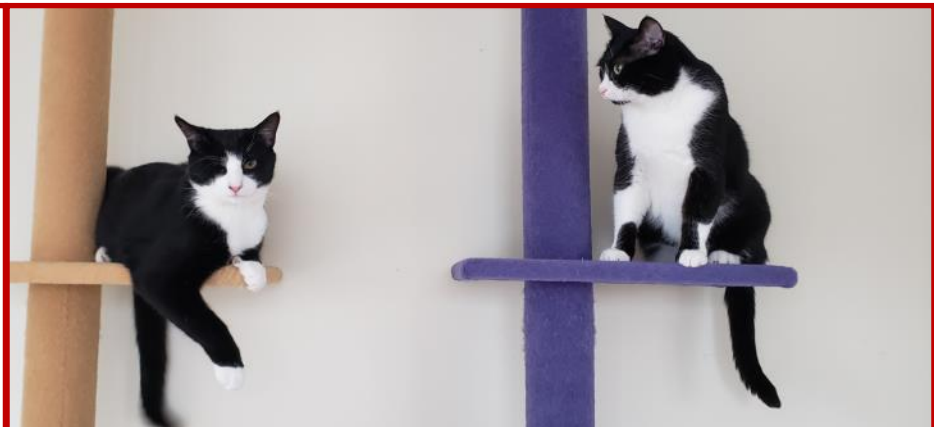
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FUN FACT ABOUT ROMA:

Dr. Mario Gaudino, the PI of the ROMA study, named his cats ROMA and DANTE. They are the mascots for the ROMA Trial. See how cute they are in this picture.



ROMA Main: Site openings

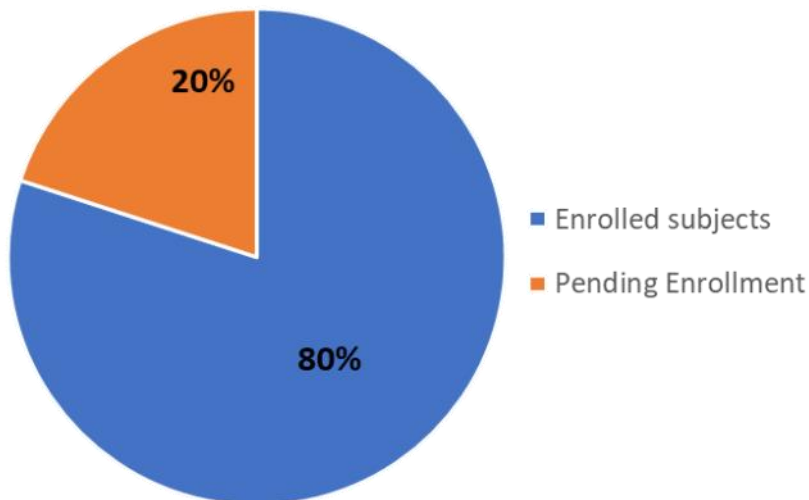



● Activated sites: 69
● Sites in progress: 19

WELCOME TO THE NEW ROMA SITES:		
Site	PI Name	Country
University Hradec Králové	Dr. Vojacek	Czech Re-public
Universitäts-Herzzentrum Bad Krozingen/Freiburg	Dr. Czerny	Germany
Institute of Cardiology – Porto Alegre RS	Dr. Kalil	Brazil

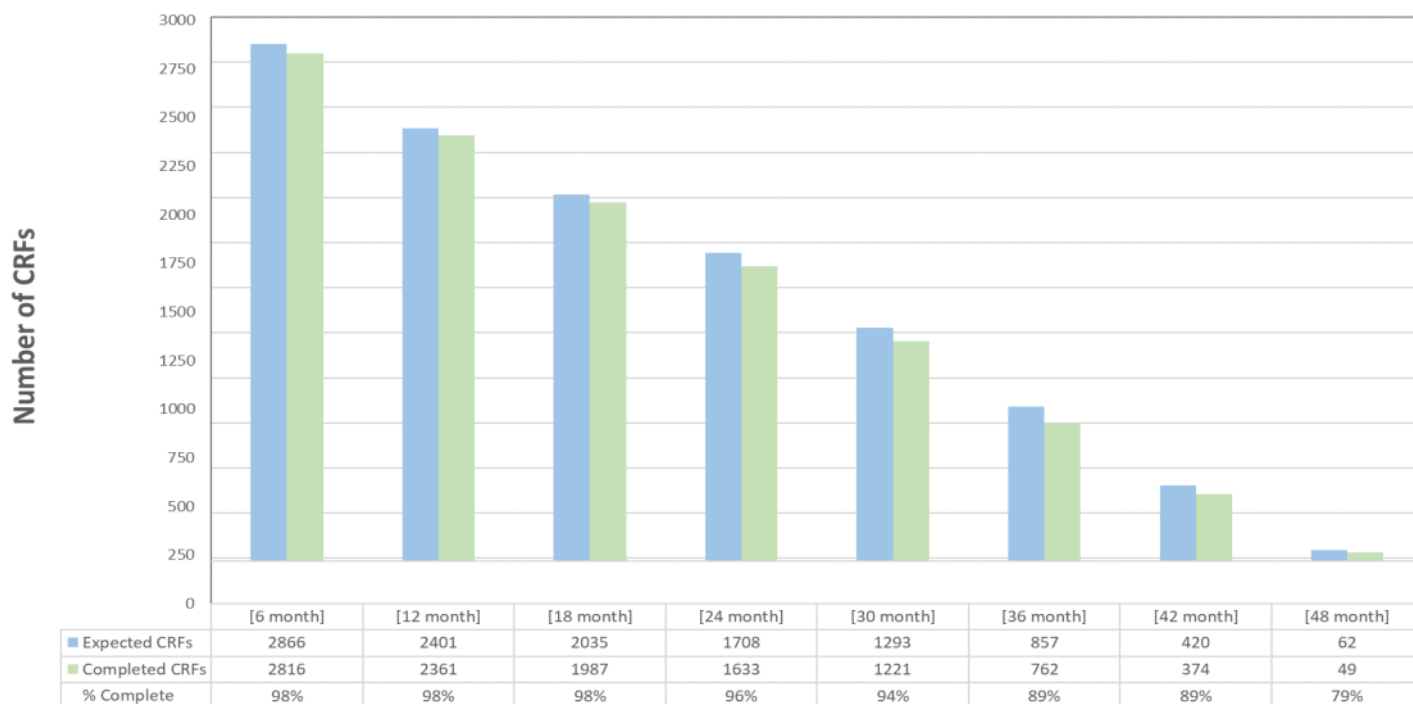
ROMA Main: Enrollment

Current Subjects Enrolled
3 4 4 0



 TOP Enrollers (more than 100 subjects enrolled)				
	Site	PI Name	Country	Number of subjects enrolled
1	Jilin Heart Hospital	Dr. Lemma	China	540
2	Dedinje Cardiovascular Institute	Dr. Milojevic	Serbia	290
3	Innsbruck Medical University	Dr. Ruttmann-Ulmer	Austria	283
4	MU Vienna	Dr. Sandner	Austria	238
5	Ruijin Hospital	Dr. Zhao	China	181
6	Heart Center Leipzig	Dr. Borger	Germany	169
7	European Hospital	Dr. De Paulis	Italy	121
8	Universite Laval Quebec (CRIUCPQ)	Dr. Voisine	Canada	103

ROMA Main: Follow-up CRFs Completion



ROMA Main: Study Tools and Resources

1. ROMA Adverse Event Training slides

Slide deck and tutorial video with step-by-step instructions on how to report AEs

2. Dashboard Tutorial

Slide deck and tutorial video to learn how to keep track of CRF completion and upcoming study visits.

3. CRF Completion Monitoring Emails

Each site should receive a copy of their dashboard via email every 3 weeks. Please let us know if you have not received these emails.

4. ROMA Website

A website entirely dedicated to the ROMA trial. You can also find all the previous newsletters and important publications . Link: <https://www.theromatrial.com/about-roma/>

ROMA QoL: Site opening

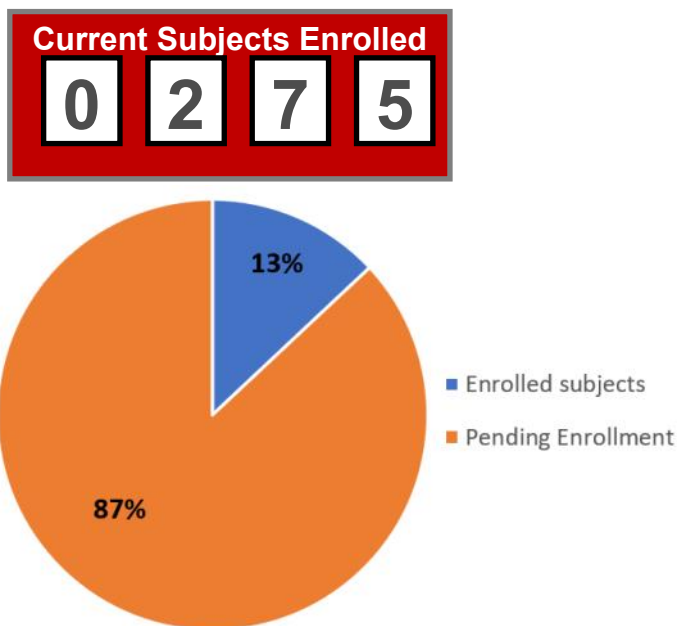


- Activated sites: 31
- Sites in progress: 12

WELCOME TO THE NEW ROMA QoL SITES:		
Site	PI Name	Country
Zbigniew Religa Lower Silesian Heart Disease Centre - Medinet	Dr. Cichon	Poland
Dedinje Cardiovascular Institute	Dr. Milojevic	Serbia
University Hospital of Montreal (CHUM)	Dr. Noiseaux	Canada
St. Boniface General Hospital	Dr. Arora	Canada
Rambam Health Care Campus	Dr. Bolotin	Israel
Essen University	Dr. Thielmann	Germany

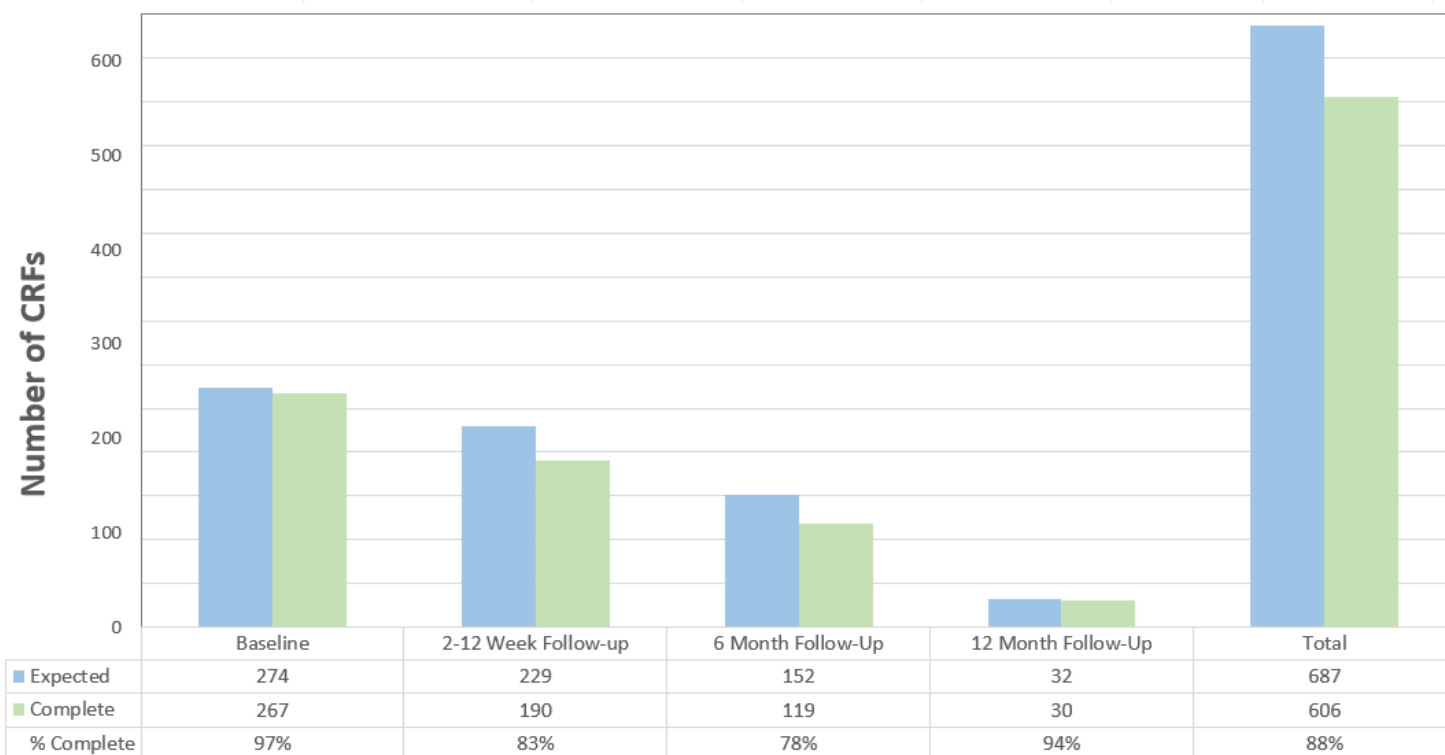
ROMA QoL: Enrollment

The ROMA:QOL study will be the first to comprehensively evaluate the impact of multiple arterial grafts versus single arterial grafts on short and long-term QOL, physical functioning, and symptoms. ROMA:QOL will also establish a new standard for the collection of patient-reported outcomes in the field of cardiothoracic surgery, which can be used in future trials both in the US and world-wide.



 TOP Enrollers (more than 10 subjects enrolled)				
	Site	PI Name	Country	N. of subjects enrolled
1	MU Vienna	Dr. Sandner	Austria	41
2	Ruijin Hospital	Dr. Zhao	China	28
3	Zbigniew Religa Lower Silesian Heart Disease Centre - Medinet	Dr. Cichon	Poland	25
4	Hospital Clinic de Barcelona	Dr. Alcocer	Spain	20
5	Lenox Hill	Dr. Patel	USA	20
6	Heart Center Leipzig	Dr. Borger	Germany	16
7	European Hospital	Dr. De Paulis	Italy	16
8	Dusseldorf University Germany	Dr. Assmann	Germany	15
9	Hospital Universitario del Vinalopo	Dr. Albors Martin	Spain	13
10	Universita Cattolica del Sacro Cuore	Dr. Massetti	Italy	11

ROMA QoL: CRFs Completion



ROMA QoL: Study Tools and Resources

1. Introduction to ROMA QoL slides

Slide deck with detailed information on ROMA QoL study, QoL dashboard and Clininvestigator QoL emailing feature

2. QoL questionnaire in the local language available in Clininvestigator

The report “Set Language” in Clininvestigator will allow each site to see the questionnaires in the local language.

1) Go to Reports Tab and Click on the report “Set Language for viewing QoL forms”

2) Open the report and select your local language and click submit

3) Go back to the subject home page and access the questionnaires in the local language

3. CRF Completion Monitoring Emails

Each site should receive the dashboard via email every 3 weeks. Please reach out to WCM ROMA team if you have not received this email.

ROMA Cognition(Cog): Updates

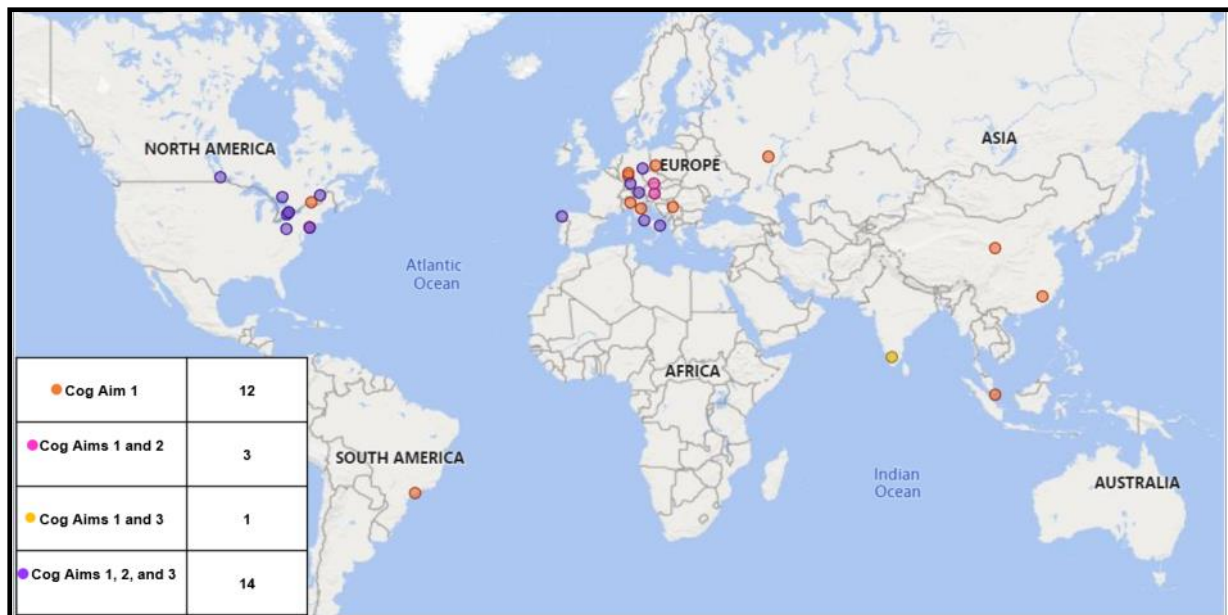
The NIH funded ROMA:COG sub-study has the objective to identify the global impact of CABG surgery and the impact of acute infarction on cognitive function. The ROMA:Cog study will help to identify people who could benefit from detailed cognitive evaluation and early interventions, and will establish whether serum biomarkers can be used as novel surrogate end-points in future studies to prevent vascular cognitive impairment.

- **Aim 1:** Determine the impact of CABG surgical technique on long-term cognitive function in an international cohort (n=2,000 from all sites).
- **Aim 2:** Compare short-term cognitive performance before and after CABG surgery stratified by surgical technique (n=280)
- **Aim 3:** Identify predictors of cognitive performance using MRI-defined infarction, CABG surgical technique, and novel serum biomarkers of brain health (n=280).

ROMA Cognition Assessments by Aim						
Assessments	Baseline	PO Day 1	PO Day 5	6 Weeks	52 Weeks	4 Years
	Prior to Surgery	12 to 48 hrs PO	+/- 2 days	2-12wks PO	+/- 4 weeks	+/- 1 year
All Aims						
Informed Consent						X*
Aim 1						
Montreal Cognitive Assessment (MoCA)						X
Seattle Angina Questionnaire (SAQ)						X
Health Survey Short (SF-12)						X
EuroQOL-5D-5L						X
Aim 2						
Montreal Cognitive Assessment (MoCA)	X				X	
Cambridge Brain Sciences Assessment (CBS)	X			X	X	
Aim 3						
Plasma Biomarkers	X	X	X		X	
MRI			X			

* For aim 1, obtain consent at any time prior to the 4 year timepoint. For aims 2 and 3, obtain informed consent at baseline prior to surgery.

Sites in the start-up process



Amendments for the ROMA study

Last approved ROMA study documents: ROMA Coordinating Center Team has recently distributed continuing reviews and amendments to all the participating sites. The last approved study documents are:

- Protocol: the last approved protocol is version 11.3.
- Appendix: the last approved appendix is version 1.3.
- Informed Consent Form (ICF) : the version to use depends on the level of sub-studies participation. The ICF template was distributed along with the amendments.
- Other study documents (depending on sub-study participation): QOL questionnaires, MoCA, CBS Assessment, etc..

Actions required:

1. Review all the received study documents
2. If requested in the email, update the ICF and sent to the ROMA Coordinating Center for review and approval
3. Submit all the amended study documents received to your local Ethics Committee (EC) for approval
4. Once the local EC approves the study documents, please send to the ROMA Coordinating Center the EC approval letter and the approved ICF along with the ICF Translation Verification Form (only applicable for non – English speaking sites).

Reconsenting Subjects

Who needs to be reconsented?

- a. ROMA patients already on the study should be reconsented for the new follow-up period that was updated to 12 years.
- b. ROMA patients who are on the study for less than 4 years should be approached and reconsented for the ROMA Cognition (Aim 1) sub-study. ROMA Cognition Aim 1 is a one-time visit that happens between 3-4 years after surgery. Patients will be compensated for their time.

How do you reconsent patients with the updated ICF?

- a. Site local EC should provide directions on how to proceed with the reconsenting of these subjects.
- b. If no official guidance is provided by your local EC, as sponsor of the ROMA study we suggest the following:
 - i. Inform the patient of the updated informed consent at the next follow-up study visit.
 - ii. Obtain verbal consent with documentation of that agreement in their research record. There will be a place to record this process in the Clininvestigator database (look out for an email announcing the reconsenting CRF).

Meet the G Kuppuswamy Naidu Memorial Hospital Team (GKNMH)



GKNM Hospital is situated in a city called Coimbatore in the state of Tamilnadu , India. It was started as a women and children's hospital in 1952. The cardiac surgery unit was started in 1974.

Currently the hospital has 680 beds and its core competence areas include cardiac services, oncology, pediatrics, and obstetrics .

The cardiac surgery service performs 1,600 open heart procedures per year from neonates to transplants. It has four dedicated adult consultants and one pediatric consultant. The unit runs a robust 6 year training program in cardiothoracic surgery. The unit has four dedicated operating rooms and a 24 bed intensive care. Apart from cardiac, the centre also performs thoracic and vascular procedures including VATS.

The most commonly performed operation is CABG; 80% is Off-Pump. The unit is very specific on quality control and the unadjusted morality for CABG which is the index procedure is 1.2%. Endoscopic harvesting of conduits including radial and Transit flow measurements are routinely performed.

Valvular heart surgery is the next most common adult procedure and includes all types of procedures. The unit also has a centre of excellence in Mitral valve repair. Recently we have started to perform Valve sparing root procedures and Ozaki operations. The heart team also performs TAVR as a routine.

Meet the G Kuppuswamy Naidu Memorial Hospital Team (GKNMH)

GKNMH is also a centre of excellence in Aortic surgery including , endovascular therapy and hybrid procedures. Recently started FET procedures for extensive arch and proximal descending disease.

The pediatric unit performs close to 350 procedures /year. It is part of the IQVIC and also collaborates with Mayo clinic through childrens heart link. Performs all types of complex procedures including double swith and Norwoods.

The GKNMH unit is well equipped and runs and ECMO service which was very valuable during covid times.

The centre was part of the STITCH trial, SIRS trail, CORONARY trial, LAAOS III, BACE and PROMOTE trials and currently ROMA.

GKNMH runs an annual live workshop for the past 20 years which is benchmarked as one of the best teaching program in the country.



In the picture Dr. Chandrasekar Padmanabhan and Ms. Ngalaton Raihing

Meet the G Kuppuswamy Naidu Memorial Hospital Team (GKNMH)

Dr. Chandrasekar Padmanabhan – PI ROMA

- Senior consultant and Chair of Department.
- Advanced fellowships from Flinders Medical centre Adelaide and Mayo clinic USA.
- Performed over 15,000 cardiac surgical procedures. Areas of expertise include OPCAB, Valve repair, aortic surgery including hybrids, post MI VSR, Redo, and surgery for Heart Failure.
- Established the Heart transplant program in GKNMH and performed the first in 2017.
- Member of several societies including Indian Association (IACTS), STS, EACTS, AHA, ACS ,ASCTVS, HVS.
- Principal investigator for 7 major clinical trials including CORONARY, SIRS, LAAOS III, BACE, PROMOTE, ROMA and PREDICT. Co-investigator of STITCH.
- Program Director for the DNB program - Successfully trained 16 residents.
- Organized 20 live workshops, annually since 1998 one of the best teaching programs in the country.

Ms. Ngalaton Raihing - Physician Assistant and study coordinator

- From Manipur, the northeast part of India and trained in GKNMH.
- She has performed more than 500 EVH procedures .
- A very skilled surgical assistant and a highly committed research person.

ANNOUNCEMENTS

Sex of prescreened patients

Moving forward, the sex of the CABG patients should be reported in the monthly pre-screening log. An updated log was sent to all the sites.

Silvia, the Multisite Research Manager, leaves the WCM ROMA Study Team

Her last date will be Monday April 4th. Moving forward, please direct any ROMA related communication to Trisha, Annette, Marlene and roma@med.cornell.edu.

Welcome Kazi to the WCM ROMA Study Team

Kazi Sultana is the new Program Specialist and will help with ICF review, collection of the pre-screening logs and more. Her email is kns4001@med.cornell.edu.

REMINDERS

Distribution of new Amendments/ CRs

Have you begun to submit the recently distributed protocol amendments? Please send us updates on your progress!

Secondary email to be added to Clininvestigator

If not already done, please add a secondary email to Clininvestigator database by updating your user settings to avoid issues when resetting your password.

Study Communication

Please include our ROMA team (ROMA@med.cornell.edu) along with our team members in all communication to ensure a prompt response.

Future analysis

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

WE WANT TO HEAR FROM YOU!

Send us feedback on suggested database tools and reports to best suit your needs.



CONTACT US

Weill Cornell Medicine ROMA Study Team

Mario FL Gaudino, MD, FEBCTS

Principal Investigator
mfg9004@med.cornell.edu

Stephen E. Fremes, MD, FRCS

Principal Investigator
Stephen.Fremes@sunnybrook.ca

General Inquiries

ROMA@med.cornell.edu

Trisha Ali-Shaw
tra2002@med.cornell.edu

Silvia Senese
sis2018@med.cornell.edu

Annette Rios
alr4005@med.cornell.edu

Marlene Alvarez
msa4002@med.cornell.edu

Database Help

CCIMsupport@med.cornell.edu

Contract & Budget Inquiries

JCTOcontracts@med.cornell.edu