jolt-ca

Joint Lung Cancer Trialist's Coalition

Newsletter for Clinical Trial Partners / August 2019

Halfway!! This month, the JOLT Stablemate's trial met an important milestone: we have enrolled our 136th patient to the trial, which is the halfway point for enrollment.

As most of you know, this was not easy. In fact, many observers in the lung cancer community predicted the trial would fail and close long ago just like the three previous trials asking a similar question. So, we've at least earned credibility as clinical researchers and, perhaps, more. Ours is already the **largest phase III trial in existence comparing sublobar resection and SAbR.** But, not to rest on our laurels, what do we need to do next….

As per the statistical design, an interim analysis will now take place (as soon as we get all the patient follow-up data into REDCAP). So please, press your colleagues to see patients on follow-up and enter their status. The interim analysis is looking for strong signals, both in favor of a therapy or recognizing a therapy has not had a chance to impact care. Most likely, you will not hear much from us about the interim analysis, which means the trial should continue as designed. In this case, we will not issue a report or publish, partly because we do not want to bias ongoing enrollment. However, if there is a strong signal that moving forward is futile for a number of reasons, you will be notified and the site PIs will enter discussions on how to proceed.

Back to the celebration! Enrolling 136 patients to a randomized trial comparing such disparate therapies has not been easy. While we are behind schedule in our pace to enroll, we should all still be proud that we are doing the right thing by our patients. For operable patients, high-level evidence is critical for decision-making and patient safety. The notion that operable patients might be routinely treated off protocol with SAbR is at a minimum disappointing. So be proud that you are collecting the important data that will ultimately make a difference for lung cancer patients.

Explaining the Pre-Randomization to Patients

While slightly improving, our current 65% rate of acceptance for the pre-randomization assignment is still well below the trial's design target of 80%. Recall that the NSABP B-06 trial, after which our trial is modeled, had an acceptance rate of over 90%. In previous issues of the newsletter, we described more successful strategies for patient acceptance. A protocol amendment also had changes aimed at improving the unexpectedly low pre-randomization assignment acceptance rate.

The sites with the highest acceptance universally discuss the trial's intent, merits, and design PRIOR TO pre-randomization or consent. The **Stablemate's website**, **joltca.org**, has a patient video on its home page that is IRB-approved and designed to get the conversation started (transcripts are in the protocol). It attempts to educate the patient as well as breakdown erroneous pre-conceptions that might otherwise lead to a lack of equipoise and drive-down our pre-randomization assignment acceptance rate.

Finally, for those patients who, despite discussions, already strongly favor one treatment over the other, PLEASE do not pre-randomize them onto the trial. While it's true they have a chance to get assigned to their preferred treatment, this tactic will obviously lead to a 50% acceptance rate, well below what is acceptable or feasible for our trial's design. While patients in all cases maintain the right to refuse the pre-randomization assignment after it is revealed, irrespective of their feeling prior to the pre-randomization, at a minimum it is prudent to have some reasonable indication that they will accept the assigned treatment, whether surgery or SAbR, prior to pre-randomization.

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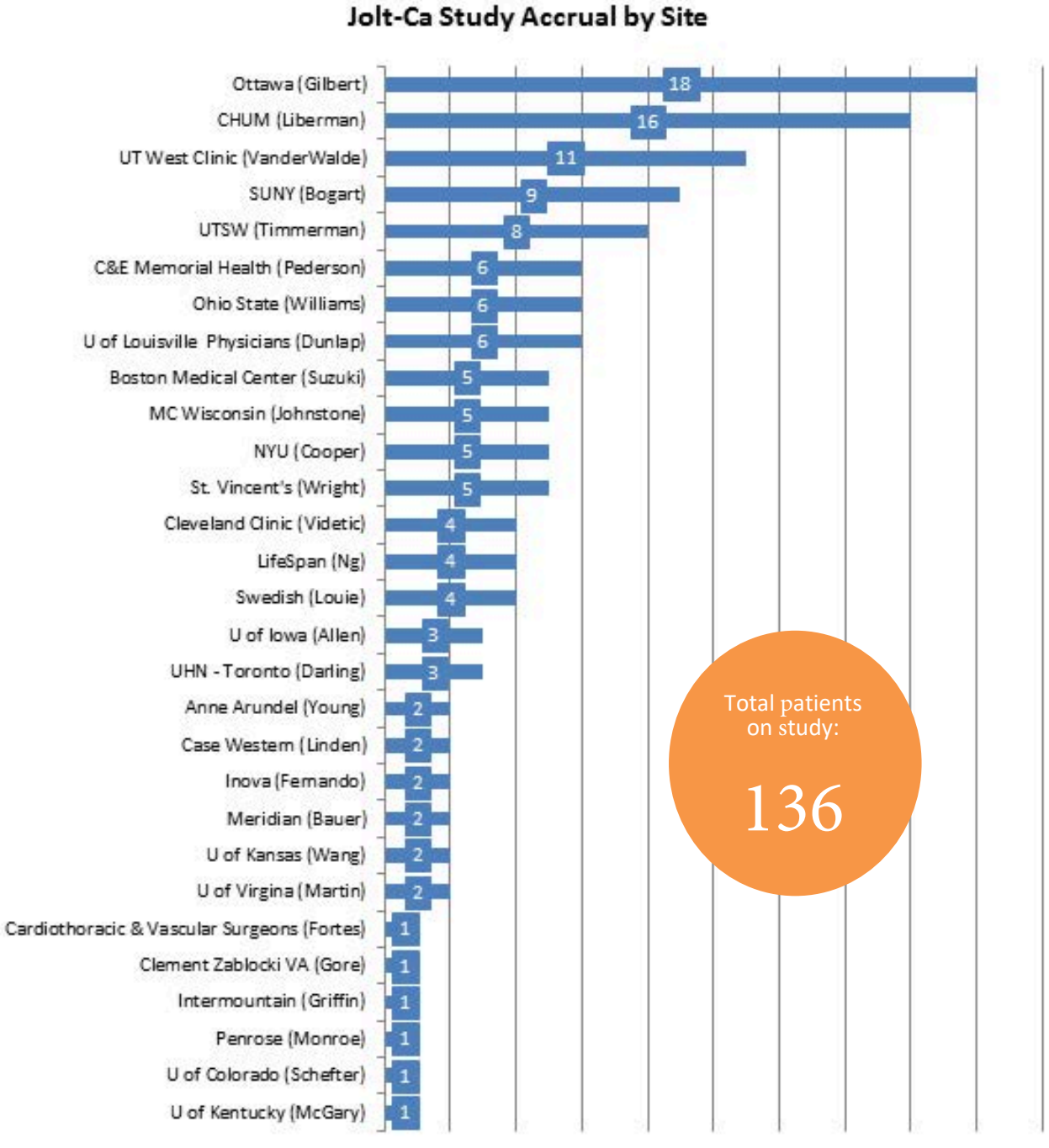
A Randomized Phase III Study of Sublobar Resection (SR) versus Stereotactic Ablative Radiotherapy (SAbR) in High-Risk Patients with Stage I Non-Small Cell Lung Cancer (NSCLC)

STABLEMATES TRIAL



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First enrollment: Clement J. Zablocki VA Medical Center, PI: Elizabeth Gore

SUBSITE UPDATE

Active:

- Anne Arundel Medical Center
- Boston University
- Cardiothoracic and Vascular Surgeons
  - Austin
- Case Western
- CHUM-Notre Dame Hospital
- Clement J. Zablocki VA Medical Center
- Cleveland Clinic
- Henry Ford Health System
- INOVA
- Intermountain Medical Center
- Lifespan Oncology Clinical Research
- Medical College of Wisconsin
- Memorial Health University
- Meridian Health
- New York University
- Ochsner Medical Center
- Ohio State University
- Ottawa
- Penn State (Mount Nittany Medical Center)
- Penrose Cancer Center
- Providence Health and Services
- St. Vincent's – Australia
- SUNY
- Swedish Cancer Institute
- Thomas Jefferson University
- University of California San Diego
- UHN - Toronto General Hospital
- University of Cincinnati
- University of Colorado/Memorial
- University of Iowa
- University of Kansas
- University of Louisville Physicians
- University of North Carolina Chapel Hill
- University of Pittsburgh Medical Center
- UT Southwestern Medical Center
- University of Virginia
- West Clinic/University of Tennessee
- William Beaumont Hospital

Completed contracts:

- Sunnybrook

Completed IRB approval:

- CERV

If there are any questions regarding how to enter data-screen patients or any other aspect of the trial, please email or call Sarah.

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