

ROMA TRIAL Newsletter - MAY 2021



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TOP Enrollers

1

Jilin Heart Hospital

2

Dedinje Cardiovascular Institute

3

Innsbruck Medical University

Thank You!



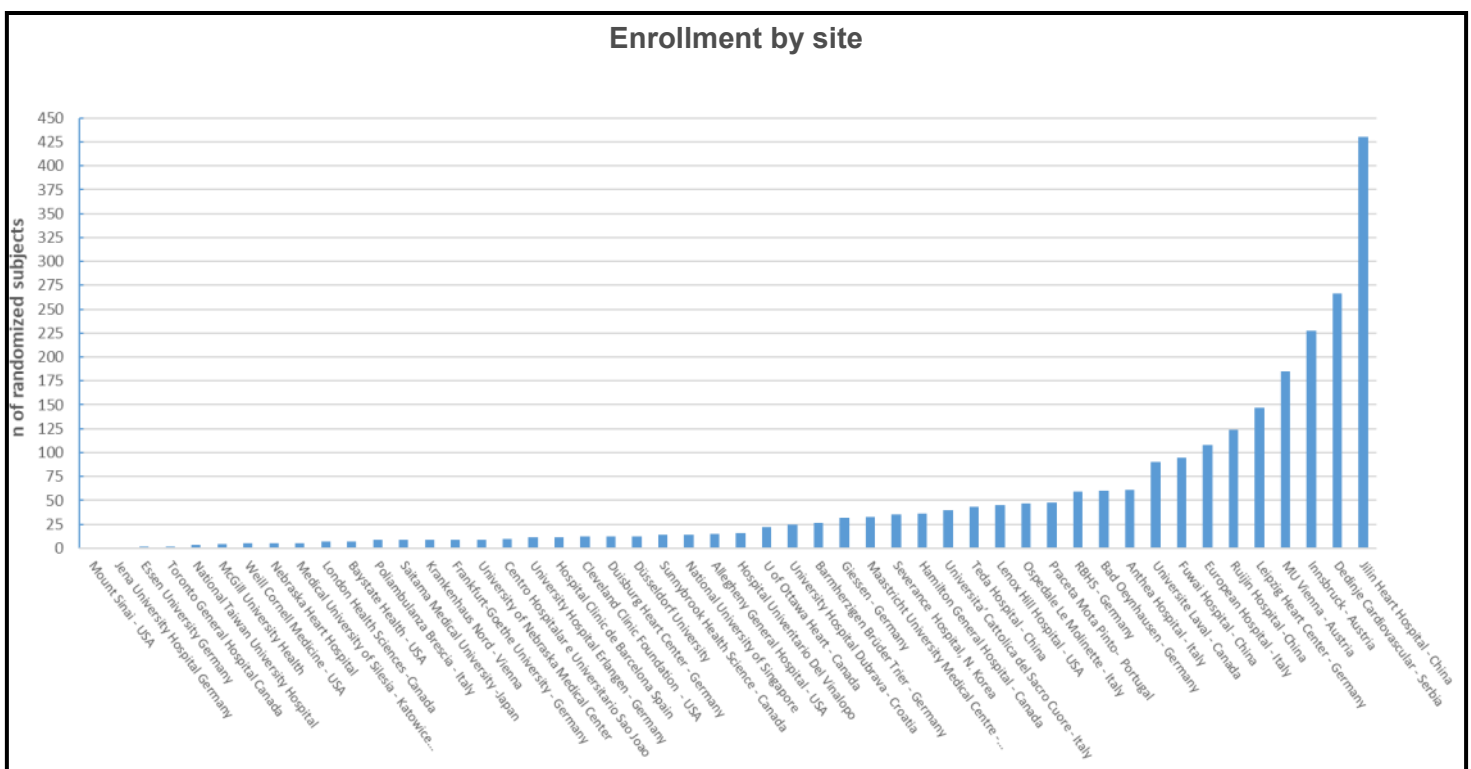
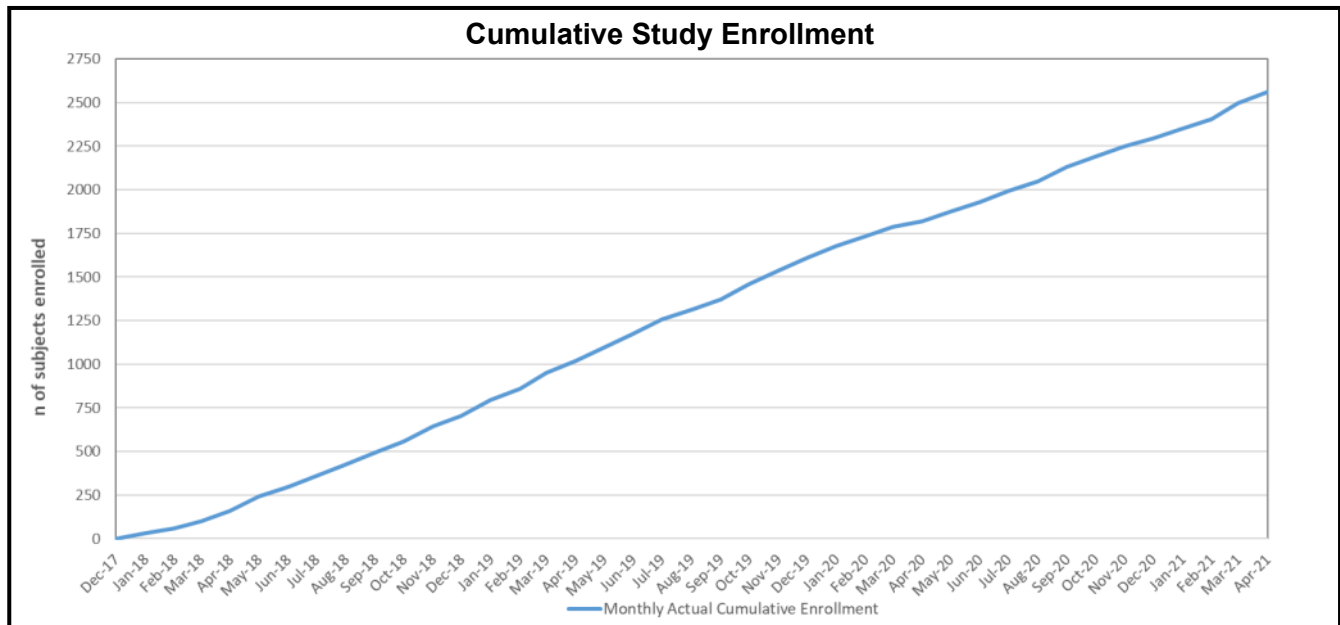
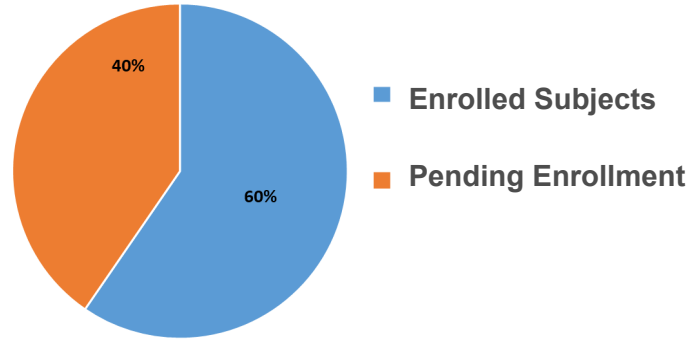
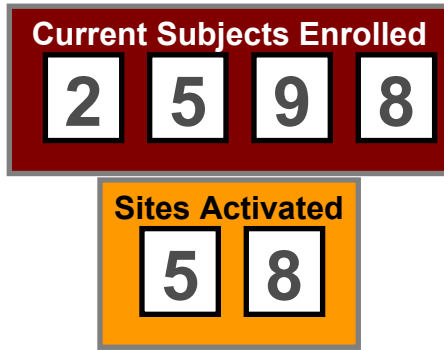
ROMA Trial: Please Welcome The New ROMA Sites

Country	City	Participating Center	PI
Germany	Göttingen	Georg August University	Dr. Bernd Danner
Italy	Cotignola, Ravenna	Maria Cecilia Hospital GVM care & research	Dr. Alberto Albertini
Portugal	Lisbon	Hospital Santa Cruz	Dr. Miguel Sousa Uva
US	Aurora	University of Colorado Hospital	Dr. Jessica Rove

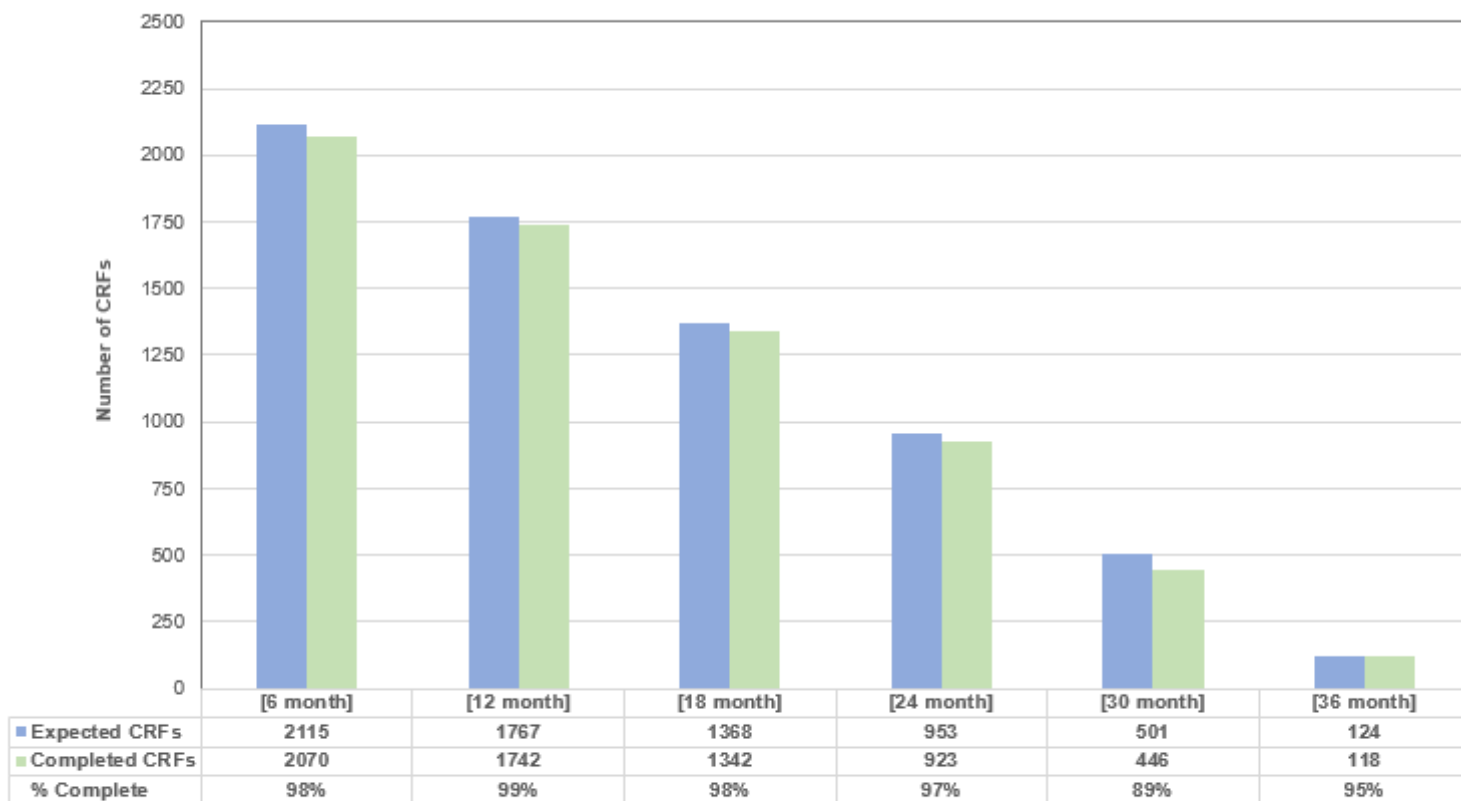
● New ROMA Sites ● ROMA Sites



ROMA Trial: Enrollment Updates



ROMA Trial: Follow-Up CRFs Completion Updates



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

1. Enter the data in Clininvestigator database within 10 business days from completion of subject's FU visit.
2. Use the dashboard feature in Clininvestigator 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 Clininvestigator 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 0 5 7

Sites Activated

1 8

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)
China	Ruijin Hospital Shanghai Jiao Tong University School of Medicine
Germany	Dusseldorf University
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
Spain	Hospital Univeritario Del Vinalopo
US	Baystate Health
US	Lenox Hill Hospital
US	Nebraska Heart Hospital
Germany	Duisburg Heart Center Germany
Singapore	National University of Singapore (NUH)

Clininvestigator: Updated ICF Uploading Requirements

What is changed: Prior to April 27th 2021, it was sufficient to upload to the Clininvestigator 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:

- The subject signing the consent forms **MUST** sign, date, and print his/her name.
- The person obtaining the consent should not date or write the print name of the subject signing the informed consent.
- The full year should be written when dating the informed consent form, for example “2021” instead of “21”.

2. Redacting Informed consent form:

- 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.

A [redacted] A [redacted]

A [redacted] A [redacted]

3/25/19

Signature of Subject

Print Name of Subject

Date

Clininvestigator: 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.

Research Participant: Please check the box below that describes your wishes:

☒ I agree to report my health status using the quality of life questionnaires every 6 to 12 months

☐ I do **not** agree to participate in quality of life questionnaires, but understand that I will still be contacted every 6 months for a brief phone interview

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

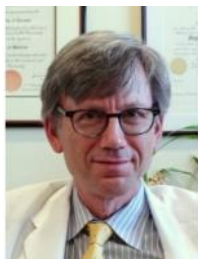
Pre-randomization

1. Is patient eligible?	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown
2. Did you confirm eligibility with site investigator or co-investigator	<input checked="" type="radio"/> Yes <input type="radio"/> No
Name of the site investigator or co-investigator	<input style="width: 100%;" type="text"/>
Did the patient sign the consent form?	<input checked="" type="radio"/> Yes <input type="radio"/> No
Date and time Consent was signed	<input style="width: 100%;" type="text"/>
Upload consent form	<input type="text" value="CMMCourseMap.pdf"/>
Should this patient be randomized?	<input type="radio"/> Yes <input type="radio"/> No
Randomization date and time	<input style="width: 100%;" type="text"/>
Randomized to	<input style="width: 100%;" type="text"/>

ROMA Investigators Meeting at AATS



Mario Gaudino



Stephen Femes



Ruth Masterson



Rick Swartz

We are happy to report that the virtual ROMA Investigators Meeting at the 101st Annual Meeting of AATS was a great success with the participation of 49 investigators across all centers.

At the meeting important updates on individual center progress were discussed as well as long terms plan for the ROMA trial.

Dr. Ruth Masterson presented the sub-study, ROMA: Quality of Life (QoL) and Dr. Swartz the sub-study ROMA: Cognition (COG)

ROMA: QoL is funded by National Heart Lung and Blood Institute of the National Institute of Health (NIH) and is now actively recruiting in 18 centers with the plan to activate other centers soon. This study will allow to have longitudinal evidence as to which CABG surgical techniques (MAG vs. SAG) are optimal for improving the most common distressing symptoms with the goal to better inform patients of the risks and benefits of surgery.

ROMA: COG has the objective to identify the global impact of CABG surgery and the impact of acute infarction on cognitive function. An NIH just-in-time application was submitted in early April 2021 with the hope to open the study in early July 2021.

Other studies that are in the pipeline were also briefly discussed: ROMA:COVID, submitted to NIH in late March 2021; ROMA:Patency, submitted to CIHR in April 2021; BEST-RA, submitted to PCORI in April 2021, ROMA:Women to be submitted to CIHR in April 2022 and STICH3 (PCI vs CABG in low EF)

We are appreciative of all the hard work each investigator and their team has invested to this point, and we look forward to the next Investigators Meeting that will be held during the 34th EACTS Annual Meeting in October 2021.

Meet the Hospital Clinic Barcelona

Hospital Clínic de Barcelona - University of Barcelona is a public and centenary institution. The hospital is in the heart of Barcelona and has an on-side Medical School and other Health Sciences degrees (Biomedical engineering, Nursing and others). The Institution has 4880 workers, and its facility has 800 beds and runs 31 operating rooms to provide an annual volume of 23,000 surgeries and 500 transplants. Hospital Clínic is a general hospital providing services to all medical and surgical specialties.

Clínic de Barcelona has been qualified as the best hospital in Spain and the 38th best world hospital according to the *Newsweek World's Best Hospital* ranking. From a research standpoint Hospital Clínic - Idibaps produces a mean of 1276 original publications annually (68% Q1) with a mean impact factor of 6,7.

The Cardiovascular Surgery Department provides services to the metropolitan area of Barcelona and Catalunya (~ 1.9 million inhabitants) but also serves as a referral center for Spanish and International patients. The department has 5 cardiac surgeons who also run a 16 bed ICU-intermediate care unit as primary intensive care specialists. The annual volume of major cardiac surgeries is around 950 (850-900 CPB cases). The department functions with up to 3 operating rooms and serves as a National referring center for complex mitral valve repair, hypertrophic cardiomyopathy (myectomy surgery), pulmonary thromboendarterectomy, adult congenital heart surgery, aorta surgery and endocarditis.

Isolated coronary surgery represents around 35% of its complex departmental activity and 60-70% are urgent revascularizations. The department holds the tradition of participation in some iconic randomized myocardial revascularization trials (EXCEL and SYNTAX) and other multicentric studies (FAST trial).



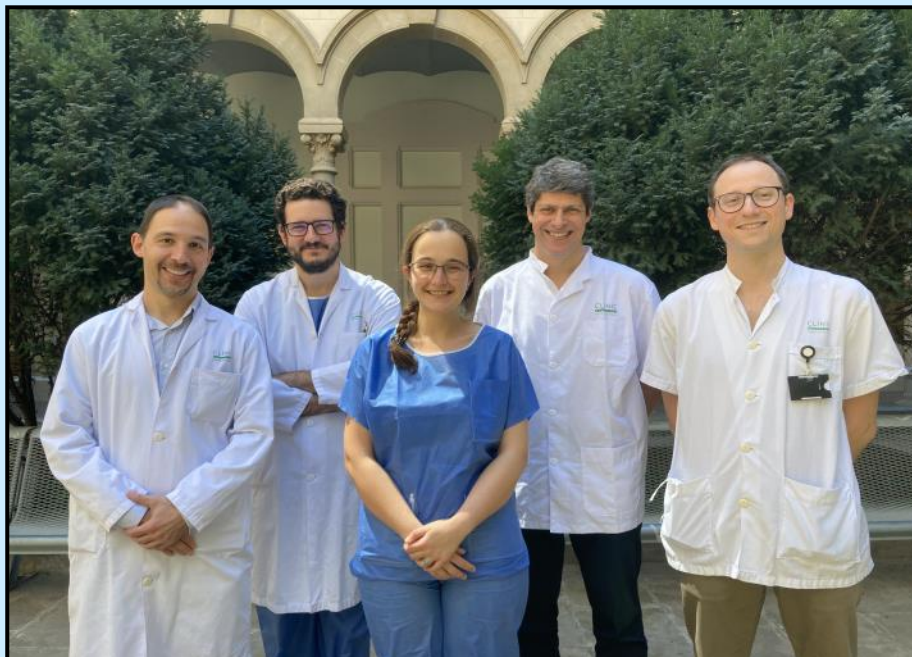
Meet the Hospital Clinic Barcelona

Dr. Jorge Alcocer (local PI) and **Dr. Eduard Quintana** are the surgeons involved in the ROMA trial recruitment and operating on the randomized patients.

Dr. Alcocer is an expert off-pump coronary surgeon and myocardial revascularization is his main area of interest. He was recruited in 2019 to expand the coronary surgery program and has an important expertise in this field with more than 500 cases of coronary operations with arterial grafts. He and Dr. Quintana launched a minimally invasive multiarterial revascularization program. CABG, aortic surgery and TAVI are some of his specific areas of interest.

Dr. Quintana is a staff surgeon at Hospital Clínic since 2014. He acts as a Board Member of the EBCTS (European Board of Cardiothoracic Surgery) and chairs its Membership (Level 1) Exam. He also serves at EACTS where he has been member of the Vascular Domain Board and chair of the Aortic Dissection Task Force. Beyond coronary surgery expertise, Dr. Quintana has special interest in complex aorta surgery, myectomy and endocarditis. He is also the residency and fellowship program director.

The other operating staff surgeons **Dr. Pereda, Dr. Sandoval, and Dr. Castella** (Departmental Chair) are world renown surgeons in their respective fields of expertise (minimally invasive mitral valve repair, MCS-Transplantation and atrial fibrillation surgery, respectively). They also serve in many national and international advisory boards and are prolific academic surgeons. The entire team supports greatly the enrollment of patients for the ROMA trial and provide intensive care management with the help of superb trainees and nurses. Their shared goal is to advance the care and prognosis of patients requiring myocardial revascularization.

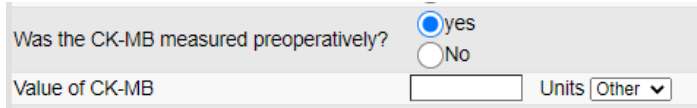


From left to right: Dr. Alcocer, Dr Pereda, Dr Sandoval, Dr Castella, Dr Quintana

ANNOUNCEMENTS

CK-MB

Units and values range for CK-MB can be now be entered in Clininvestigator Database in the pre- and post-operative eCRFs.



Was the CK-MB measured preoperatively? ☒ Yes ☐ No

Value of CK-MB Units

ICF Uploading into Clininvestigator

New requirements for ICF Uploading to Clininvestigator database are described at pages 6-7 of this newsletter.

REMINDERS

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. Froles 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

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