

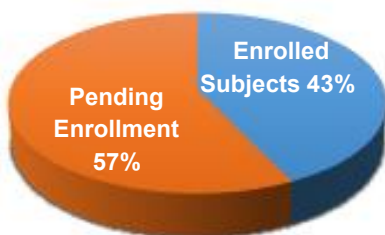


Randomized comparison of the clinical
Outcome of single versus
Multiple
Arterial grafts



**Weill
Cornell
Medicine**

ROMA TRIAL Newsletter - MAY 2020



Number of subjects enrolled

1 8 4 1

Keep Up The Great Work!

Recent ROMA Achievements

NHLBI Funding Awarded for ROMA QOL study

We are pleased to share that Dr. Mario FL Gaudino, Stephen and Suzanne Weiss Professor in Cardiothoracic Surgery and Director of Translational and Clinical Research in Cardiothoracic Surgery, at Weill Cornell Medicine and Dr. Ruth Masterson Creber, Assistant Professor of Population Health Sciences at Weill Cornell Medicine have received funding from the National Heart, Lung, and Blood Institute for a new study, "Randomized comparison of the clinical Outcome of single versus Multiple Arterial grafts: Quality of Life (ROMA: QOL)."



Dr. Gaudino and Dr. Masterson Creber are joined by co-investigators Dr. Monika Safford, Dr. Karla Ballman, and Dr. Stephen Fremes, who currently serves as the co-PI with Dr. Gaudino on the ROMA trial.

The overall goal of this five-year R01 is to compare health related quality of life (HRQOL) and symptoms following SAG vs. MAG CABG surgery. A secondary goal is to quantify minimally important clinical differences post CABG surgery. Pre-specified subgroup analyses will evaluate HRQOL and symptom burden in women compared with men, and patients with and without diabetes. The hypothesis is that both groups will experience improvements in HRQOL and symptoms at 12 months, but MAG will be superior to SAG.

ROMA Research Letter Published in *Circulation*

"Response of Cardiac Surgery Units to COVID-19: An Internationally-Based Quantitative Survey: was published on 11 May 2020 in *Circulation* (<https://www.ahajournals.org/toc/circ/0/0>). The ROMA team compiled survey data related to COVID-19 response at participating ROMA centers. The majority of respondents, "reported reduced cardiac surgery activity, redeployed personnel, and curtailed educational and research activities in response to the COVID-19 pandemic."

A sincere thank you to all who participated.

Please Welcome Four New ROMA Sub-Sites



Please take a moment to share in our deep gratitude for all healthcare workers as they continue to dedicate their lives to the wellbeing of our patients.

We stand with you in this fight against COVID-19!

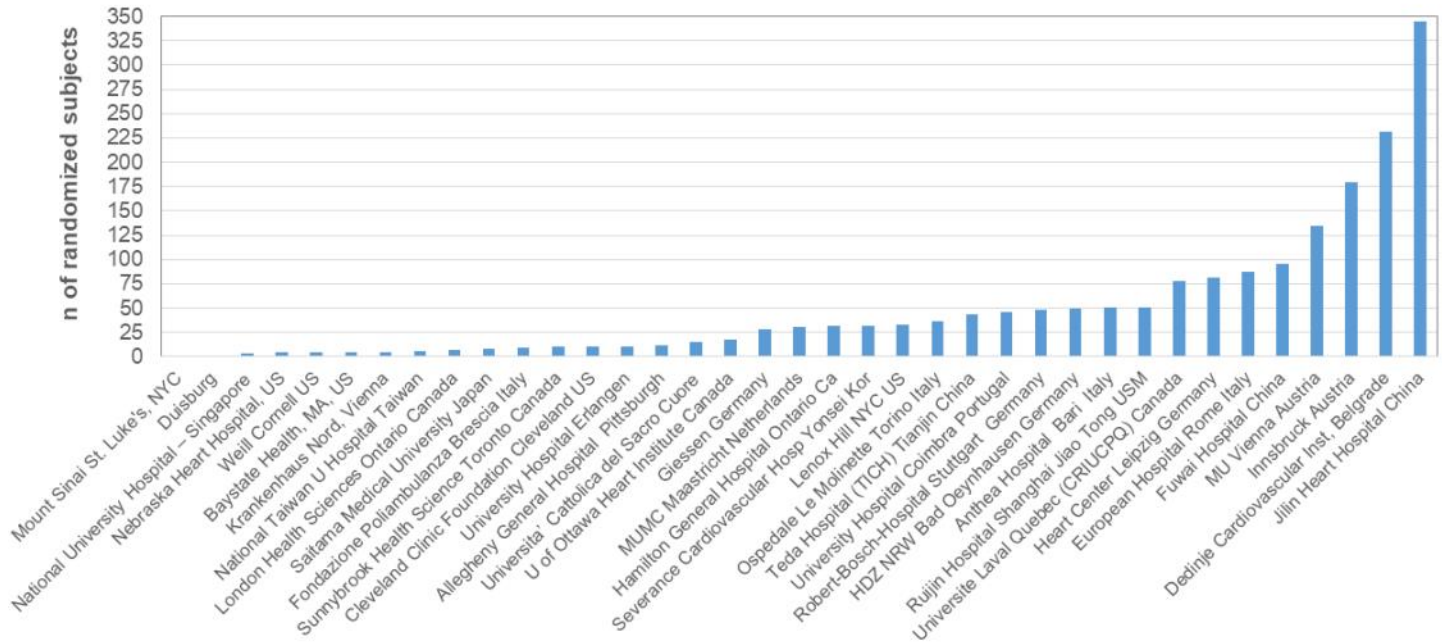
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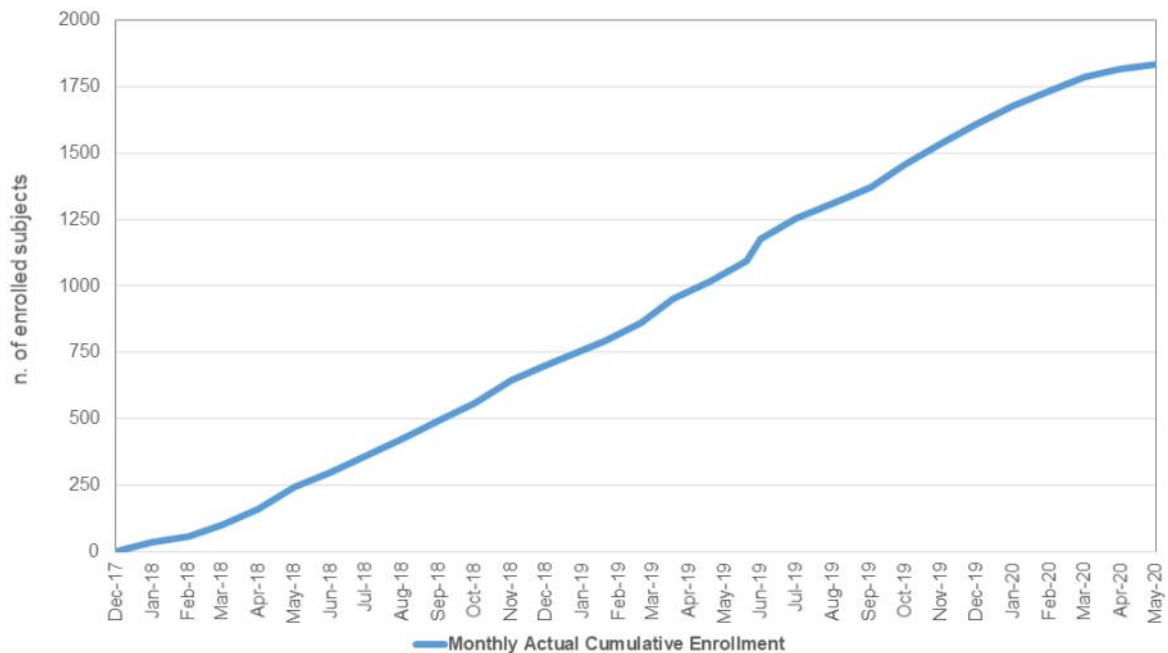
ENROLLMENT UPDATES



Randomization by Center



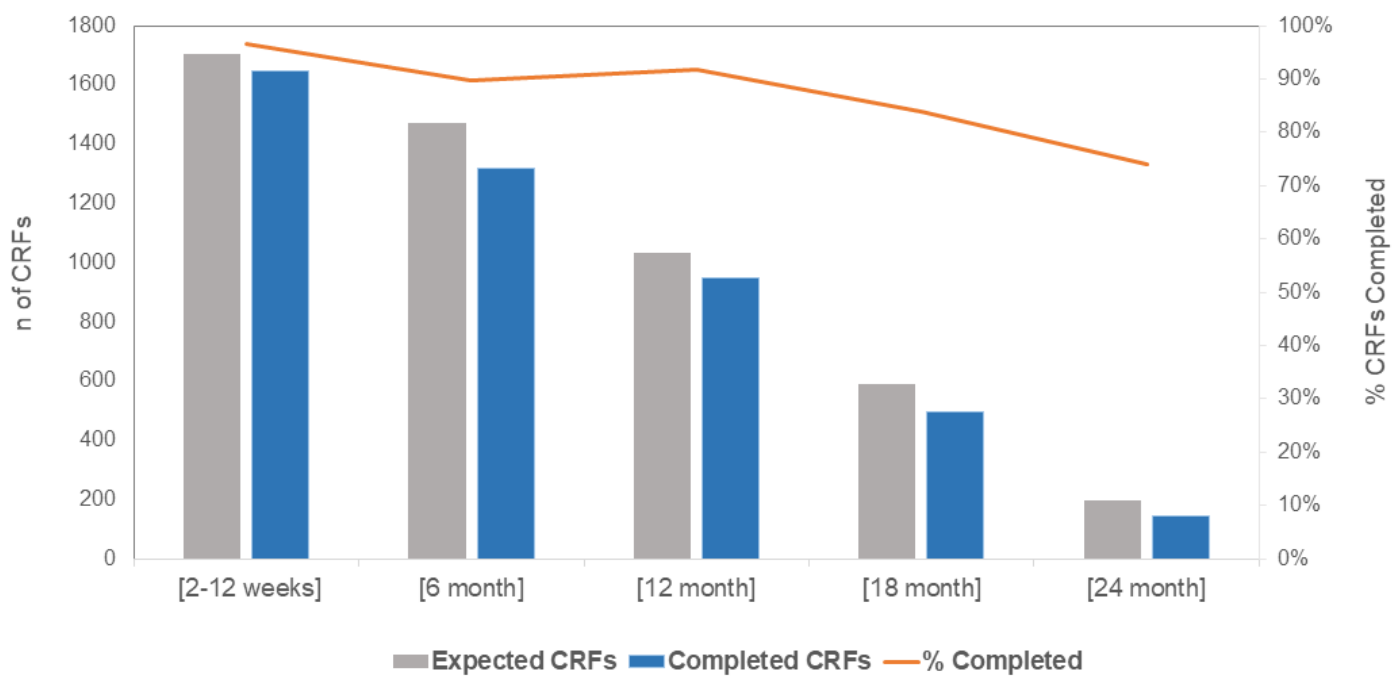
Cumulative Enrollment



CRF COMPLETION STATUS

Case Report Form	Total	Complete (n=)	%Complete	Missing (n=)	%Missing
Eligibility	1841	1794	100%	0	0%
Intraoperative	1768	1676	95%	92	5%
[2-12 week Follow-Up]	1703	1646	97%	57	3%
6 month Follow-Up	1469	1318	90%	151	10%
12 month Follow-Up	1034	948	92%	86	8%
18 month Follow-Up	591	496	84%	95	16%
24month Follow-Up	197	146	74%	51	26%

Expected vs Completed CRFs



THE DASHBOARD: A NEW DATABASE TOOL

The Dashboard will give you the power of “Real-Time” Data Monitoring:

1. Table 1 identifies subjects with Late Case Report Forms (CRFs) that should have already been completed.
2. Table 2 and 3 identify subjects with Upcoming Follow-Up visits due within the next 30 days. In Table 3, these subjects are listed in order of days remaining to complete the follow-up visit on time.

Study: Roma
No Patient Selected
User: sis2018@med.comail.edu 14.14.30

Patients Dashboard REPORTS Messages My Account Contact Logout

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

The Dashboard
Site: Test Dashboard (1)

Table 1

Case Report Form Status: LATE				
Timepoint	# eCRFs Partially Completed	# eCRFs Missing	Subject IDs For Partially Completed eCRFs	Subject IDs For Missing eCRFs
Preoperative	0	1		1
Intraoperative	0	0		
Postoperative	0	3		1, 2, 5
ST	1	0	3	
6m FU	0	1		4
12m FU	1	0	6	

Table 2

Case Report Form Status: DUE		
Timepoint	# of Subjects Due For Follow-up Visits	Subject IDs
ST	3	7, 8, 9
6m FU	2	3, 2
12m FU	1	1

Table 3

Subjects Due For Follow-Up within the next 30 days			
Subject ID	RomaID	Next follow-up Visit	Days Before CRF is Late
7	01-007	ST	4
2	01-002	6m	5
8	01-008	ST	9
9	01-009	ST	10
1	01-001	12m	15
3	01-003	6m	30

Back to Reports Run this report again

➡ Please watch the **Dashboard video tutorial** distributed with this newsletter for more information, further guidance and tips!

➡ Please note that the Dashboard will be sent every three weeks via email to the study teams. Look out for the **CRF Completion Monitoring Emails**.

ROMA Participating Site Highlight:

Institut Universitaire de Cardiologie et de Pneumologie de Québec (IUCPQ) Toronto, Canada

Quebec Heart and Lung Institute has been a supra-regional center since 1918. Affiliated to Laval University, this center offers specialized and ultra-specialized care and services in cardiology, pneumology and bariatric surgery to the Central and Eastern Quebec population. The Institute relies on 3500 employees, physicians, professionals, researchers, managers and volunteers.

The research center is also unique in Canada and regroups three main research axis in cardiology, pneumology and obesity. These three domains have received highest priority due to their considerable economic and social impacts.

The cardiac surgery research team is composed of cardiac surgeons, anesthesiologists, fellows, residents, nurse practitioners, nurses, perfusionists and other health professionals. In 2018-2019, 2800 patients underwent cardiac surgery at the Institute, which makes it the largest cardiac surgery center in Canada.



The Principal Investigator, Dr Pierre Voisine, is a cardiac surgeon who has been working at The Institute since 2004.

ROMA Participating Site Highlight:

Institut Universitaire de Cardiologie et de Pneumologie de Québec (IUCPQ) Toronto, Canada

Dr Voisine is also an Associate professor of medicine at Laval University. He acts as the local principal investigator for the CardioThoracic Surgical Trials Network (CTSN). Besides clinical studies done in collaboration with the CTSN, he's actively involved in numerous clinical trials with the Industry and also local initiated studies. With the CTSN, he serves on the steering committee and the publications committee. He is also vice-chair on the Executive Committee for cardiac surgery Exams (Royal College of Surgeons of Canada). Dr. Voisine is also involved as an Elected member for the American Association for Thoracic Surgery and a member of the Scientific Program committee for the Cardiovascular Surgery and Anesthesia Council (AHA). Finally, he is a reviewer for several peer-reviewed publications. His main research interests and scientific contributions are in the fields of angiogenesis, management of antiplatelet therapy in cardiac surgery, optimal use of conduits for coronary artery bypass surgery, bioprosthesis durability – optimal choice of prosthesis, and mitral valve disease.

Our research team is composed of two Ph.D.'s, four nurses, two medical students and one administrative assistant. The performance of our research group has always been outstanding in terms of patient enrolment and rigorous data collection.

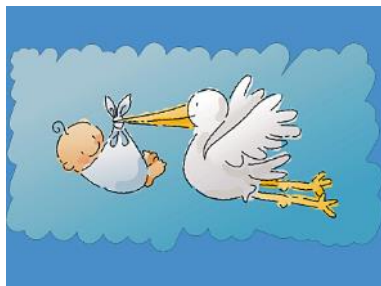
We are proud to contribute actively to important clinical trials such as ROMA.



From left to right: Annie Bergeron, Hugo Tremblay, **Dr. Pierre Voisine (PI)**, Nathalie Gagné, François Laforge, Audrey Grenier and Shanoor Nazary.

ANNOUNCEMENTS

Welcome Baby Boy!



**Congratulations
to Dr. Marc Albert
of Robert-Bosch-Hospital, Germany**

Check out the **ROMA Trial Website** for a list of
participating centers, publications, and more!

Visit: www.TheROMATrial.com

REMINDERS

As of January 1, 2020

Protocol Deviation and Prescreening Logs are collected
once per month, instead of every two weeks

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

ROMA Pulse

What's new at your site?

Please send us information on local accomplishments,
collaborative opportunities, and news of interest.

WE WANT TO HEAR FROM YOU!

CONTACT US

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