



BRINGING
MEDICAL DEVICES
AND INNOVATION
TO MARKET

Hart Clinical Consultants, LLC **Novate Clinical Trial Support Case Study**

Goal: "Proctoring insertion of novel device designed to catch and dissipate blood clots originating from the leg."



Hart Clinical Consultants (HCC) was contracted by NOVATE Medical Ltd. to proctor physicians during the Sentry IVC clinical trial. According to the company, the bio-convertible Sentry IVC filter is designed to provide protection from PE during the period that a patient is at risk, and then bioconvert to a non-filtering configuration after a minimum of 60 days. This feature removes the requirement for an additional interventional procedure to retrieve the device. In addition, Sentry has a cylindrical frame that is designed to reduce the reported complications of existing IVC filter technologies, including tilt, migration, fracture, and vessel perforation. The procedure requires insertion of the device into a patient's inferior vena cava, a large vein that carries deoxygenated blood to the heart and is designed to filter for blood clots so they don't migrate to the lungs.

This is currently the only known medical device that actually bioconverts inside the body, meaning it can change once inside to react to its environment.



“Testing new devices and performing investigational procedures on patients can be stressful. In many instances, we must make ourselves available at a moment’s notice to catch a plane and head to a site” states Patti Lawrence, HCC Sr. Clinical Research Associate. “This is what makes HCC proctors unique, our ability to accommodate the sponsor when timing is critical to the success of their clinical trial.”

Patti’s past experience in cath labs and knowledge of surgical etiquette made her the perfect CRA to proctor during this trial. Throughout the case, she guided physicians through procedures and, with little notification, has made herself available to assist the sponsor as needed.

NOVATE had only praise for their experience with Patti. “Patti’s knowledge and clinical experience has served us well. Not only is she confident, but she portrays that confidence and knowledge to those she comes in contact with. You have a gold mine.”

“My experience in working with NOVATE and the Sentry IVC Filter Clinical Trial has been fabulous” Patti responded. “I love this job and all the cutting-edge medical technology I get to be a part of.”

HCC is unique among other CROs. Each member of the HCC team has practical, hands-on, clinical expertise and proficiency in clinical trial operations. This is not the norm. This unique combination allows study sponsors to focus HCC resources where they are needed most at various times throughout the trial – whether that be in device training, case proctoring, site management or study monitoring. This reduces the number of committed staff for completing trial activities and often ensures the same person will be the sponsor’s point of contact throughout each trial.