



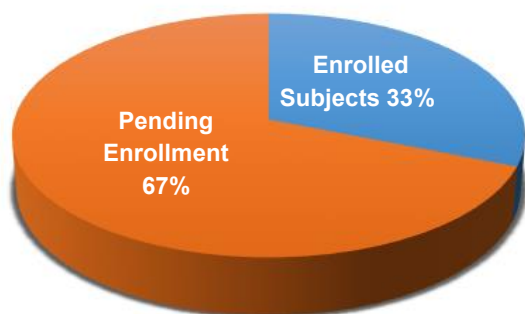
Randomized comparison of the clinical
Outcome of single versus
Multiple
Arterial grafts



**Weill
Cornell
Medicine**

ROMA TRIAL Newsletter - OCTOBER 2019

Overall Enrollment



Number of subjects enrolled

1 4 4 4

Congratulations!

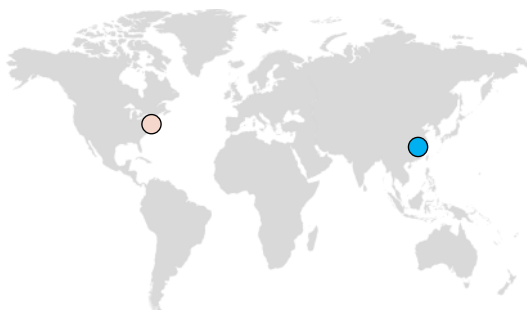
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Health Science

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Please Welcome 2 New Sites:

Baystate Medical
PI: Dr. Engelmann
Springfield, MA
USA



Ruijin Hospital
PI: Dr. Zhao
Shangai
China



TOP
Enrollers

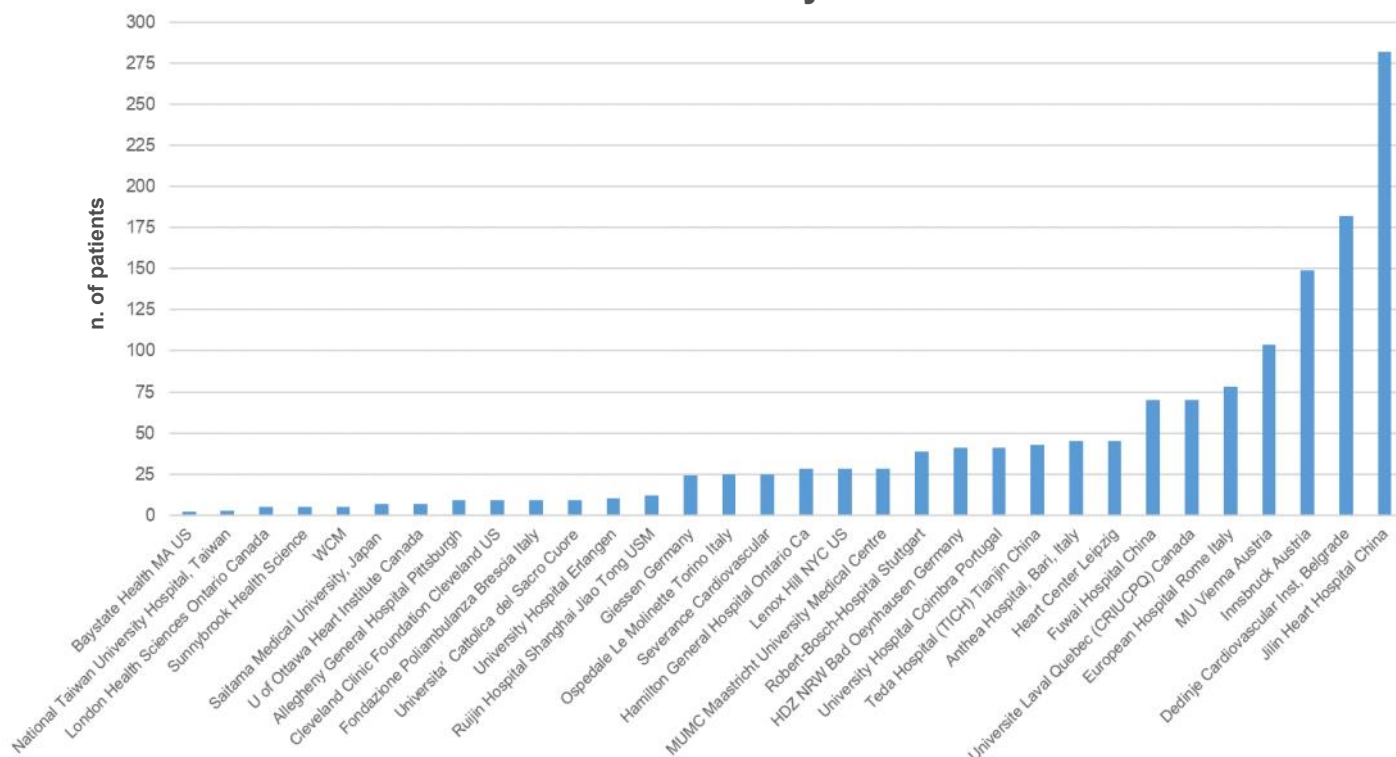
1	Jilin Heart Hospital –China
2	Dedinje Cardiovasculatr Institute—Serbia
3	Innsbruck Medical University– Austria
4	Medical University of Vienna— Austria
5	European Hospital—Italy

THANK YOU!

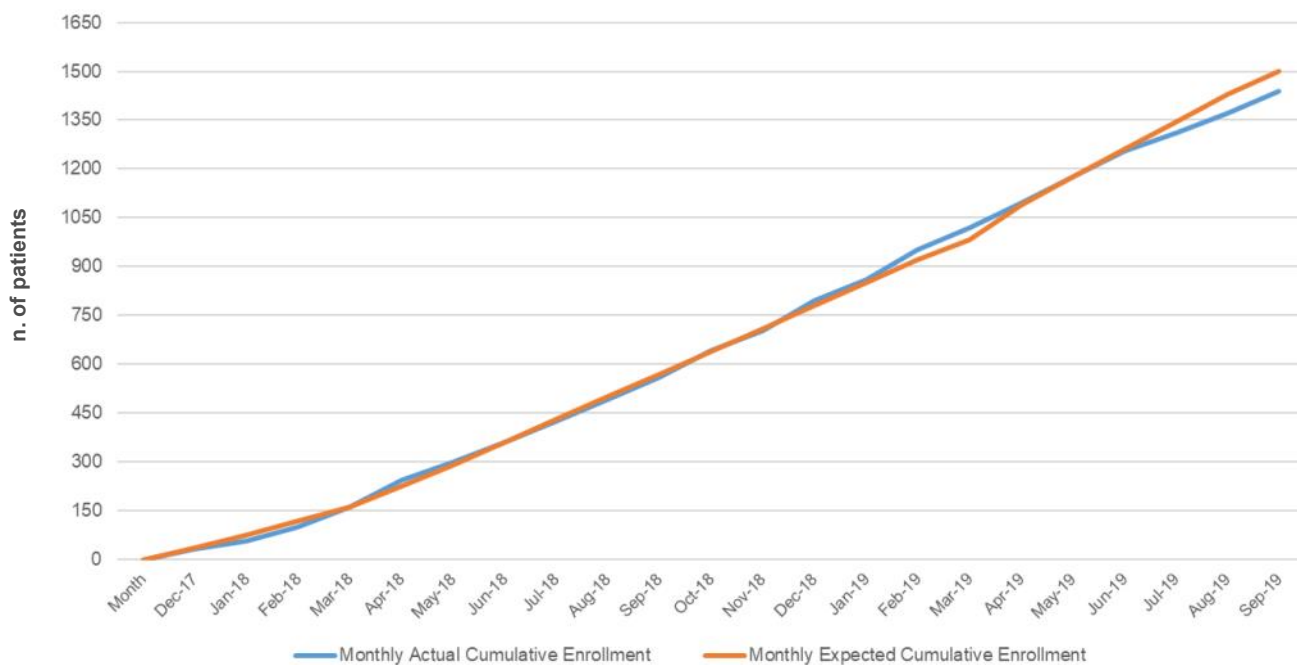


ENROLLMENT UPDATES

Randomization by Center



Cumulative Enrollment

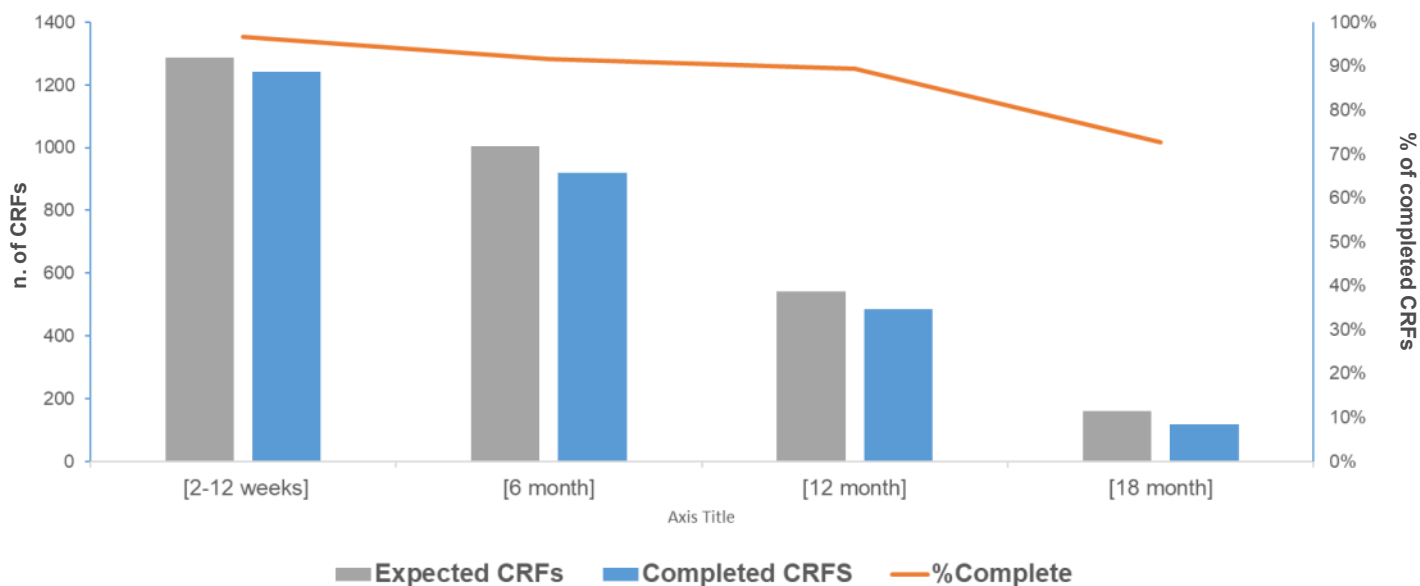


CRFs STATUS COMPLETION

Case Report Form	Total	Complete (n=)	%Complete	Missing (n=)	%Missing
Eligibility / Randomization	1439	1439	100%	0	0%
Intraoperative	1330	1314	99%	16	1%
[2-12 weeks]	1286	1243	97%	43	3%
[6 month]	1004	920	92%	84	8%
[12 month]	543	485	89%	58	11%
[18 month]	161	117	73%	44	27%

The 24 month FU window will be opening in December 2019.

Expected vs Completed CRFs



ROMA Participating Site Highlight:

Sunnybrook Health Sciences Center

Toronto, Canada

Sunnybrook Health Sciences Center based in midtown Toronto Canada situated on 154 acres of land, is one of the largest tertiary care hospitals in Ontario. Since 1948, Sunnybrook has evolved from its original role as Canada's largest veterans care hospital and became part of University of Toronto in 1966. University of Toronto is the only medical school in Toronto and all the teaching hospitals are affiliated to it. Sunnybrook was the largest employer in North York prior to amalgamation of the six municipalities as the city of Toronto in 1988. Today approximately 11,000 staff, physicians, volunteers and students transform health care daily.

Some of the first adult closed heart operations in Toronto were initially performed at Sunnybrook in the 1950s. A cardiac catheterization lab was opened in 1969. The cardiac surgical unit was initially considered in 1970. The Cardiac surgery unit finally opened in 1989 in response to lengthy waiting lists for cardiac surgery in Ontario. Dr Bernard Goldman was the first Chief of Cardiovascular Surgery, with Dr Stephen Fremes and Dr George Christakis as his fellow colleagues. Later on Dr Fremes was the Chief of Cardiovascular Surgery at that hospital for almost 13 years and is the recipient of the Bernard Goldman Chair in Cardiovascular surgery since 2010.

Our team is composed of Staff surgeons, Cardiac surgery residents, Cardiologists, cardio-anesthesiologists in addition to nurses, perfusionists and other allied healthcare professionals. Our division is a part of the Schulich Heart Center and manages approximately 600 patients undergoing cardiac surgery every year. Sunnybrook has one of the largest TAVI programs in Canada and manages approximately 200 TAVI's per year.



ROMA Participating Site Highlight:

Sunnybrook Health Sciences Center

Toronto, Canada

Also, on site is ICES, a health services research organization with separate funding from the Ministry of Health. The main research themes at Sunnybrook have been: 1) improving coronary bypass graft outcomes following coronary surgery; 2) myocardial protection / cardiopulmonary bypass management; 3) Bioprosthetic valve studies and transcatheter aortic valve surgery. The methodologies include clinical trials, observational studies (single center and health systems research), systematic reviews and meta-analyses, and recently health economics (applied to transcatheter aortic valve surgery).

Dr Fremes is one of the leading trialists in Cardiac surgery in Canada for almost 30 years. One of his key scientific contributions has been demonstrating that the radial artery has superior 1-year and late graft patency than the saphenous vein for non-LAD targets (RAPS, NEJM 2004) and that radial graft patency is dependent on high grade proximal target vessel stenosis. Dr Fremes along with Dr Gaudino developed the ROMA Trial proposal, pilot and definitive grant submissions for CIHR.

We are honored to collaborate with you all in the ROMA Trial.



Dr. Stephen Fremes (center) with Research staff and summer research students

Adverse Event Reporting

Not all the Adverse Events need to be reported for the ROMA study. Here you can get some clarity on which events are or are not reportable as Serious Adverse Events

A) Adverse Events to report regardless of seriousness:

- Pulmonary embolism
- Deep vein thrombosis
- Sternal wound infection
- Sternal reconstruction
- Gastrointestinal complication
- Any hospital admission (exclude ER only)
- Postoperative complications
- Myocardial infarct
- PCI
- Re-CABG
- Stroke
- Harvest site infection
- Death
- New Atrial Fibrillation –drug therapy

How to report an SAE:

1. Complete the SAE CRF
2. Upload in the scanned document section the redacted source documentation supporting the event.
3. Complete the specific event CRF for events of death, myocardial infarct, PCI and Re-CABG.
4. Report the SAE to your local ethics and safety committee following local guidelines.

B) Adverse Events to NOT report:

- Unplanned procedure during surgery → to be documented in the intraoperative CRF (question n.7)
- CTA performed as standard of care → to be documented in the Follow up CRF.

Protocol Deviation Reporting

Deviations are any difference in study conduct from the criteria or procedures prescribed in the approved protocol, without affecting the subject's safety, rights, and welfare or the integrity of the study.

Most common Deviations:

- **Consenting procedures**
 - ◊ Expired regulatory documents used during consenting
- **Randomization procedures**
 - ◊ Subject was found to be ineligible after randomization
- **Surgical Plan:**
 - ◊ Intraoperative Crossover (randomization arm not conserved)
 - ◊ Graft conduit used differs from planned (i.e. Planned: RA; Used: RITA)
- **Study procedures:**
 - ◊ Visit schedule: subjects follow up was performed outside the event window
 - ◊ Timeline for reporting serious adverse events

How to report a Deviation:

1. Notify the ROMA team by email roma@med.cornell.edu.
2. List the deviation in the deviation log
3. Report the deviation in the Eligibility and randomization CRF (Post-randomization section)
4. If the deviation is a crossover, document the crossover in the Intraoperative CRF also (question n. 6)

ROMA Investigator Meeting

33rd EACTS Annual Meeting

Lisbon, Portugal

We are happy to report that the ROMA Investigators Meeting at the 33rd Annual Meeting of the European Association for Cardio-Thoracic Surgery in Lisbon, Portugal was a great success. More than 50 investigators across all centers were able to attend.

Discussed topics included important updates on individual center progress with recruitment and outcomes, as well as future planning including a newly introduced separate study focusing on gender (ROMA-WOMEN).

We are happy to report that we anticipate the opening of 20 new sites in the coming weeks.

As always, we are appreciative of all the hard work each investigator and their team has invested to this point, and we look forward to the continued success of ROMA!



Lisbon Congress Center, Praça das Indústrias 1, 1300-307 Lisbon, Portugal

ANNOUNCEMENTS

New feature coming to ROMA database:

New Dashboard

will be released soon.

Look for an email announcing it!

Dr. Taggart's Editorial comment will be
published on November 5th!

The Role of Multiple Arterial Grafts in CABG

JOURNAL OF AMERICAN COLLEGE OF CARDIOLOGY

REMINDER

Alert the coordinating center of any patients
that consistently do not respond to your
contact attempts for follow –up visits.

Send feedback on how we develop 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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