



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



**Weill
Cornell
Medicine**

ROMA Trial Newsletter

April 2018

Dear ROMA Study Teams,

The ROMA trial is now open at 15 sites, thank you all for all your hard work and dedication to this study. We look forward to the work ahead and our collaboration on this exciting trial!

Study Updates

We are pleased to announce that a Canadian Institute of Health Research (CIHR) grant has been awarded to ROMA!

As a result of all of the efforts of our collaborating sites, as of April 6, 2018 the total enrollment is **106** subjects randomized.

The WCM study team has created a new email address that can be used for all ROMA correspondence. Please use ROMA@med.cornell.edu for future study-related correspondence.

As a reminder, please send your center's **Screening Log** on the 1st and 15th of each month to ROMA@med.cornell.edu.

THANK YOU to
Dr. Massimo Lemma
and Jilin Heart Hospital
for your tremendous en-
rollment efforts, with 43
subjects enrolled.

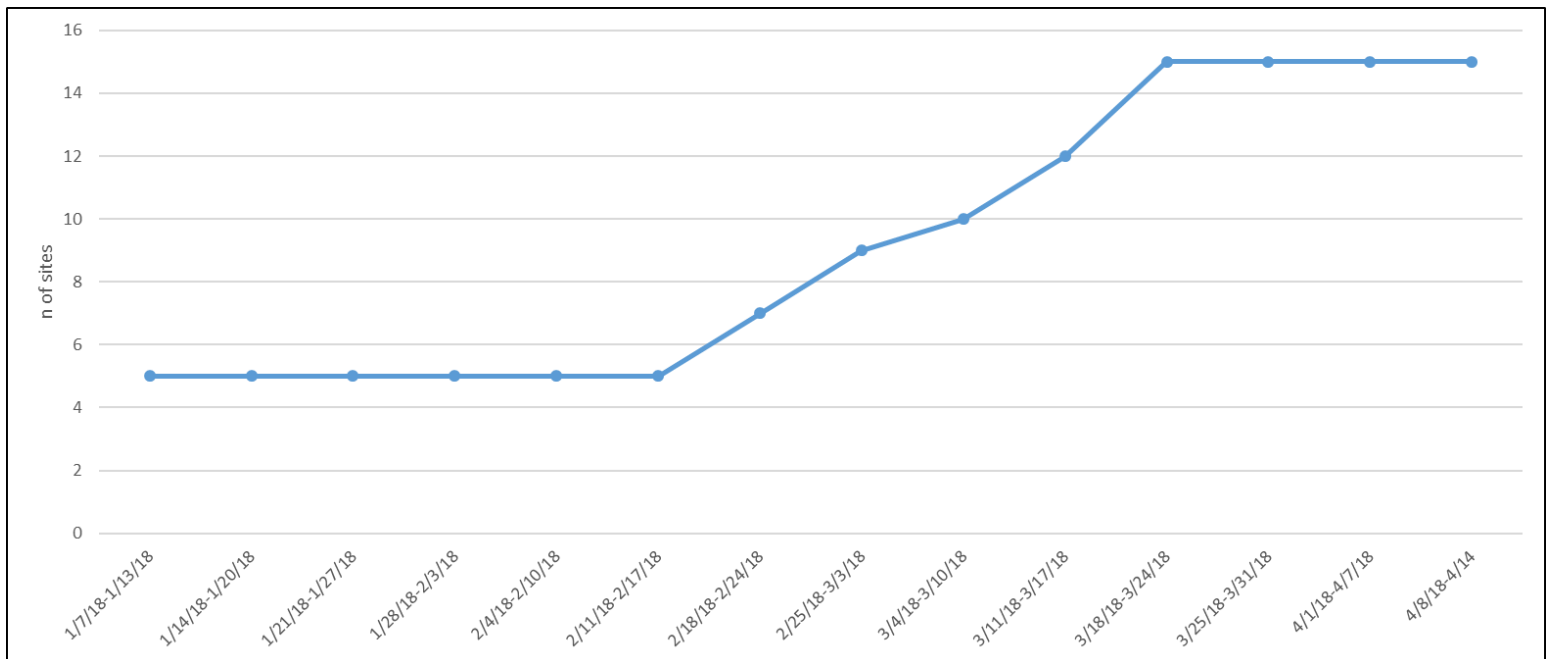
Site status	Number of sites
Open to enrollment	15
IEC approved but pending contract	6
Contract finalized but IEC approval pending	4
IEC approval and contract pending	11
Total sites (including WCM/ NYP Hospital)	36

ENROLLMENT SUMMARY

As of April 13, 2018

Overall Subject Enrollment Status	Number of subjects
Randomized	130
SAG	65
MAG	65

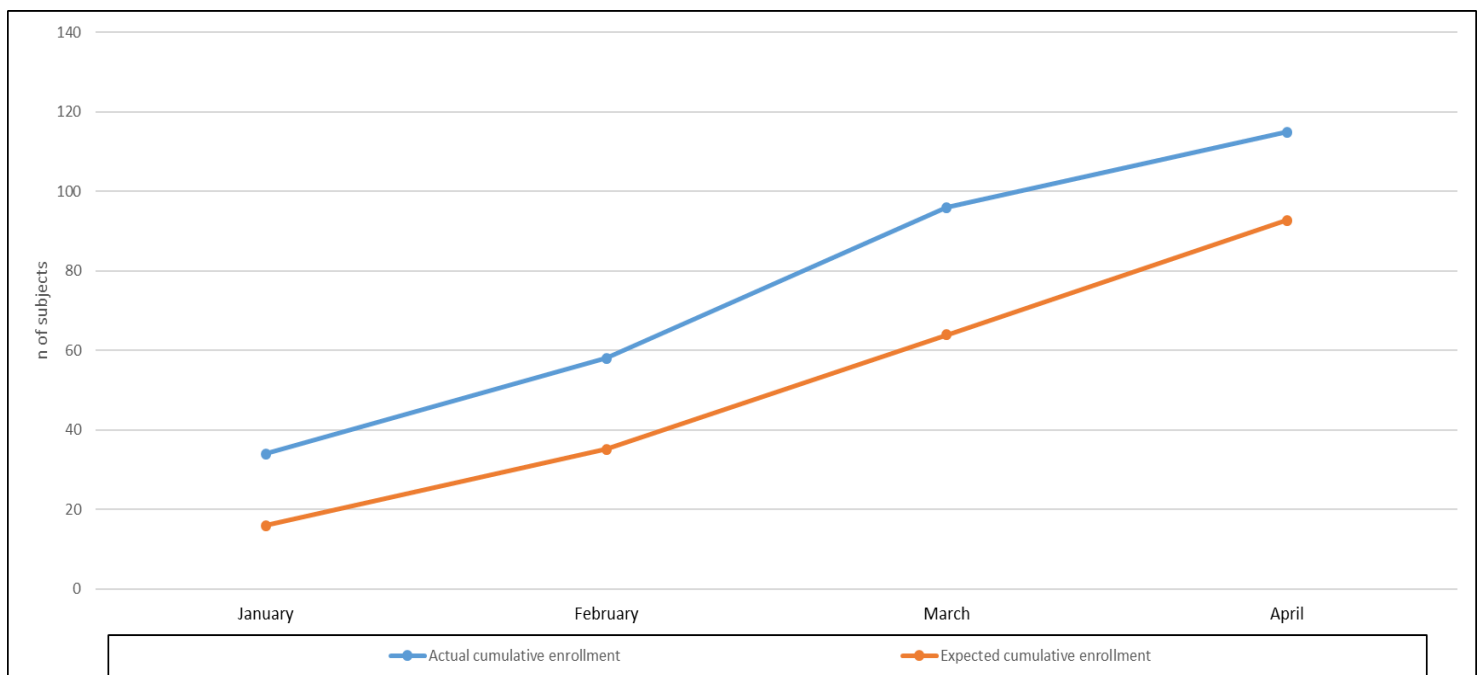
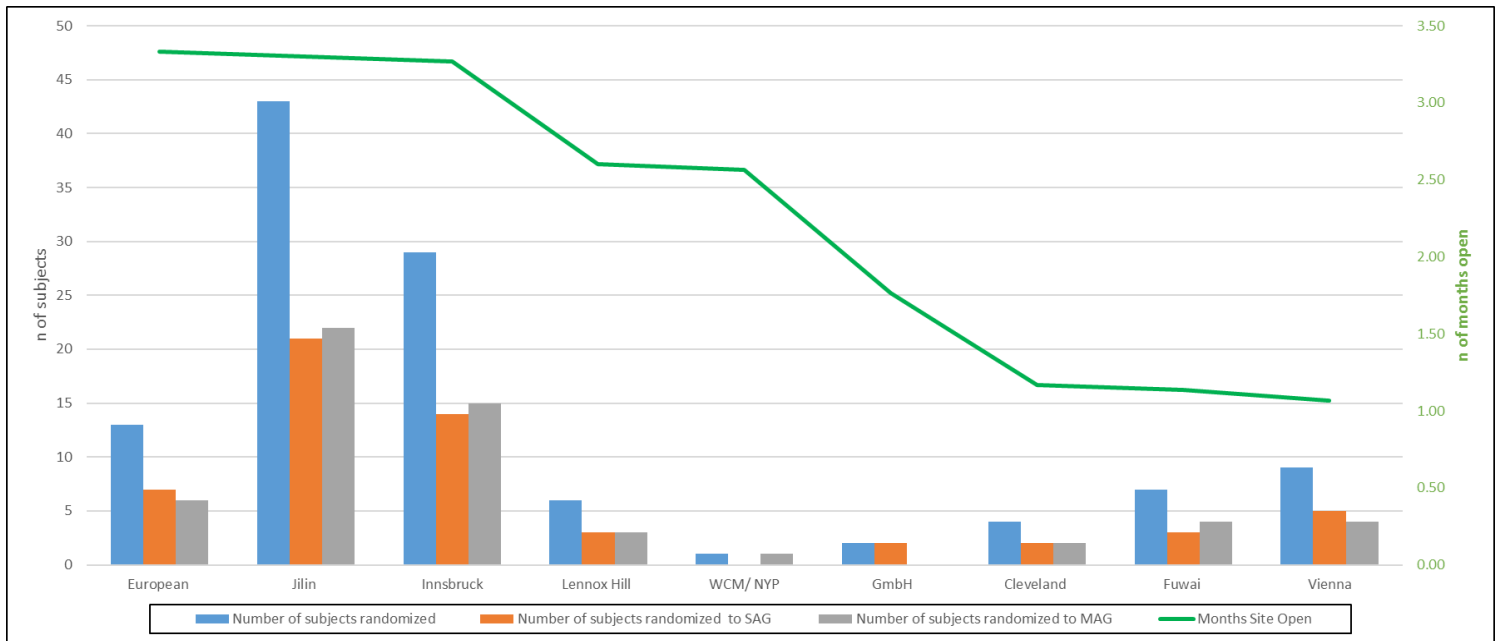
Cumulative Number of Open Sites as of 4/13/2018



ENROLLMENT SUMMARY

As of April 13, 2018

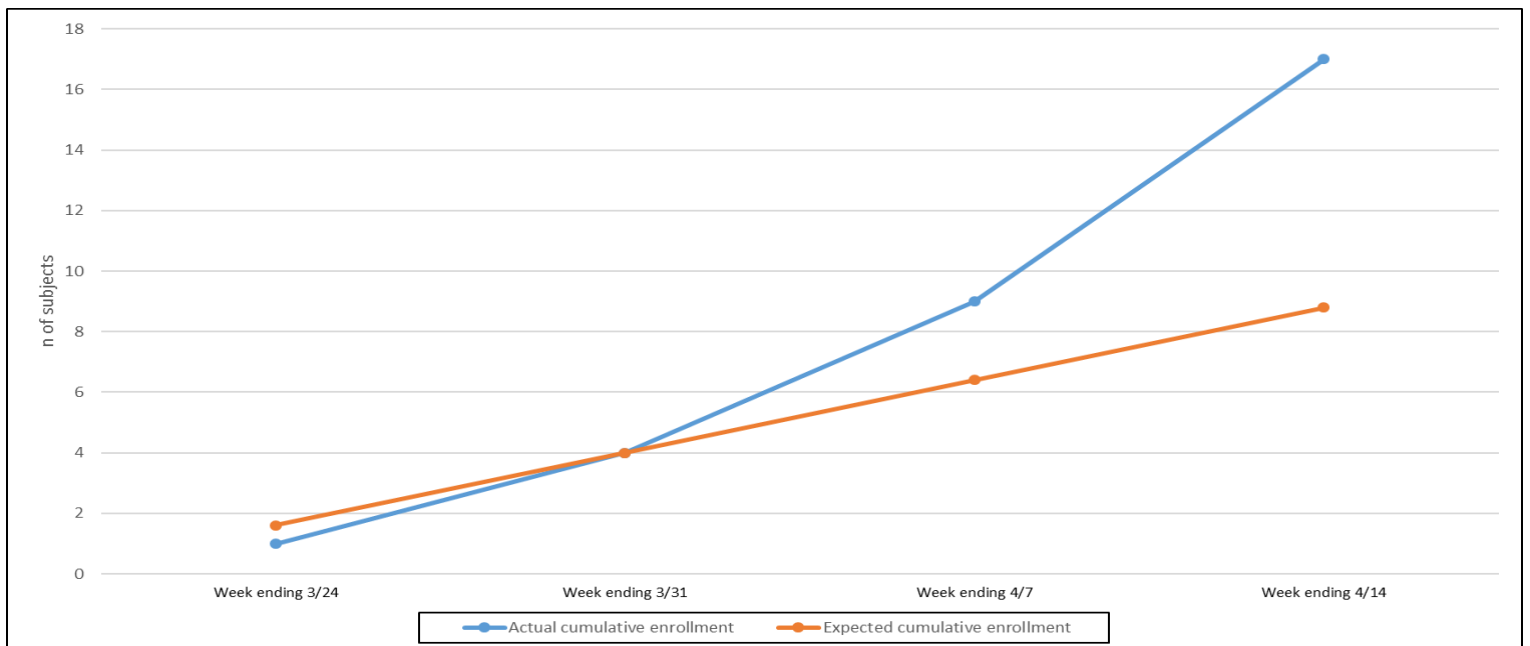
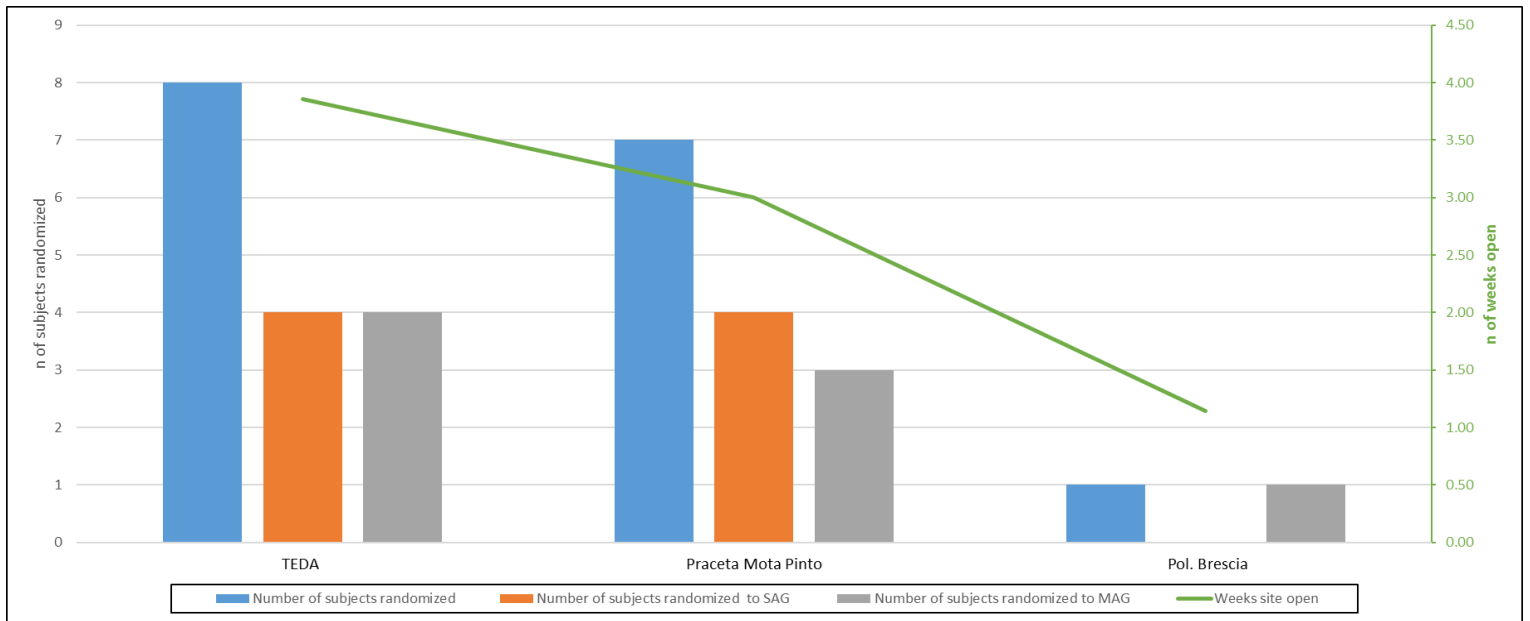
Subject Enrollment Updates for Sites Open > 1 Month



ENROLLMENT SUMMARY

As of April 13, 2018

Subject Enrollment Updates for Sites Open < 1 Month





World-class Healthcare in the Heart of a Rust Belt: The Jilin Heart Hospital



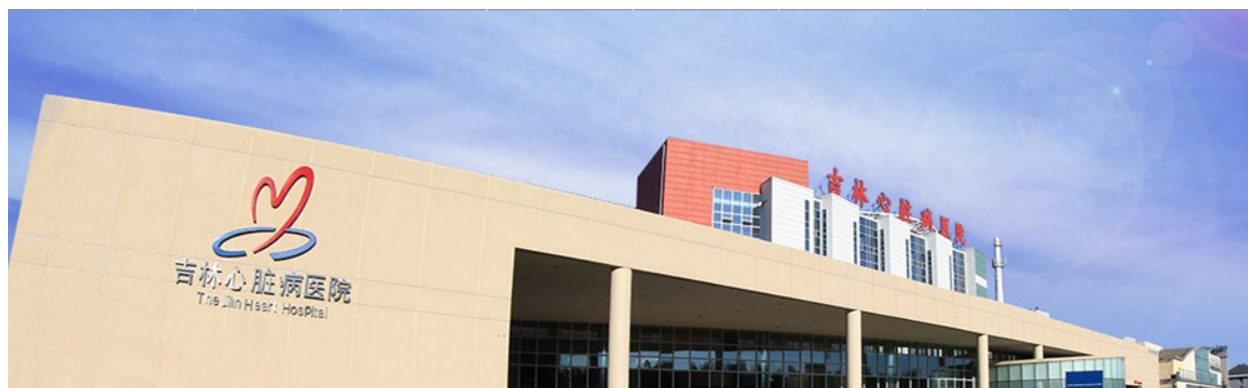
The People Republic of China has become the world's largest economy since a few years, and the interest in its has rapidly grown worldwide. However, if many know where Beijing and Shanghai are, only very few know where the city of Changchun is located. It is the capital and larger city of Jilin Province, and is also the core city of north-east Asia, being its largest industrial, educational, scientific and transportation hub.

Changchun means "long spring" in Chinese. Between 1932 and 1945, Changchun became the capital of the Japanese puppet

state Manchukuo. After the foundation of the PRC in 1949, Changchun was established as the provincial capital of Jilin in 1954.

Jilin Hospital Spotlight, continued

According to the 2010 census of China, Changchun had a total population of nearly 8 million under its jurisdiction, currently grown to more than 10 million. The **Jilin Heart Hospital** is located in the south-east part of the city of Changchun. It has been built brick by brick according to the specifications of the famed Community Heart and Vascular Hospital in Indianapolis, with a blueprint supplied by the Clinton Foundation.



Completed in October 2011, the hospital is specialized in heart disease, featuring 300 beds (40 ICU beds), 4 cardiac surgery OR, 3 cath-labs and 1 hybrid theatre. Owners Huang Hai and Huang He, brothers with diverse backgrounds whose names literally mean Yellow River and Yellow Sea, have built the 300-bed hospital with a 300 million yuan investment. They nurture an ambition to make it the best of its kind not just in China, but in Asia.

The mission of the hospital is to provide excellent care services for patients with cardiovascular disease, with the vision to establish a regional heart center with the integration of health care, education and scientific research, compliant with international standards. According to its vision the hospital has adopted western management procedures based on

international guidelines and protocols (ACC/AHA/ESC). It has also recruited cardiac surgeons, anaesthesiologists, ICU specialists, cardiologists and other physicians from countries like Italy, United Kingdom, Spain, Bulgaria, Germany, Brazil, along with importing state-of-the-art medical equipment.

The Jilin Heart Hospital offers a full spectrum of surgical and interventional treatment for adult and paediatric cardiac disease, where coronary artery surgery represents a big part of it. Being the north-east of China the world area with the highest incidence of cerebro-vascular and vascular disease, aortic off-pump myocardial revascularization, either via full sternotomy or left mini-thoracotomy, represents the preferred strategy for coronary artery surgery. Composite arterial graft are routinely performed using the Internal Thoracic Arteries and the Radial Arteries, rarely the Saphenous Vein.

In order to obtain a high quality standard, each coronary anastomosis is intraoperatively evaluated using Transit Time Flow Measurement and Epicardial Ultrasound Imaging. When either cardiopulmonary bypass or an aortic anastomosis is necessary, the ascending aorta is always scanned via epiaortic ultrasound imaging to identify any aortic disease. The combined effect of aortic surgery and epiaortic ultrasound imaging has helped to contain the incidence of preoperative cerebrovascular accident below 0.2% in 2017.

Being composed by professionals passionate about their job, the Cardiac Surgery Team has responded enthusiastically to the ROMA trial. Every one knows that to be part of this study is at the same time a honour and a burden. We will do our best to continue providing a high volume of excellent quality data.

Mario and Steve, thank you one more time for this great opportunity.

Greetings from the whole team!



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JCTOcontracts

Important Study Reminders

- ◆ Please ensure that the following **adverse events**, as per the protocol, are entered into the database:
 - Death from any cause
 - Stroke
 - Myocardial infarction
 - Major postoperative complications:
 - * Revision for bleeding
 - * Perioperative myocardial infarction
 - * Any stroke
 - * Need for dialysis
 - * Need for tracheostomy
 - * Surgical site infection
 - Intra-Aortic Balloon Pump
 - Sternal wound complication
 - Re-Percutaneous Coronary Intervention (PCI)
 - Re-CABG
 - SAE (event resulting in death, requiring or prolonging hospitalization, life-threatening, persistent or significant disability or incapacity, other medically important event)
- ◆ **Informed consent** should be obtained from subjects prior to any study-related procedures occurring, including randomization into the database.

ClinvestiGator



<https://ccim.med.cornell.edu>

DATABASE REMINDERS

- ⇒ Please enter **subject initials** only in the database when randomizing subjects.
- ⇒ Please upload a copy of a de-identified (subject name redacted) **informed consent form** for each entered subject.
- ⇒ On the "Medication" form in the database, please mark "YES" or "NO" for each option (blank responses are considered incomplete).