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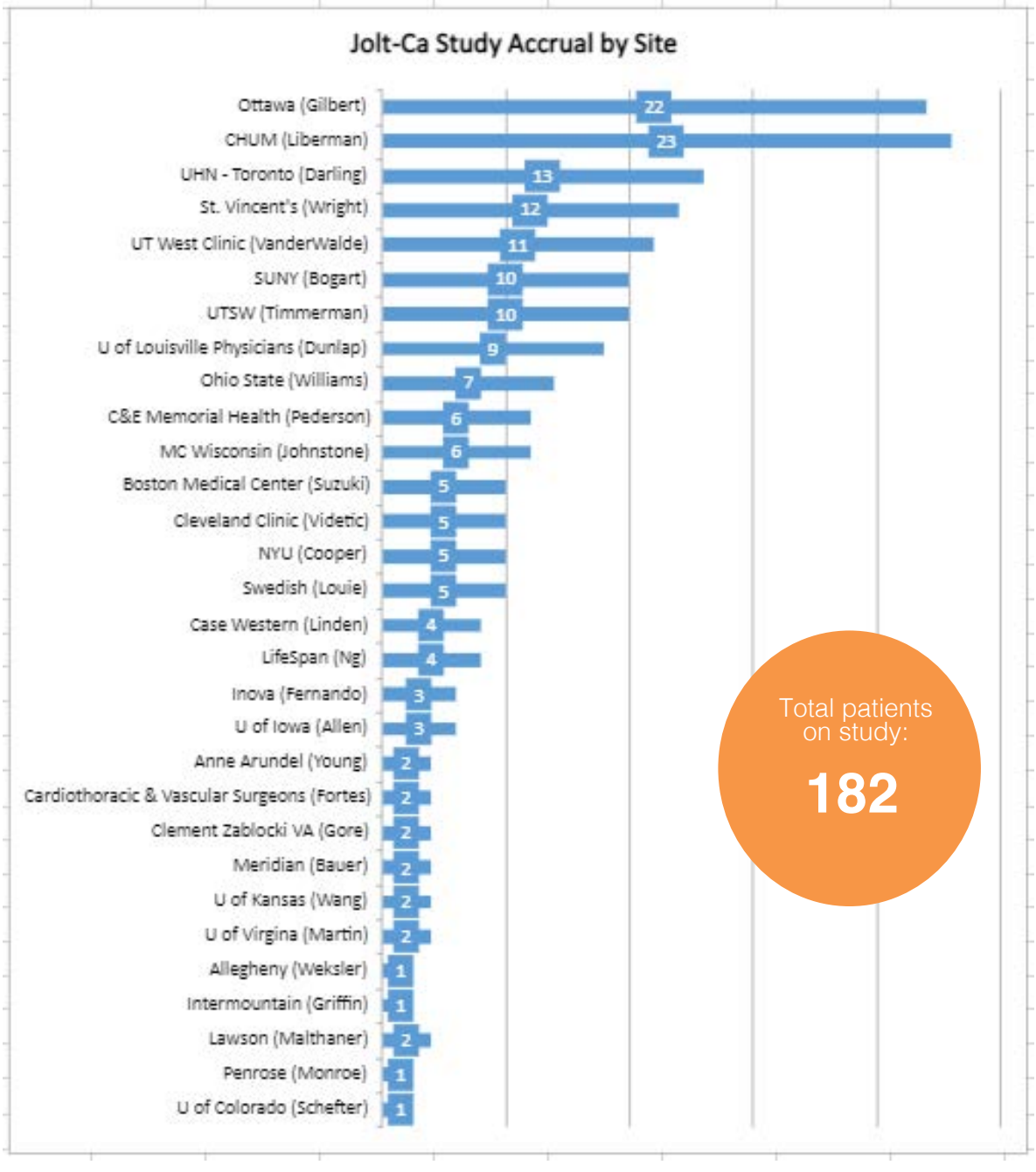
Joint Lung Cancer Trialist's Coalition

Newsletter for Clinical Trial Partners / April 2021

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



Please note: The REDCap eligibility checklist has been updated to match the protocol wording exactly. Please be aware and answer questions in REDCap appropriately.

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SUBSITE UPDATE

Active:

- Allegheny
- 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
- Intermountain Medical Center
- Lawson Health Center
- Lifespan Oncology Clinical Research
- Medical College of Wisconsin
- Memorial Health University
- Meridian Health
- New York University
- Ohio State University
- Ottawa
- Penrose Cancer Center
- St Vincent's – Australia
- SUNY
- Sunnybrook Health Sciences Centre
- Swedish Cancer Institute
- Thomas Jefferson University
- Trillium Health Partners
- UHN - Toronto General Hospital
- University of Cincinnati
- University of Colorado/Memorial
- University of Iowa
- University of Kansas
- University of Louisville Physicians
- University of Pittsburgh Medical Center
- UT Southwestern Medical Center
- University of Virginia
- West Clinic/University of Tennessee
- William Beaumont Hospital

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

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Read the below article and interview featuring Dr. Gavin Wright from St Vincent's – Australia. St. Vincent's has a 100% randomization acceptance rate and Dr. Wright was kind enough to share their approach to clinical trial conduction with us!

St Vincent's Hospital in Melbourne - Dr. Gavin Wright

by Damiana Chiavolini, MS, Ph.D.

A specialist thoracic surgeon and Associate Professor at the University of Melbourne Department of Surgery, Gavin Wright, MBBS, FRACS, Ph.D., works on two campuses within an alliance of hospitals known as the Victorian Comprehensive Cancer Centre (VCCC) in Melbourne, Australia. He is the research and education lead for lung cancer in the VCCC.

Dr. Wright graduated from the University of Melbourne Medical School in 1988 and completed his General Surgery Fellowship in 1998. He completed his Cardiothoracic fellowship in 2001 and started his practice at the Peter MacCallum Cancer Centre and St Vincent's Hospital in Melbourne.

He is interested in surgical oncology, especially upper GI and colorectal, and passionate about the finesse, complexity, and "dark art" of thoracic surgical oncology.

"Other than a few exceptional surgeons, the level of thoracic cancer surgery was poor in Australia, so I felt it shouldn't be too difficult to set a new standard with commitment and passion," says Dr. Wright.

His research career started quite small because surgical units are rarely offered any infrastructure or staff support. He decided that his best bet was to collaborate and help others. The networks he built and supported eventually paid back and enabled him to progress to increasingly complex translational and clinical research studies. He eventually co-funded the salary of a clinical trial coordinator with his cardiac colleagues, which allowed his clinical research to soar.

The VCCC appointment provides Dr. Wright with great scope to develop multidisciplinary and multi-center collaborations that ultimately help most of the approximately 6 million people living in the state of Victoria. This appointment also allows him to efficiently run a hub-and-spoke system of trial sites and sub-sites, where appropriate.

Dr. Wright successfully contributed to the ACOSOG Z30, CALGB 140503 and 30506, and the NCIC BR31 trials. Unfortunately, he and his team lost the ACOSOG membership when the groups merged into Alliance.

"This was a shame because our single site would commonly add more patients than many states in the US. So, for us, the opportunity to join the JoLT StableMates was a real boon. We had the capacity required to run group trials at the time, but no big trials left to answer the important questions," says Dr. Wright.

His team also runs investigator-initiated trials, including an NHMRC-funded longitudinal study of ctDNA pre- and post-lung cancer resection. They are identifying unique gene rearrangements from whole genome sequencing and detecting them by droplet digital PCR. They recruited about 100 patients into this study despite the pandemic, which significantly reduced their operative numbers and curtailed their research activities for many months.

They also run select phase I and II sponsored trials to conduct some interesting studies, while keeping finances healthy and supporting the less well funded Australian lung group trials.

Dr. Wright's approach to enrolling patients is strongly centered on collaboration. The first important component is to have trials available. The team's clinical trial coordinators trawl the upcoming clinic lists for potentially suitable patients, then flag them. Also, they include a 2-3 slide PowerPoint presentation on a trial at the very start of their

multidisciplinary meetings (tumor boards), along with a laminated one-pager with pathways for patients with non-small cell lung cancer at different stages in their disease.

They end each discussion about particular patients by asking, “Is there a trial for this patient?”

He then lets his counterparts in radiation oncology know there is a potential case.

Dr. Wright believes that his accrual success depends on empowering patients with making the final decision, and also conveying to them this is a shared decision. So far, none of his patients have rejected randomization, and very few have rejected recruitment by personal choice.

“The beauty of pre-randomization is that once equipoise, treatment explanation, and our need for answers have been discussed, the patient’s next stop can be with the team, probably to deliver the randomized treatment,” explains Dr. Wright. “I tell patients that they should keep an open mind and that we would not recommend the trial if we knew the answer already. Then, I stress that if they get cold feet at the last minute, they can take the decision back into their own hands,” he adds.

The second and equally important factor is the research team he works with.

“My team includes very professional and passionate clinical trial staff with an enthusiastic ‘can do’ attitude; I realize how lucky I am to have this,” says Dr. Wright.

He has a team of four in his coordinating center at St Vincent’s and the valuable assistance of the radiation oncology clinical trials staff at the Peter MacCallum Cancer Centre, where he has arranged for a radiation oncologist to be a sub-site PI.

“Our multidisciplinary team shares a balanced and mutually respectful relationship, and our lung cancer surgical and radiation oncology teams share a thirst for scientific truth. I am fortunate and grateful.” says Dr. Wright. “The culture in Australia also probably drives this collaborative atmosphere. Decisions are often made for the community’s benefit, rather than for the individual person’s ‘freedoms’. This makes Australia (and my state of Victoria, in particular) punch above its weight in many international trials.”

Dr. Wright first heard about the JoLT StableMates trial from his colleague, Professor David Ball, who conducted the Chisel trial of stereotactic ablative radiotherapy (SAbR) vs conventional radiation for peripheral lung cancers. At the time, he was unsure he and his team could be part of JoLT StableMates because they were outside North America. However, St Vincent’s Hospital agreed to take on the role of local sponsor, which was needed for ethical and regulatory approvals.

“Our track record with international and national group trials along with a good word from Professor Ball encouraged the trial leaders to work with us,” says Dr. Wright. “After meeting Dr. Timmerman and Dr. Fernando, I realized we could make a good contribution. My research team worked tirelessly to make it happen and the rest is history,” he adds.

We asked Dr. Wright a few questions about his approach and success in accruing patients into his sub-site of the JoLT StableMates trial.

What is your approach when you initially present the trial to a potential JoLT candidate?

I start by reassuring the patient that we will attempt to aggressively treat their cancer. However, I also point out that their fitness for surgery also means that the risks of treatment start to add up. I explain that SAbR has been used successfully as an alternative in patients who are clearly unfit for surgery, so next we need to know whether that is a viable option in those with higher risks of surgical complications, including mortality. I explain the generalities of each treatment and what to expect in terms of attendance and hospitalization in layman's terms. Next, I highlight the concept of randomization, and why it is important to rule out my bias or the patient's bias, and find the truth about a new treatment. I stress that this is the most valuable contribution they can make to science, but the parachute plan of choosing their own option is still available if they cannot cope with the randomizing process or the arm allocated to them. In the latter case, I tell them we would like to follow their journey on a registry basis, so that we have an idea of what happens in the real world outside the trial. Finally, I explain I will notify them of their allocation at our next meeting, and that we will make arrangements for them.

Do you use any trial aids such as handouts or videos?

We sometimes show the video on the JoLT StableMates website if we think a patient is struggling with our explanation. An additional phone or in-person discussion with my clinical trials coordinator allows the patient to have more time to absorb the information before committing to the consent process.

Do you have any suggestions that you think might be helpful for other sites?

As mentioned earlier, recognizing potential recruits in advance is essential to facilitate a less biased first approach. The patient needs to be aware up front that surgery is available for fit patients and SAbR for unfit patients. Then, the grey areas of the borderline fit patient should be approached. I would also stress that random allocation has a self-destruct clause that the patient may exercise without explanation or fear of prejudiced treatment thereafter.