Randomized comparison of the clinical

Outcome of single versus

Multiple

ROMA

Weill Cornell Medicine

ROMA TRIAL Newsletter - July 2021

In this issue:

TOP Enrollers

1	Jilin Heart Hospital
2	Dedinje Cardiovascular Institute
3	Innsbruck Medical University

ROMA: Cognition (ROMA:COG)

Ruth Masterson Creber, PhD, MSc, RN
Weill Cornell Medicine
New York - Presbyterian Hospital

Richard Swartz, MD, PhD
Sunnybrook Health Sciences Center

Mario Gaudino, MD
Weill Cornell Medicine
New York - Presbyterian Hospital

We are excited to announce that the ROMA: Cognition study has been funded by the NIH National Institute of Neurologic Disorders and Stroke (NINDS). Congratulations to Dr. Masterson Creber, Dr. Swartz, and Dr. Gaudino!

The objective of the study is to reduce cognitive impairment after CABG surgery and identify the global impact of CABG surgery and the impact of acute infarction on cognitive function.

Our hypothesis is: CABG using multiple arterial grafts (MAG) will be associated with less cognitive impairment than CABG with single arterial grafts (SAG), due to less intraoperative aortic manipulation, better patency of arterial compared to saphenous grafts, and lower risk of revascularization.

There are three specific aims:

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)

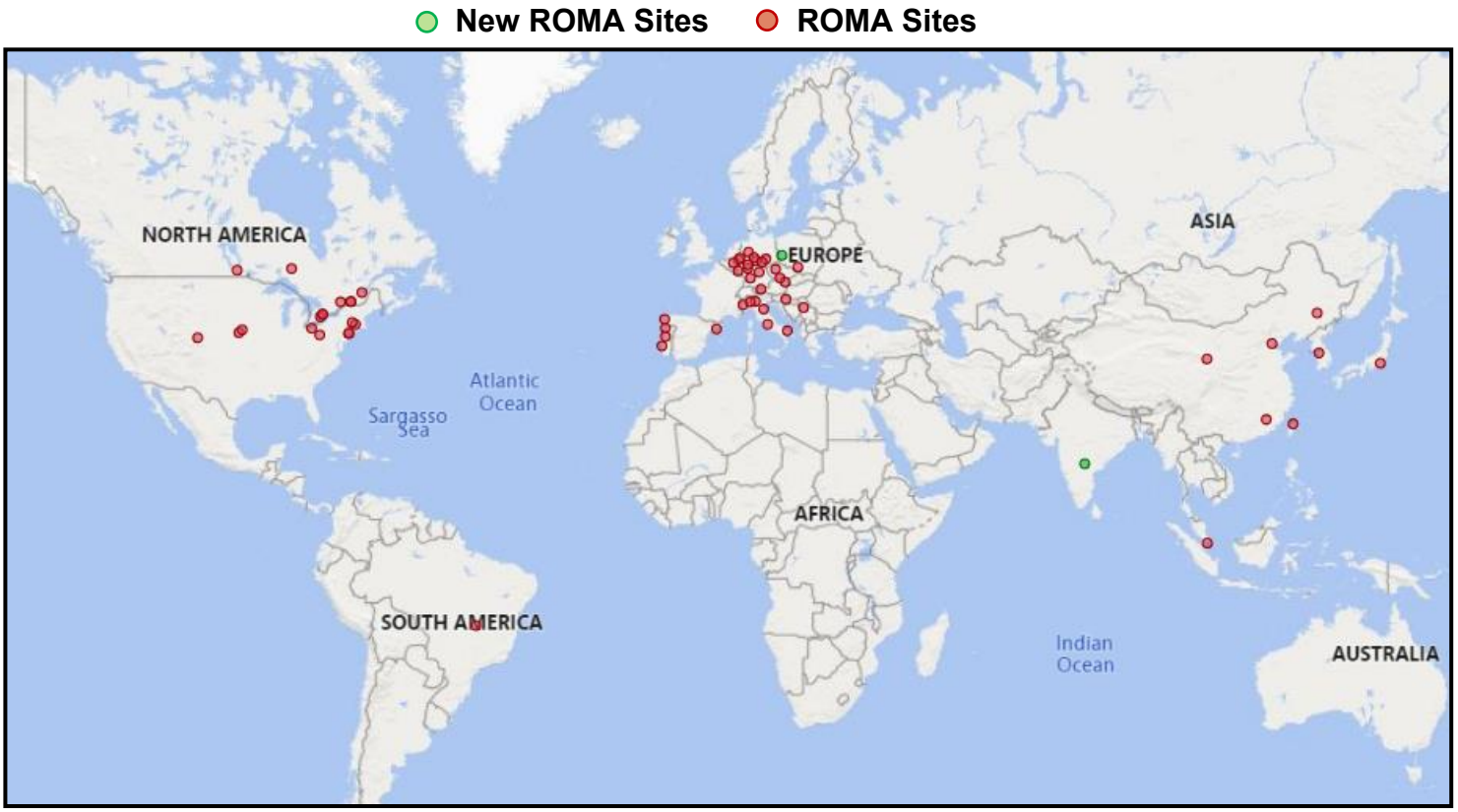
Aim 3: Identify predictors of cognitive performance using MRI-defined infarction, CABG surgical technique, and novel serum biomarkers of brain health (n=280)

On June 25th, 2021 we held a ROMA Cognition Study Informational Webinar to provide an overview of the upcoming ROMA Cognition sub-study's objectives and required resources for potential sites. Thank you to all who were able to participate in our discussion with Dr. Masterson Creber, Dr. Swartz, and Dr. Gaudino.

If you were unable to join the webinar and would like more information, or have questions regarding ROMA COG, please email Trisha Ali-Shaw (tra2002@med.cornell.edu) and Dr. Masterson Creber (rmc2009@med.cornell.edu) to schedule a 1 on 1 call with one of the investigators on the trial .

ROMA Trial: Please Welcome The New ROMA Sites

Country	City	Participating Center	PI
Poland	Zabrze	Zbigniew Religa Lower Silesian Heart Disease Centre	Dr. Cichon
India	Hyderabad	Star Hospital	Dr. Mannam & Dr. Sajja



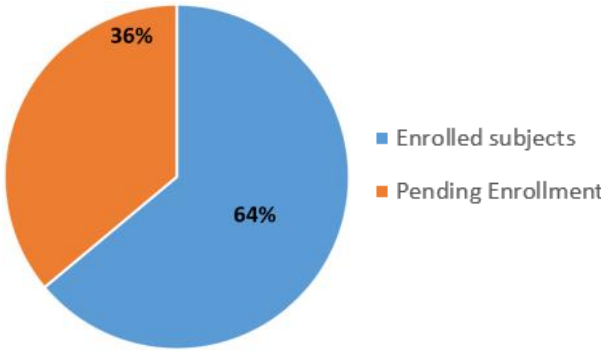
ROMA Trial: Enrollment Updates

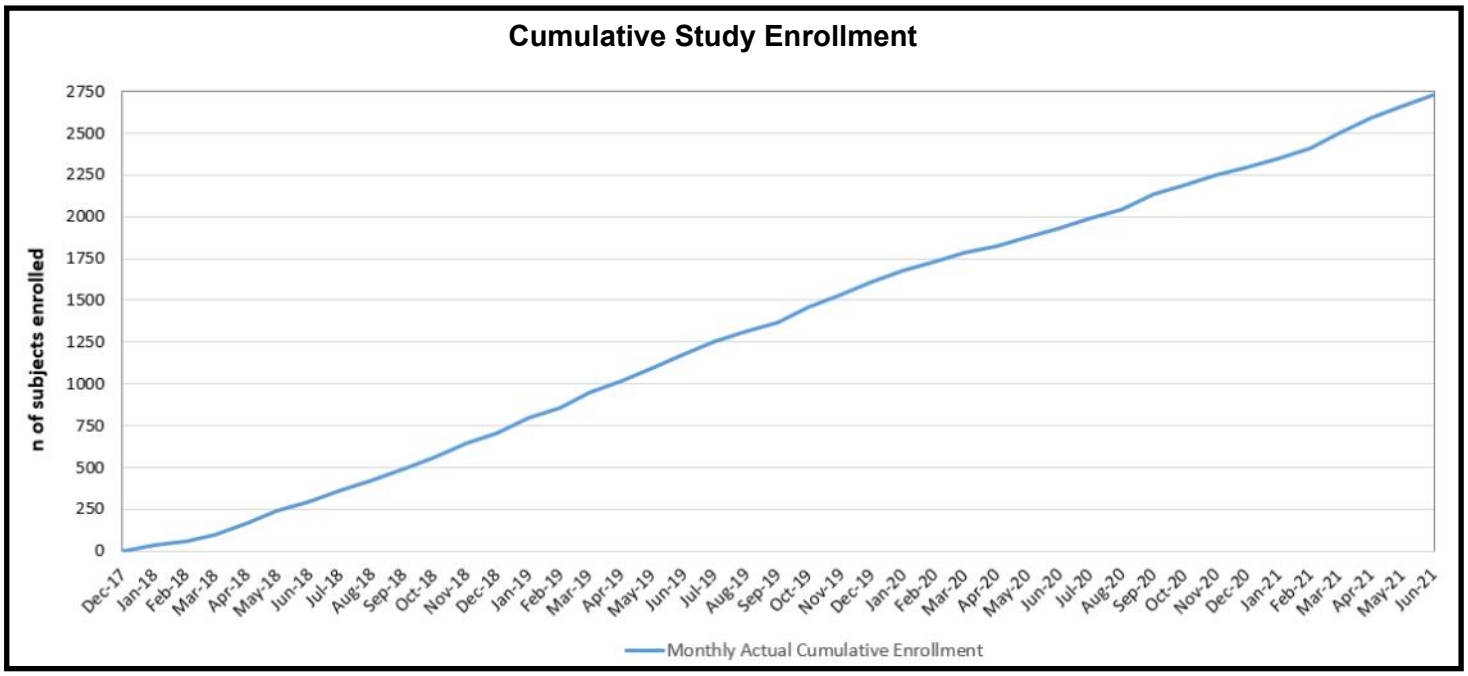
Current Subjects Enrolled

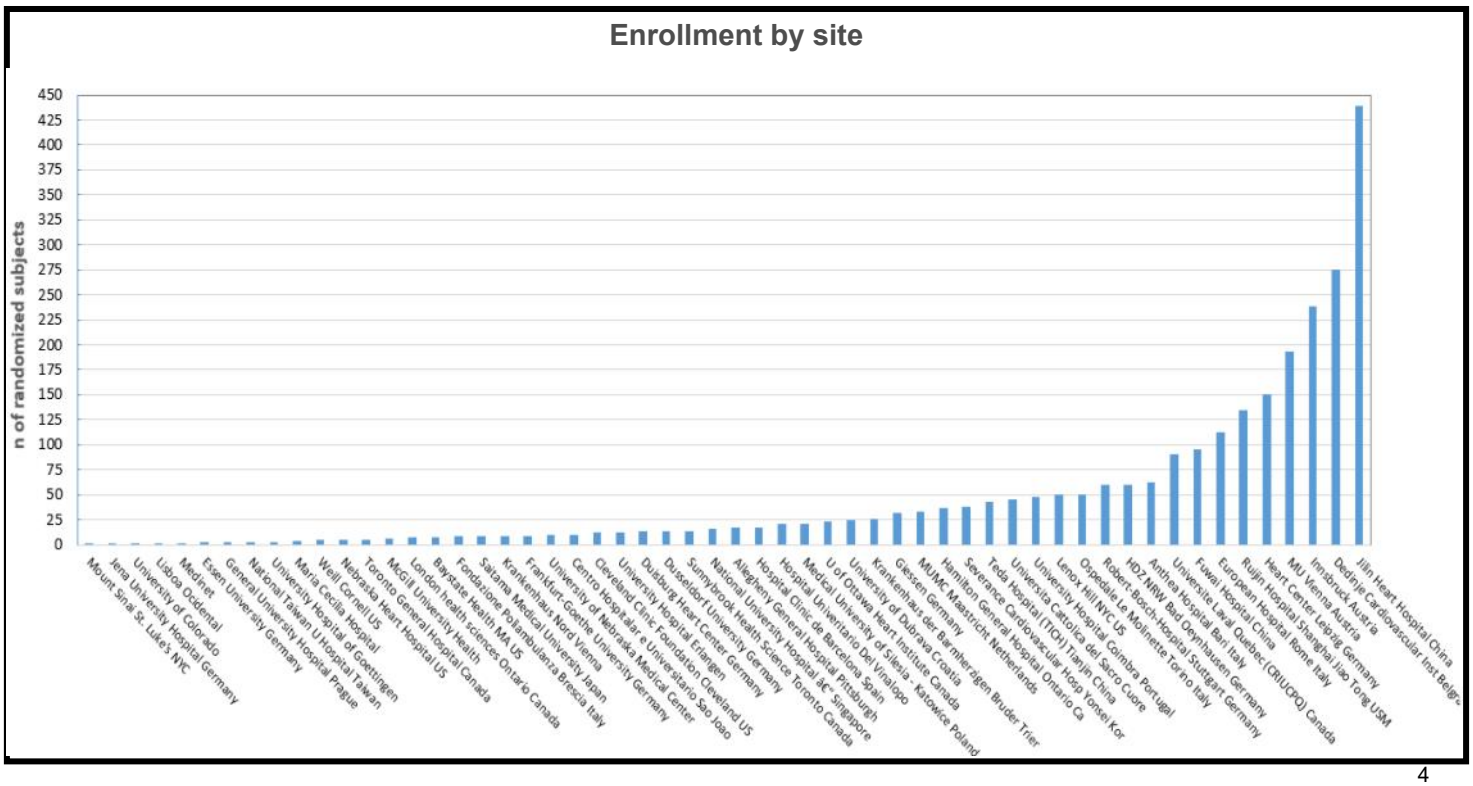
2 7 4 9

Sites Activated

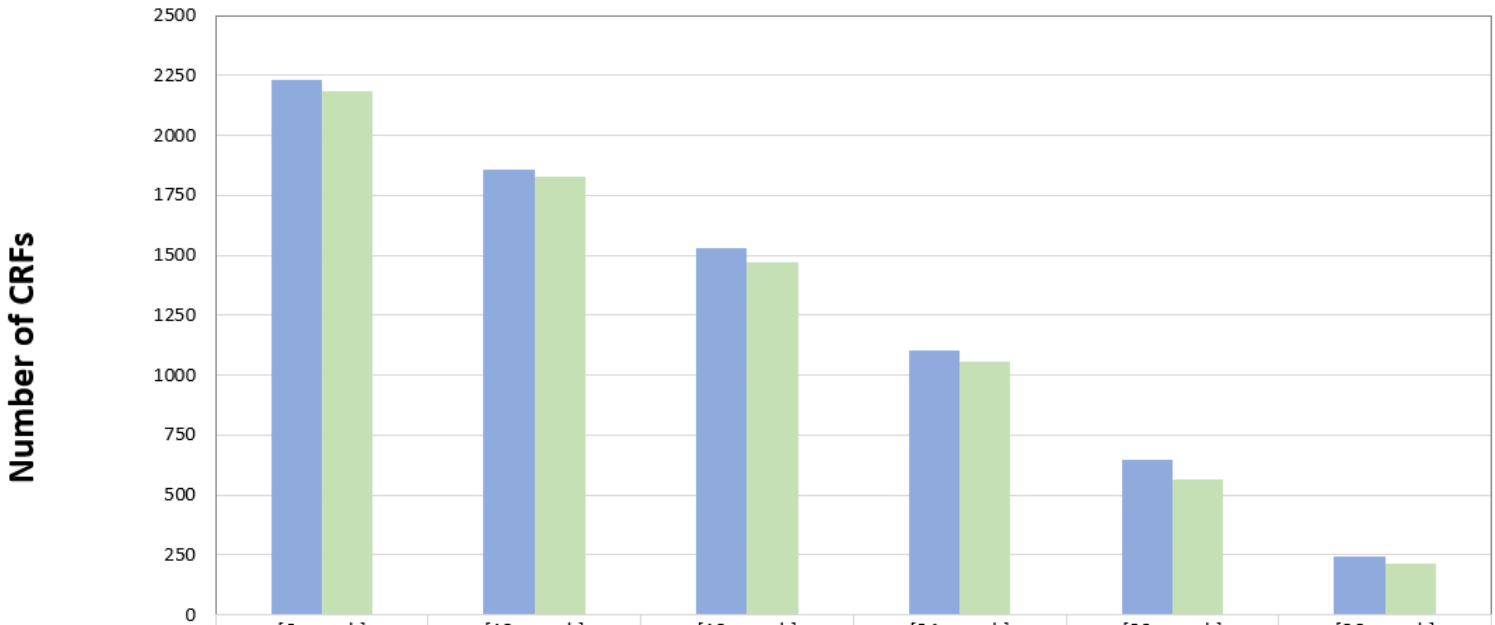
6 1







ROMA Trial: Follow-Up CRFs Completion Updates



	[6 month]	[12 month]	[18 month]	[24 month]	[30 month]	[36 month]
Expected CRFs	2231	1855	1528	1102	644	242
Completed CRFs	2186	1825	1473	1053	562	216
% Complete	98%	98%	96%	96%	87%	89%

The completion of follow-up visits is vital for the success of the ROMA trial.

1. **Enter the data in Clinvestigator database within 10 business days from completion of subject's FU visit.**
2. **Use the dashboard feature in Clinvestigator to keep track of upcoming FU Visit. A video tutorial, explaining how to use the dashboard is available and can be sent upon request.**
3. **If there is any difficulties in reaching out subjects to perform FU visits, please reach out to ROMA team at roma@med.cornell.edu.**
4. **If there is a delay in transferring data collected on paper CRFs to the database, please inform the ROMA team at roma@med.cornell.edu.**
5. **The ROMA team periodically verify data entered in the Clinvestigator database and reach out to the PI and study team in case of any issues.**

ROMA QoL: Enrollment and Sites Updates

Current Subjects Enrolled

0 1 0 3

Sites Activated

2 6

All ROMA active sites are encouraged to participate to the ROMA Quality of Life (QoL) sub-study.
Please contact the ROMA team at roma@med.cornell.edu for more information.

Country	Participating Center
Austria	MU Vienna
Canada	University of Ottawa Heart Institute
Canada	Hamilton General Hospital
Canada	Sunnybrook Health Science
Canada	Universite Laval Quebec (CRIUCPQ)
Canada	Toronto General Hospital
China	Fuwai Hospital
China	Ruijin Hospital Shanghai Jiao Tong University School of Medicine
China	TEDA Hospital
Germany	Duisburg Health Center
Germany	Dusseldorf University
Germany	Heart Center Leipzig
Germany	Jena University Hospital
Germany	University Hospital Erlangen
Germany	University Hospital of Giessen and Marburg
Italy	European Hospital Rome
Italy	Universita' Cattolica del Sacro Cuore
Poland	Zbigniew Religa Lower Silesian Heart Disease Centre
Serbia	Dedinje Cardiovascular Institute
Singapore	National University of Singapore (NUH)
Spain	Hospital Clinic de Barcelona (ICCV)
Spain	Hospital Universitario Del Vinalopo
US	Allegheny General Hospital
US	Baystate Health
US	Lenox Hill Hospital
US	Nebraska Heart Hospital

Clinvestigator: Updated ICF Uploading Requirements

What is changed: **Prior to April 27th 2021, it was sufficient to upload to the Clinvestigator database only the first and last pages and any pages including signatures and checkboxes of the Informed Consent Form (ICF). Now, sites must upload ALL the pages of the ICF. An email to notify the activated sites about this change was sent on April 27th 2021.**

Why are we making this change: **The rationale is that we need to see sections where subjects mark off participation in optional studies, such as the QOL study. This is important for us as the coordinating center of trial to maintain the utmost compliance.**

Who to contact with Questions/Feedback: **Contact the ROMA team at roma@med.cornell.edu**

Instructions on how to redact and upload the ICF:

1. Signing the Informed Consent form:

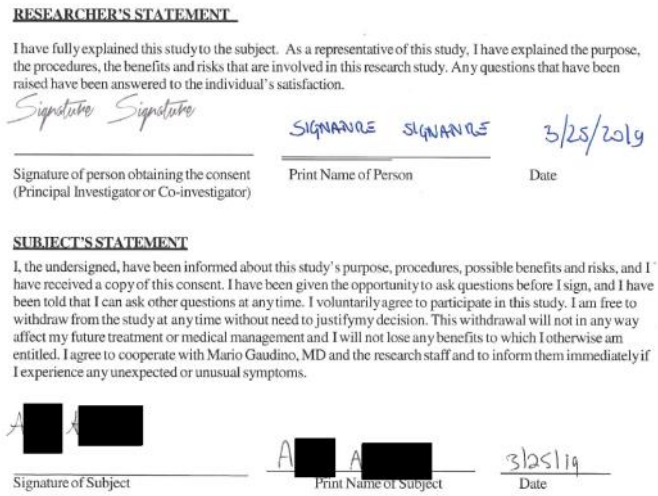
a) **The subject signing the consent forms MUST sign, date, and print his/her name.**

b) **The person obtaining the consent should not date or write the print name of the subject signing the informed consent.**

c) **The full year should be written when dating the informed consent form, for example "2021" instead of "21".**

2. Redacting Informed consent form:

a) **The consent form should be deidentified to remove any sensitive patient information or PHI (Protected Health Information) as required by local regulations. We recommend the use of Acrobat Pro for the de-identification of the PHI. Please visit the following link for more information: https://helpx.adobe.com/acrobat/using/removing-sensitive-content-pdfs.html. See below redacted informed consent as an example.**



RESEARCHER'S STATEMENT

I have fully explained this study to the subject. As a representative of this study, I have explained the purpose, the procedures, the benefits and risks that are involved in this research study. Any questions that have been raised have been answered to the individual's satisfaction.

Signature Signature — SIGNATURE SIGNATURE — 3/25/2019

Signature of person obtaining the consent (Principal Investigator or Co-investigator) | Print Name of Person | Date

SUBJECT'S STATEMENT

I, the undersigned, have been informed about this study's purpose, procedures, possible benefits and risks, and I have received a copy of this consent. I have been given the opportunity to ask questions before I sign, and I have been told that I can ask other questions at any time. I voluntarily agree to participate in this study. I am free to withdraw from the study at any time without need to justify my decision. This withdrawal will not in any way affect my future treatment or medical management and I will not lose any benefits to which I otherwise am entitled. I agree to cooperate with Mario Gaudino, MD and the research staff and to inform them immediately if I experience any unexpected or unusual symptoms.

[redacted] — A [redacted] — 3/25/19

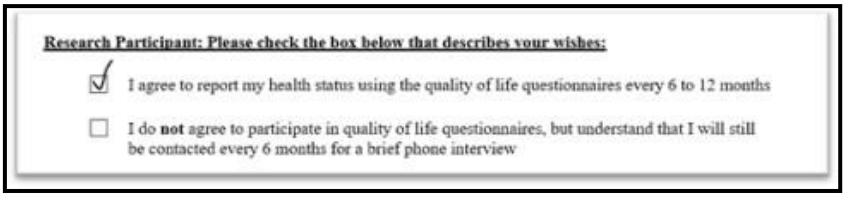
Signature of Subject | Print Name of Subject | Date

Clinvestigator: Updated ICF Uploading Requirements

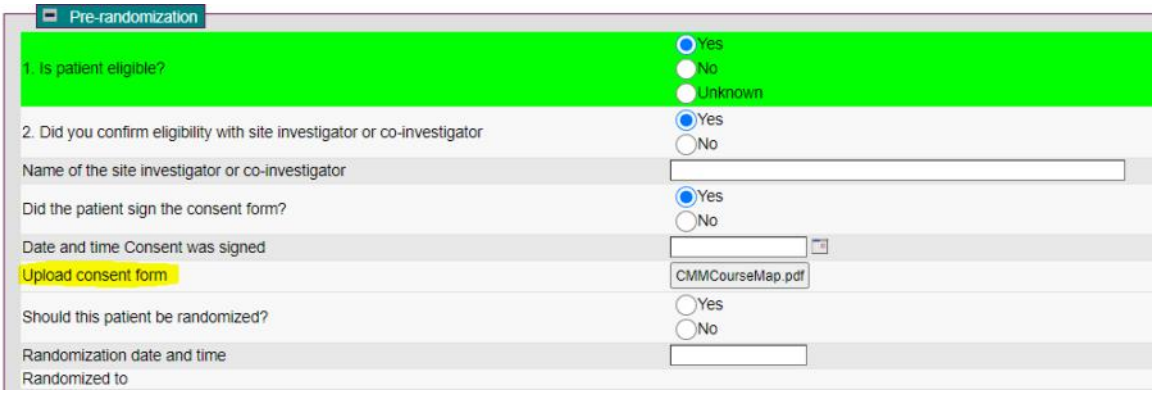
3. Uploading Informed Consent Form:

a) Full ICF MUST be uploaded prior to subject randomization

b) **Ensure that all the pages including signatures and checkboxes are included in the redacted ICF ready to be uploaded. See below an example of a consent form that contains checkboxes/consent options.**



c) Upload the full ICF to the Clinvestigator database in the Eligibility/Randomization eCRF under the Pre-randomization section (see below).



Meet the University of Nebraska

Nebraska Medicine and its academic partner, University of Nebraska Medical Center (UNMC), combine 40 outpatient clinics with access to more than 1,000 physicians and 809 licensed hospital beds in Omaha, Nebraska, and Bellevue, Nebraska.

Nebraska Medicine is the primary clinical teaching partner for the UNMC, which allows patients to benefit from one of the nation's leaders in cutting-edge research and education. Many Nebraska Medicine physicians trained at and now teach at UNMC. Together, the two organizations have approximately 12,000 employees, making it the largest employer in Omaha.

Heart and vascular specialists and researchers from Nebraska Medicine and UNMC are uniting to offer the most innovative procedures, from helping you lower your cholesterol, to using the newest pacemakers without leads, meaning they keep your heart beating flawlessly for several more years on average than older models. We offer one of the largest ventricular assist device programs in the nation, implanting 60 ventricular assist devices annually. In addition, we're the only heart transplant center in Nebraska, offering life-saving treatment to 40 individuals annually – providing them longer lives.

The health care professionals of the Division of Cardiothoracic Surgery offer comprehensive diagnostic and surgical care for cardiovascular diseases and congenital heart defects of adults and children, and comprehensive diagnostic and therapeutic care for cancerous and noncancerous diseases of the airway, blood vessels, chest wall, esophagus, heart, lungs and mediastinum.

Adult cardiac surgery procedures include coronary artery bypass procedures, valve procedures, aortic procedures, heart failure procedures, MAZE procedures, LVAD implants and heart transplant surgeries.

Meet the University of Nebraska

The Heart and Vascular Clinical Research Office (HVCRO) embodies a collaborative framework for clinical research, representing the UNMC divisions of Cardiovascular Medicine, Vascular Surgery and Cardiothoracic Surgery. Built upon the UNMC mission, the HVCRO promotes and advances excellence in research through the optimization of support and resources for cardiovascular faculty.

Program Statistics (as of July 2020)

- First heart/lung transplant in the state of Nebraska (2018)
- More than 450 left ventricular assist device (LVAD) patients
- More than 400 heart transplant patients
- More than 600 extracorporeal life support (ECLS\ECMO) patients
- More than 440 transcatheter aortic valve replacement (TAVR) patients
- 10 total artificial heart patients
- More than 30 lung transplant patients since the program started in 2016

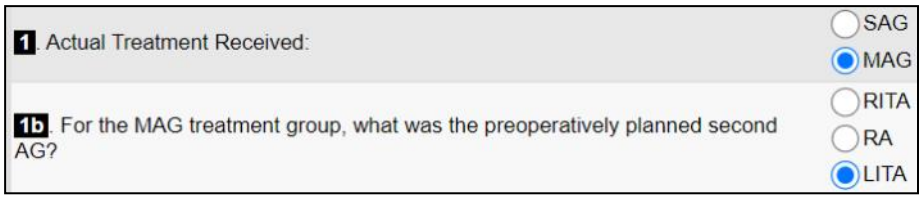
Dr. Siddque is the Principal Investigator for the ROMA trial at Nebraska Medicine/UNMC in Omaha, Nebraska. Dr. Siddique is the surgical director for the Lung Transplant Program and Aortic Program at Nebraska Medicine and the University of Nebraska Medical Center. He focuses on evidence-based treatments to provide the best outcomes for lung transplant and aortic patients. His other clinical interests include mechanical circulatory support and heart transplantation, aortic surgery, mitral valve repair, endocarditis, and the use of bilateral internal mammary arteries (BIMA) for arterial grafting in coronary bypass surgery (CABG).

From bottom left to top right: Sarah Hays, RN/BSN (Lead Research Coordinator), Tamara Bernard, RN/BSN/MPH (Nurse Manager), Aleem Siddique, MBBS, FACS, FACC (Principal Investigator), Nathan Muhn, MS (Data Coordinator II)

ANNOUNCEMENTS

Update to Intraoperative eCRF

The Intraoperative eCRFs was updated to accommodate all potential types of secondary arterial grafts. LITA was added as an option for as second arterial graft for question # 1b).



REMINDERS

Study Logs

Deviation and prescreening logs should be filled out and returned by email to roma@med.cornell.edu on the 1st business day of each month. The log should not be cumulative. If there were no prescreening or deviations for the month, please submit the logs stating that there are no updates.

Secondary email to be added to Clinvestigator

If not already done, please add a secondary email to Clinvestigator 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.

ROMA

CONTACT US

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