

MISTIE-ICES Study

Monthly Newsletter

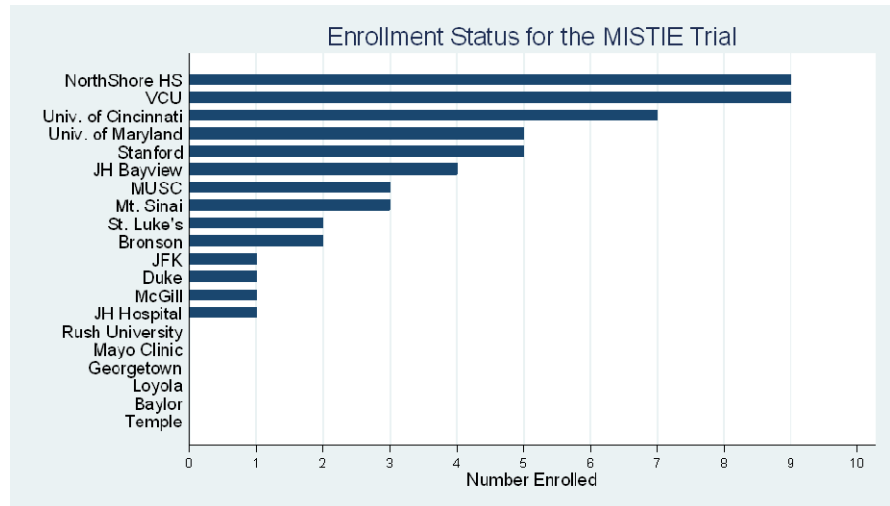


MINIMALLY INVASIVE SURGERY PLUS T-PA FOR INTRACEREBRAL HEMORRHAGE EVACUATION: MISTIE

Inside this issue:

<i>New Sites Welcomed</i>	1
<i>Safety Review</i>	1
<i>HIPAA Language</i>	1
<i>Electronic Trial Master File Launched</i>	2
<i>Recent Enrollments</i>	2

Site Participation, Study Status (last update: 05/30/2009)



MISTIE Trial Welcomes New Sites

The Mayo Clinic in Jacksonville, FL, St. Luke's Baptist Hospital in San Antonio, TX and Sutter Medical Center in Sacramento, CA all received their first shipment of drug, signifying their official start to the MISTIE Trial. Congratulations and welcome to our PI's and Coordinators!

Safety Review

The MISTIE Endpoint Committee reviews all subjects who experience a safety endpoint or medical event of interest. Safety endpoints include new hemorrhage, hemorrhage extension, bacterial and non-bacterial cerebral/intraventricular infection, and death. Medical events of interest include all neurological adverse and serious adverse events, systemic bleeding, angioedema, and any other event that is classified by the site investigator as attributed to the MISTIE/ICES procedure or to rt-PA administration. The Committee reviews all pertinent source documentation, CRF data, the SAE report written by the site PI if applicable, the Surgical Center report, the Medical Monitor report, the ICU Complications Monitor report, and available radiographic images. The Committee independently votes on each event using a set of standard questions to determine if consensus can be reached on whether or not the event occurred and if it was correctly

classified. The Committee then meets by teleconference to discuss each question where consensus was not reached by voting. Once all votes are finalized, the site PI is asked to review the Committee's findings and sign off on the Safety Endpoint form within the VISION/Prelude EDC system. By providing an independent review of the safety events, in addition to the QA and Medical Monitors, this process is an essential step in assuring data quality.

Coming Soon: Version 7.0 Protocol & Consent

We are drafting protocol version 7.0 and will be releasing it soon. The following is recommended HIPAA language for your consent form. It better accommodates the remote monitoring system we use in MISTIE.

"The people working on this study will collect information about you. This includes things learned from the procedures described in this consent form.

They may collect other information including your name, address, date of birth, and other details. The research team will need to see your information. Sometimes other people at [YOUR INSTITUTION] may see or give out your information. These include people who review the research studies, their staff, lawyers, or other [YOUR INSTITUTION] staff.

People outside of [YOUR INSTITUTION] may need to see your information for this study. Examples include government groups (such as the Food and Drug Administration), safety monitors, other hospitals in the study, and companies that sponsor the study.

We cannot guarantee absolute confidentiality because of the need to deliver information and documents to Dr. Daniel F. Hanley, MD of the Johns Hopkins University and his agents, as well as the companies and agencies. Information will be delivered using standard means of communication such as telephone

calls, faxes, email attachments, secure website entries or uploads, document courier services or the U.S. mail.

Release of your records is necessary for you to participate in this investigational study. If you do not wish to participate, you will still receive full routine medical care. No publication will reveal your identity."

New Electronic Trial Master File is launched

In the ongoing quest to simplify and reduce the paperwork in our trials, we are delighted to announce that the study sites and the coordinating center now have available an online Trial Master File for maintaining all regulatory documentation. Emissary International (our monitoring CRO) and Prelude Dynamics (which develops and hosts our online clinical data system) have jointly developed a way to maintain both site and sponsor study documentation in an online, regulatory-compliant system, called the VISION Electronic Trial Master File (VISION-eTMF™).

Document management systems have been available for decades and more recently vendors have begun developing software specifically for clinical trial documentation, but these are generally expensive, usually non-integrated systems with steep learning curves. In contrast, this new version of VISION is one of the first Internet-based clinical trial software platforms that integrates regulatory documentation (RDMS) and clinical trial management information (CTMS) directly within the patient data capture (EDC) system in a truly user-friendly manner.

Perhaps unsurprisingly, the very first commercial system to integrate RDMS, CTMS and EDC was also the motivation of Emissary. That platform, originally called TeamTrials and now sold commercially by one of the large EDC vendors, won Emissary the 2003 Frost & Sullivan E-Clinical Performance Award and recognition as one of the most innovative CROs in the industry. "Whereas, TeamTrials established the enormous potential of a truly-integrated clinical trial software platform, Prelude's VISION system has shown that ease-of-use is perhaps even more important to the ultimate success of a clinical trial," remarked Steven W. Mayo, PD, Emissary's founder and president.

That ease-of-use was obtained by taking advantage of Prelude Dynamic's robust EDC platform. In fact, the regulatory document management system is simply a collection of custom forms within the patient data collection system itself. Dr. Mayo added, "Initial development of TeamTrials required 18 months and a dozen programmers; incredibly, we created specifications and a mock-up and then Prelude Dynamics was able to build it using their VISION platform in only 2 weeks!"

Trial Master File (TMF) is the name given to the huge collection of documents that must be compiled before and during a clinical trial, and then retained for many years

afterwards. In accordance with Good Clinical Practice regulations, every clinical site must maintain all study documentation typically in one or more 3-ring binders called the Investigator Document File (IDF). Along with additional documents such as drug shipment records, the sponsor must ensure that it maintains copies of all versions of all the documents in all IDFs across the multiple sites in a large trial. "VISION not only replaces an entire room of file cabinets and saves thousands in administrative costs both at the coordinating center and at the sites, but it also improves our regulatory compliance and improves our communications across our internationally-dispersed team" added Karen Lane, director of the MISTIE coordinating center.

The eTMF is currently being implemented for MISTIE. All future documentation should be maintained in the online document repository. We request that you use this system rather than faxing or sending documents to us by mail or courier. Older documents will be scanned and uploaded by the coordinating center over the next several months. Study coordinators that have not already done so should complete the online training course and generate a training certificate. Meanwhile, we hope you enjoy using this new tool!

Recent Enrollments

Congratulations to Dr. Paul Camarata, his Research Coordinator, Jennifer McIntire, and the rest of the MISTIE Study research team at the St. Luke's Hospital in Kansas City, MO for enrolling their first and second subjects on March 31, 2009 and May 23, 2009.

Congratulations to Dr. William Broaddus, his Research Coordinator, Randy Merchant, and the rest of the MISTIE Study research team at the Virginia Commonwealth University for enrolling their seventh, eighth, and ninth subjects on April 15, 2009, April 24, 2009, and May 18, 2009.

Congratulations to Dr. Judy Huang, her Research Coordinator, Shannon LeDroux, and the rest of the MISTIE Study research team at the Johns Hopkins Bayview Medical Center for enrolling their third and fourth subjects on April 17, 2009 and May 27, 2009.

Congratulations to Dr. Jeffrey Fletcher, his research coordinator, Karen Bergman, and the rest of the MISTIE Study research team at the Bronson Methodist Hospital for enrolling their second subject on May 11, 2009.