



Clinical Research Update

2014



Virginia-Maryland College of Veterinary Medicine

2014 Highlights:

- New office showcases companion animal research
- Memorial Fund carries on a legacy of love
- Getting to the heart of heart disease
- A day in the life of a regenerative medicine researcher

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2014 - A Banner Year for Companion Animal Research

I'm delighted to report that 2014 has been the busiest year yet for the College's clinical research. From innovative laboratory studies using fish as an alternative animal model for drug testing to trials seeking to improve the fertility of beef cattle, the College's translational research program is on its way to achieving national prominence. Of particular note is the uptick in activity in companion animal clinical research. The opening of the new Veterinary Clinical Research Office in January 2014 catalyzed our long-standing efforts to advance scientific knowledge by offering cutting-edge therapies to our pets.

Companion animal clinical research activity is essential to the College's mission: to protect and enhance animal, human, and environmental health and well-being by: creating, disseminating and applying medical knowledge through discovery, learning, and engagement; preparing professional and post graduate students for careers in veterinary medicine, biomedical sciences, and "One Health;" and providing quality clinical care and compassionate service to animals.

I look forward to watching this initiative continue to flourish.

Sincerely,

Dr. Cyril Clarke

Dean, Virginia-Maryland College of Veterinary Medicine

A One-Stop Shop for Clinical Research

Clinical research tests new devices, therapies or treatments to determine whether they can be used safely and effectively in humans or animals. Since our pets suffer from many of the same conditions and diseases we do, discoveries in animal health can sometimes lead to better treatments for humans.

Although the College already had the research infrastructure to see this complex process through from beginning to end—world-class faculty to develop research questions, expert laboratory researchers to do the initial testing, biostatisticians to help with study design and analysis, and an array of support services to ensure safe and transparent research—it lacked a place to pull it all together.



So in January 2014, Mindy Quigley was hired to do just that. Under Ms. Quigley, who comes to the college from the University of Edinburgh's College of Medicine and Veterinary Medicine, where she helped set up a new neurology research clinic with funding from author J.K. Rowling, the program has grown to host over a dozen trials in disciplines including neurology, cardiology, oncology and many more. We look forward to 2015!

Working with veterinary patients and their owners, the Veterinary Clinical Research Office facilitates clinical trials and translational research studies that advance human and animal health.

“When a specialist tells you that your dog or cat meets the inclusion criteria to enroll in a three-arm, double-blinded, placebo-controlled phase 1 study of an investigational therapy, it may not be apparent that that’s a good thing!”

Don’t Know a Protocol from a Placebo?

Researchers have more than one way to learn about a disease or condition. In some cases, we use an observational study—monitoring the effects of a given treatment, device, or therapy without altering the standard patient care. In other cases, we design a clinical trial to measure the outcome of a new treatment.

The college follows a widely adopted four-phase clinical trial process to evaluate new therapies for safety and effectiveness. Clinical trials range from Phase 1 studies on small test populations to determine safety and dosage, to Phase 2 studies on medium-sized test populations to evaluate effectiveness and monitor test results, to Phase 3 studies on large test

populations — typically across multiple sites — to confirm effectiveness and monitor long-term results. Phase 4 deals with reporting and monitoring after market approval.

The terminology we use when describing clinical research can sometimes be confusing. When a specialist tells you that your dog or cat meets the inclusion criteria to enroll in a three-arm, double-blinded, placebo-controlled phase 1 study of an investigational therapy, it may not be apparent that that’s a good thing!

Never be afraid to ask questions if you don’t understand something. We’re always willing to explain things (multiple times!) and give you written

information to discuss with your local vet. We want to be sure that our clients understand what’s expected of them and their animal. After all, veterinary research is a three-way process involving owners, pets, and veterinarians.

Depending on the study, owners might need to make sure they attend recheck visits, give the right dose of medication at home, and tell us if they notice anything unusual. It’s important that owners are totally on board with all requirements. The vet conducting the study is responsible for communicating clearly, safeguarding animal welfare, and collecting data. Your pet is, of course, responsible for being its adorable self!

Willow the Wonder Whippet

Cathy Nunn of Wake Forest, North Carolina knows a lot about heart disease. After all, she’s a cardiac nurse who coordinates a large, multi-site trial looking at atherosclerosis, a.k.a. "hardening of the arteries." So when her beloved whippet, Willow, was diagnosed with a heart condition called mitral valve disease, Cathy looked for a way to get her involved in research. Willow and Cathy traveled to Virginia Tech, where they enrolled in a heart disease research study run by Dr. Michele Borgarelli. The study seeks to determine whether the standard method of measuring potentially-dangerous high blood pressure in the lung vessels is accurate in dogs like Willow. According to Cathy, their experience was top-notch. “I knew the reputation of the College of Veterinary Medicine and was confident that Willow would receive excellent care there, and indeed she has!”

Cathy encourages other owners to get involved in clinical research. “Allowing your pet to participate in clinical research is a win-win opportunity. You not only gain access to the best in veterinary care, but you also contribute to the health and well-being of other animals both now and in the future. Please consider it; it is well worth your time and effort.”



Willow (seated) with her owner, Cathy Nunn, and her canine siblings, Flye and Jackson



Partnership to Foster Faster-Paced Research

When Matthew Moore and Frank Saltarelli of Washington, D.C., discovered that their seven-year-old miniature schnauzer, Leyna, was having seizures, they knew they wanted the best possible care for her. Their local veterinarian performed a variety of tests, including an MRI, only to learn that Leyna had an aggressive brain tumor.

After a consultation with Bush Veterinary Neurological Services, one of the region's top specialty neurology practices, Leyna's owners learned about a clinical trial at VA-MD Vet Med for dogs with gliomas, dangerous tumors with a very low chance of survival. They decided to enroll Leyna in the study and now, three years later, she is thriving.

"Leyna is doing incredibly well," said Moore, whose other dog, Maxwell, also had successful cataract surgery at the college. "You would never know she had cancer or had gone through the treatment."

The college is now hoping to expand enrollment in clinical trials like the one that helped Leyna and smooth the way for specialty practices like Bush Veterinary Neurological Services to participate in the latest research studies. This summer, the college formed a Collaborative Research Network to enable specialty practices in Virginia and Maryland to participate in the pioneering research at the veterinary college.

"Because the number of cases seen in the greater Washington, D.C., Richmond, and Baltimore areas far exceeds the number seen in Blacksburg, this specialist referral network is already increasing our ability to complete clinical trials quickly," said Mindy Quigley, clinical trials coordinator at the veterinary college. "And by increasing the number of cases within our studies, the results and findings will have greater scientific merit."

The Collaborative Research Network brings together specialty practices with advanced services such as 24-hour emergency care, on-site diagnostics, on-site cross-sectional imaging, and board-certified specialists in the college's major research areas. Six veterinary practices have already joined the network, including Dogwood Veterinary Specialty and Referral Center in Richmond, Virginia; VCA Southpaws in Fairfax, Virginia; VCA Veterinary Referral Associates in Gaithersburg, Maryland; The LifeCentre in Leesburg, Virginia; The Hope Center in Vienna, Virginia and Rockville, Maryland; and the Chesapeake Veterinary Referral Center in Annapolis, Maryland.

Dr. Bill Tyrrell, medical director at The LifeCentre, explained that participation in the Collaborative Research Network offered a "tremendous benefit" for specialty practices.

"We do independent research at The LifeCenter and have FDA trials here, but we don't have some of the resources available at the veterinary college, such as access to statisticians or National Institutes of Health funding," said Tyrrell, a 1992 alumnus of the college. "If we can help out in the Collaborative Research Network by referring clients to clinical trials, it's a win-win for both parties."

Dr. Greg Daniel, head of the Department of Small Animal Clinical Sciences, echoed that sentiment. "We see this as a real two-way exchange," he said. "In the future, we want to utilize the experience and expertise of the specialists in our Collaborative Research Network to refine and improve our research protocols or explore new research directions."

Andrew Furtado, administrator at the Chesapeake Veterinary Referral Center, commented that the center joined the Collaborative Research Network "because we are excited by the opportunity to offer our patients access to cutting-edge research."

He added, "We hope that the studies we participate in will generate new and innovative treatment options to help animals live longer and more productive lives. In addition, our specialists view research and education as critical components of their practices and are excited to add their expertise to the network."

Although Dr. John Rossmesl, the neurologist at the veterinary college who treated Leyna, has since completed his study on the use of electrical currents to deliver cancer-fighting medication past the blood-brain barrier, he is now testing a new chemotherapy drug and drug delivery method on the same type of tumors. He is one of several researchers at the college who will benefit from increased enrollment in clinical trials through the Collaborative Research Network.



Veterinary Referral Associates



Memorial Fund Boosts Research

The Veterinary Memorial Fund exists to help pet owners and families cope with the grief associated with the passing of their loved ones and to raise funds to support scientific investigations which improve the quality of health care available for future generations.

The Veterinary Memorial Fund receives contributions from veterinarians and owners in memory/honor of a pet, as well as from families and friends in memory/honor of a person.

Each year, funds are awarded on a competitive basis to research projects of high clinical relevance.



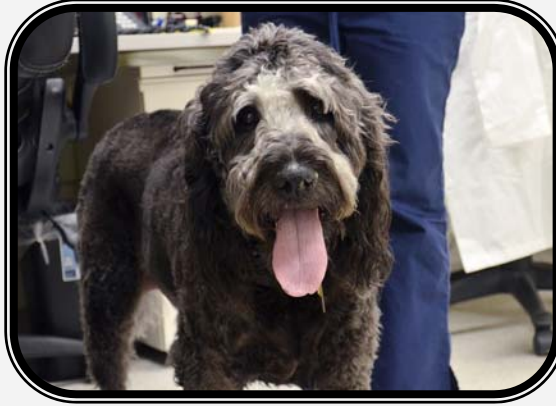
Year funded	Lead Investigator	Study Title	Purpose	Proposal Amount
FY13-14	Cissell, James	Treatment of infiltrative skin malignancies in horses using H-Fire: Phase I-II clinical trial	To assess the effectiveness of a new therapy that delivers high voltage, high frequency electrical pulses in the treatment of invasive skin cancer (SCC and EMM) in horses	\$18,900
	Herring, Ian	Effect of perioperative administration of fixed combination Dorzolamide Hydrochloride 2% Timolol Maleate 0.5% on incidence and severity of post-operative ocular hypertension in dogs undergoing cataract surgery	To investigate whether pre-treatment with topical anti-glaucoma medications will reduce the frequency or severity of elevated eye pressures following cataract surgery in dogs	8,005
	Pancotto, Theresa	Determination of atlanto-axial separation during cervical ventroflexion of immature dogs	To determine if spinal laxity in young dogs can help us understand more about how to treat dogs with spinal problems	5,600
	Zajac, Anne	The value of PCR in the diagnosis of canine Giardiasis	To compare how the accuracy of a common laboratory technique called PCR screening compares to the currently-recommended 3-part screening procedure for the parasitic disease, Giardia, and to evaluate which genetic variants of Giardia are present in dogs in Southwest VA	15,126
FY14-15	Dahlgren, Linda	Serum amyloid A as an aid in the diagnosis of septic arthritis in horses	To evaluate the reliability of a new handheld test to diagnose joint infections in horses	20,000
	Dervisis, Nikolaos	Diffusion weighted MR imaging in the differentiation between metastatic and benign regional lymph nodes in canine oral melanoma	To assess the ability of magnetic resonance imaging (MRI) to differentiate between benign and cancerous lymph nodes	12,800
	Klahn, Shawna	Phase-I clinical trail of oxaliplatin in canine cancer patients	To determine a safe and effective dose of the chemotherapy drug oxaliplatin in the treatment of solid tumors in dogs	18,688
	Lanz, Otto	Cytokine and Growth Factor Profiles in Healthy Canine Autologous Conditioned Serum	To study methods of using a dog's own blood products to determine inflammatory and immune responses	18,920
	Pancieria, David	Normalization of Hypothalamic-Pituitary-Thyroid Axis after Discontinuation of Levothyroxine in Euthyroid Dogs	To improve the accuracy of thyroid tests by establishing an optimal time to test thyroid levels in dogs who have been withdrawn from thyroid hormone supplementation	20,000
	Witonsky, Sharon	Can levamisole up-regulate the macrophage (M1) dendritic cell (DC1) CD4 T-helper 1 (Th1) CD8 equine cell-mediated immune response in vitro?	To assess whether the anti-parasitic drug levamisole can enhance the immune response of equine white blood cells and potentially be used as a supplemental treatment for horses with infectious diseases like EPM, Lyme and Rhodococcus equi.	12,425

Nanoparticles Give Ladradoodle a New “Leash” on Life

When Michael and Sandra Friedlander first came to the Virginia-Maryland College of Veterinary Medicine three years ago with their dog, Grayton, they learned some bad news: Grayton had nasal adenocarcinoma, a form of cancer with a short life expectancy.

“Most dogs with this form of cancer are with their owners no more than a few months after the diagnosis, but here Grayton is three years later,” said Michael Friedlander, who is the executive director of the Virginia Tech Carilion Research Institute and senior dean at the Virginia Tech Carilion School of Medicine.

Friedlander was referred by Veterinary Teaching Hospital clinicians to an experimental treatment at the University of Florida called stereotactic radiation therapy, which delivers precise, high dosages of radiation to a tumor and can only be performed once. “That shrunk the tumor down to almost nothing,” said Friedlander, who is also the associate provost for health sciences at Virginia Tech. “We knew when Grayton had the procedure that we couldn’t do it again, but now the cancer is back.”



Today, the 11-year-old Ladradoodle is the first patient at our hospital to enroll in a new clinical trial that is testing the use of gold nanoparticles and a targeted laser treatment for solid tumors in dogs and cats. Although medical researchers have tested gold nanoparticles with targeted laser treatments on human patients with some success, the treatment is still new to both human and veterinary medicine. The college is one of four veterinary schools around the country testing the AuroLase therapy developed by Nanospectra Biosciences Inc., a startup company based in Houston, Texas.

Dr. Nick Dervisis, assistant professor of oncology in the Department of Small Animal Clinical Sciences, is leading the Nanospectra-funded study. Following a rhinoscopy performed on Grayton by Dr. David Grant, associate professor of internal medicine, Dervisis began the one-time, experimental therapy.

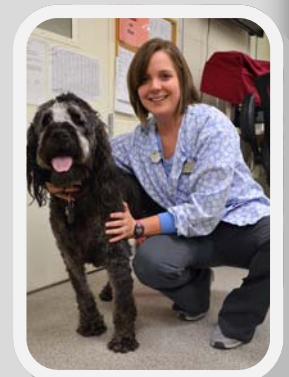
“The treatment involves two phases,” Dervisis said. “First, we infuse the patient with the gold nanoparticles. Although the nanoparticles distribute throughout the body, they tend to concentrate around blood vessels associated with tumors. Within 36 hours, they have cleared the bloodstream except for tumors. The gold nanoparticles are small enough to circulate freely in the bloodstream and become temporarily captured within the incomplete blood vessel walls common in solid tumors. Then, we use a non-ablative laser on the patient.”

Dervisis explained that a non-ablative laser is not strong enough to harm the skin or normal tissue, but “it does cause the remaining nanoparticles to absorb the laser energy and convert it into heat so that they damage the tumor cells.”

Like all clinical trials, the study involves many unknowns, including the treatment’s usefulness and effectiveness. One month after the AuroLase treatment, the nosebleeds that initially brought Grayton back to the Veterinary Teaching Hospital had stopped and Grayton has no other side effects.

“I’m delighted with the care and service that Grayton has received at the veterinary college,” said Friedlander, who explained that the treatment appears to be safe even though researchers do not know whether it is effective yet. “Grayton recently came with us on our annual vacation at the beach. We didn’t know if he would be able to come again, so it was great to have him with us swimming, catching fish and crabs, and doing what dogs do.”

“We didn’t know if Grayton would be able to come on our annual beach trip again, so it was great to have him with us swimming, catching fish and crabs, and doing what dogs do.”



Grayton poses with oncology technician Lauren Scaletta

A Breath of Fresh Air for Veterinary Anesthesiology

Three years ago, anesthesiologist Noah Pavlisko and his colleagues were awarded \$18,000 from the Veterinary Memorial Fund as part of a project to better monitor oxygen delivery to critically-ill veterinary patients. Now they're ready to put what they've learned into practice in the clinic.

Oxygen is a key component in the reactions that fuel cells and is essential to survival. In mammals, the circulatory system can deliver oxygen to tissues, like fingers and toes, that are far away from the airways. Under normal conditions these tissues get plenty of oxygen. However, during severe illness or injury, oxygen delivery may not be able to keep up with the demands of the cells. When cells become

deprived of oxygen, patients are at risk for developing organ failure and death. Because the delivery of oxygen is critical to survival, monitoring oxygen delivery in critically-ill patients has rapidly become the standard of care in most human intensive care units. As Pavlisko explained, "Although we've understood the importance of oxygen monitoring for many years, traditional methods for evaluating oxygen delivery in veterinary patients have been considered too invasive and too expensive to be adopted widely."

Human clinical trials have demonstrated that near-infrared spectroscopy (NIRS), a new, non-invasive technology that provides real time assessment of oxygen delivery, can identify patients in early stages of distress and provide a way for doctors to evaluate

them. Because this technology is non-invasive and relatively cost effective, it may be possible to apply it in veterinary practice.

Initial work by Pavlisko and his collaborators at the College used NIRS to focus on understanding oxygen tissue saturation in dogs under general anesthesia. Results from those studies have been promising, and the group is now moving ahead with applying the technology in the clinic to try to improve patient outcomes.

The group's VMF-funded preliminary research was published earlier this year in the highly-respected *American Journal of Veterinary Research* ([doi: 10.2460/ajvr.75.1.48](https://doi.org/10.2460/ajvr.75.1.48)), and has been presented at national and international meetings in San Diego, CA, San Antonio, TX, and Davos, Switzerland.



InSpectra StO₂
Tissue Oxygenation
Monitor

Doctors at VA-MD Vet Med are exploring new ways to monitor the well-being of critically-ill veterinary patients

Our Heart Docs Explain the Research That Makes Your Pet's Ticker Tick...

In pets, as in people, a healthy heart is essential to overall well-being. So when your dog or cat shows symptoms like coughing, fainting, or fatigue, sometimes a malfunctioning ticker is at the "heart" of the problem.

Heart disease can be divided into two types, congenital (present at birth) or acquired (developed with age). Congenital heart diseases are often caused by malformations, or "heart defects," and some can effectively be cured if the diagnosis is accurate and timely. Using the latest minimally invasive techniques, we can often correct congenital heart diseases like pulmonic stenosis and patent ductus arteriosus.

The most common acquired heart disease in dogs is chronic degenerative mitral valve disease, while in cats it's hypertrophic cardiomyopathy. Luckily, these diseases aren't necessarily fatal, and affected pets can remain symptom free for a long time.



Both congenital and acquired diseases can have a genetic basis, and research is now directed toward identifying the genes that play a role. Another important area of research focuses on improving treatments and identifying patients that have a higher risk of dying of their disease. To improve treatments, multicenter clinical trials are used to evaluate the effectiveness of different treatment strategies. We're currently involved in two such studies: C-635 and EPIC. We are still enrolling cases for the C-635 drug study, but the enrollment period for the EPIC study is closed. Dogs with heart failure due to mitral valve disease are potential candidates for the C-635 study, and owners can contact the Clinical Research Office to learn more.

Cardiac ultrasound (echocardiography) is a non-invasive test used in the diagnosis of heart disease. At VA-MD Vet Med, we use a cutting-edge version of echocardiography that can show the heart in three dimensions. This technology can potentially help to identify dogs with mitral valve disease that have a higher risk of progression, and tell us which dogs might develop the disease in the future.

We're also investigating whether echocardiography can tell us which dogs have a higher risk of developing cardiac disability or death. One of our studies will determine if echocardiography can identify potentially dangerous high blood pressure in the lung vessels of dogs with valve disease. Our initial findings suggest that this type of high blood pressure may be associated with a shorter survival time, even in dogs that aren't yet showing symptoms, so we need to find out if echocardiographic studies can detect such patients at an early stage.

We hope our work contributes to a better understanding of heart disease and helps us keep your pet's heart ticking!

-Dr. Abbott, Dr. Borgarelli and Dr. Lahmers



Get involved

We conduct clinical trials in dogs, cats, and horses in oncology, neurology, cardiology, and many other areas. Usually, we're looking for animals with a particular diagnosis, but sometimes we need healthy volunteers, too! To find full details of our studies, including eligibility criteria, please check our website. We are currently seeking participants for these studies:

Dogs

Accuracy of Non-Invasively Determined Pulmonary Artery Pressure in Dogs with Myxomatous Mitral Valve Disease

Purpose: To assess the accuracy of using heart sonograms to determine blood pressure in the pulmonary vessels of dogs with heart valve disease.

Diffusion weighted MR imaging in the differentiation between metastatic and benign regional lymph nodes in canine oral melanoma

Purpose: To assess the ability of MRI to differentiate between benign and cancerous lymph nodes.

Evaluation of C635, in Comparison to Benazepril, in Dogs with Heart Failure Caused by left Atrio-Ventricular Valvular Insufficiency (AVVI)

Purpose: To evaluate the effectiveness and safety of a new combination drug therapy plus furosemide (a diuretic) in dogs with heart failure, in comparison to a standard drug therapy plus furosemide.

Histiocytic Sarcoma Research Study

Purpose: To determine the genetic basis of the disseminated form of Histiocytic Sarcoma and identify potential therapeutic targets.

Molecular Combinatorial Therapy for Canine Malignant Gliomas

Purpose: To determine the safety and effectiveness of a new chemotherapy drug and drug delivery method in the treatment of brain tumors (gliomas) in dogs.

Pilot Study of AuroLase® Therapy for the Treatment of Canine and Feline Solid Tumors

Purpose: To determine the safety and efficacy of AuroLase® (nanoparticle infusion plus targeted laser treatment) therapy in the treatment of canine cancers.

Phase-1 Clinical Trial of Oxaliplatin in Canine Cancer Patients

Purpose: To determine a safe and effective dose of the chemotherapy drug oxaliplatin in the treatment of solid tumors in dogs.

Blinded, controlled clinical trial comparing regenerative medicine therapies to treat tendon injury in dogs

Purpose: To evaluate the effectiveness of stem cell and platelet therapy for the treatment of naturally occurring tendon injury in dogs and to compare efficacy of two different types of regenerative therapies

Longitudinal Study of Progression and Pathogenesis of Atypical Hyperadrenocorticism in Scottish Terriers

Purpose: To better understand the genetic basis of hyperadrenocorticism

Cats

Pilot Study of AuroLase® Therapy for the Treatment of Canine and Feline Solid Tumors

Purpose: To determine the safety and efficacy of AuroLase® (nanoparticle infusion plus targeted laser treatment) therapy in the treatment of feline cancers.

Horses

Treatment of infiltrative skin malignancies in horses using High-Frequency Irreversible Electroporation [HFIRE]: Phase I-II clinical trial

Purpose: To assess the effectiveness of a novel therapy that delivers high voltage, high frequency electrical pulses in the treatment of invasive skin cancer (SCC and EMM) in horses.

Comparison of seroprevalence of anti-Borrelia burgdorferi (Lyme disease) antibodies in horses with unexplained multiple limb lameness or stiffness and sound horses

Purpose: To determine if a relationship exists between Lyme disease infection and multiple limb lameness in horses.



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Donate

Animals need help from people like you, who want every pet to live a long, healthy life. Finding ways we can work together to make that happen is our “pet project!”

If you’re interested in making a gift to support clinical research, please get in touch with Mindy Quigley in the Veterinary Clinical Trials Office or visit:

www.vetmed.vt.edu/clinical-trials/donate.asp

Together, we can improve companion animal health, for today and tomorrow.

Find us on the web:

www.vetmed.vt.edu/clinical-trials/

Staff Spotlight: Research Specialist Shay Seager

Prior to joining the biomedical research laboratory staff at Leesburg’s Equine Medical Center in June 2014, Shay Seager worked for several start-up non-profits. She holds an MS from Georgetown and an undergrad degree from University of California Berkeley, where she also rowed for Cal’s top-ranked NCAA Div 1 team. Shay has six years of cellular and molecular biology research experience.

Between large animal research, small animal research, working with the FDA to develop standards for stem cell therapies, and regular clinical practice, your lab has been busy this year! If you had to choose the one thing that you’re most excited about, what would it be?

It’s all really exciting! Our tendon injury clinical trial is particularly special because we’ve seen incredible results from our stem cell therapy in both horses and dogs. This trial allows us to demonstrate the efficacy of stem cell therapies and produce the data needed for clients to make educated decisions about their pet’s health.

Your team has a number of patents pending. Can you tell us more about the technologies involved?

To protect patient safety and ensure product efficacy it’s really important to go through regulatory approval and patent our technologies. We have patents pending on two devices which create scaffolds—the framework we use to grow stem cells into a new organ or tissue type such as a tendon or ligament. Additionally, we’ve innovated regenerative cell treatments, such as new formulations of Platelet Rich Plasma (PRP) from blood to enhance its healing capabilities and speed recovery time.

You’ve just begun a clinical trial of regenerative medicine therapies for dogs with tendon injuries. How can owners get involved?

We’re excited that this study is occurring at VOSM in Annapolis Junction, MD. It’s close to an airport, which facilitates clients coming from a long distance. To enroll you’ll first need to schedule a consultation for your dog, so that the dog’s injury can be evaluated against the study criteria to determine eligibility. To schedule a consultation please contact Jayme Pfisterer, Surgical Coordinator. Phone: (240) 295-4400 Ext. 210, or visit: www.vetsportsmedicine.com/akcchf-study.



Shay Seager spends some time with horse pal Fast Country at the Marion duPont Scott Equine Medical Center in Leesburg, VA