



Clinical Trial Support Case Study

Velomedix VELOCITY Clinical Trial

“Rapid Induction of Therapeutic Hypothermia in the Setting of STEMI AMI”

Hart Clinical Consultants was contracted by Velomedix, Inc., to train physician investigators and their staff on an innovative procedure, percutaneous peritoneal lavage, for the purpose of rapidly inducing therapeutic hypothermia in subjects experiencing ST-Elevated Myocardial Infarction (STEMI). In addition, the HCC staff trained the physician investigators and hospital support staff on the proper prep, set-up and use of all equipment and supplies used in support of the hypothermia procedure in accordance with established IFUs. Further, the HCC staff remained with the subjects through their therapeutic hypothermia period in the intensive care area.

Keith Jackson, LPN, CCRC was assigned to Huntsville Hospital. Relationships Keith established with investigators and research staff allowed him to immerse himself into established operations resulting in logging more than 200 hours helping to screen for appropriate subjects and proctoring procedures in the cath lab. This effort propelled the site to be the highest enrolling center in the study, which was a driving force in helping to achieve study enrollment goals. Keith attributes his success to core beliefs that the use of exceptional communication and interpersonal skills are paramount when establishing new relationships, and that “coaching” (gentle but persuasive guidance) is critical to helping sites overcome fear and trepidation when embracing a new devices, technology or procedures.

The site’s comments to the sponsor organization and HCC management staff included:

“...Keith should be the trainer for all CRAs proctoring procedures...”

“...Keith is a walking encyclopedia of knowledge and knows the study protocol and device inside and out...”

“...Keith became like family to us and we will never forget him...”

Comments such as these and the results achieved during the trial speak to the level of dedication Keith and the HCC staff showed for the support of this trial.