10-1-2009

Truly One Medicine: Clinical Trials at Penn Vet

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Clinical Trials at Penn Vet
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about the cover:
Dr. Dottie Brown examines Rocky, a participant in a clinical study.
Right off the historic courtyard of the University of Pennsylvania School of Veterinary Medicine sits a large, sparsely decorated office, broken into a maze of cubicles.

The nondescript nature of this space belies the fact that for the past six years it has served as the nerve center for an array of small-animal clinical trials, stretching from this campus to the bench research facilities of biomedical partners near and far.

Outside, a simple placard announces it as the Veterinary Clinical Investigation Center (VCIC). Inside, a blackboard mounted high on the back wall carries an inventory of some two dozen current trials. A cursory review of partner institutions past and present – the National Institutes of Health, Johns Hopkins University, Penn State Hershey, as well as nearby Penn Medicine and Children’s Hospital of Philadelphia – indicates two things: the caliber and aspirations of these activities are high, and most of the intended benefits serve both animal and human patients.

Of the 28 veterinary schools in the United States, Penn Vet is the first to create a research facility dedicated to the immense promise of translational research.

The Power of One

The words behind the Penn Vet mission – “Many Species, One Medicine” – represent an understanding that veterinary practice comprises diverse enterprises with a common purpose.

Much more recently, biomedical leaders have latched on to the expression “one medicine” to describe the correlation between many human and animal diseases, especially those found in domesticated animals, primarily cats and dogs. A short list of related conditions includes numerous cancers, infectious diseases, allergies, autoimmune deficiencies, osteoarthritis and chronic pain.

Joan Hendricks, V’79, GR’80, the Center’s founding director and current Dean, was in many ways a perfect fit for such an innovative concept. A passionate researcher who specializes in the molecular basis of sleep regulation and function, she holds a secondary appointment from Penn’s School of Medicine and served as section chief for critical care at the Matthew J. Ryan Veterinary Hospital.

“The best investment we can make as a School and a community is to build our clinical research capabilities,” says Dean Hendricks. “It helps us recruit and retain the best faculty,
When Dr. John Lewis, ’97 went to the 2005 groundbreaking ceremony for the Vernon and Shirley Hill Pavilion, he never expected that just being there would help him break new ground in treating patients with feline oral squamous cell carcinoma.

“It turned out a Penn Vet classmate is married to Dr. Tom O’Brien, a Lankenau researcher working on an experimental squamous cell drug,” says the assistant professor of dentistry and oral surgery. “One thing led to another and we began working together.”

With the support of the VCIC, the two men embarked on a fruitful collaboration. Like many biomedical researchers, O’Brien was looking for an intermediary step between mouse models and human clinical trials to provide important insights into his drug’s potential adverse effects. Lewis sought better options for the usually advanced and often inoperable head and neck tumors he saw in his feline patients.

As with many joint projects, a creative combination of funding underwrites their collaboration, from governmental – the National Institutes of Health – to very personal – a Penn Vet donor, Kathleen Jack, whose cat Bud passed away from a squamous cell tumor.

Across medicine, finding more efficient ways to identify promising drugs is a key goal. Of all the drugs developed, only one in five make it from Phase I human clinical trials to the market. Using small-animal studies to identify downsides early on has major advantages: biomedical partners are able to use human resources more sparingly and funders and pharmaceutical companies can target financial resources to those studies that continue to produce results.

Of course, not all human drug development can leverage the advantages of veterinary trials. Those that can Lewis likes to call “sparedels” – a new term he credits to his Penn Vet colleague Dr. Lillian Duda, ’90, an adjunct associate professor of radiation oncology.

“It stands for ‘spontaneous parallel reciprocal models’ with human disease,” explains Lewis. “I think this may soon be accepted shorthand as more and more researchers on the biomedical/human side of things realize translational medicine is the future of bench-to-bedside research. ‘Sparedels’ will always provide you with more information and more advances than experimental, induced cancers.”

In addition to the parallel advances he is achieving with O’Brien, Lewis counts himself fortunate to advance understanding about how his feline patients tolerate medications.

“The VCIC is allowing us, as clinician educators, to perform scholarly activity,” says Lewis. “You’re usually pulled in four different directions at a time – educating fourth-year students, rotating through service, educating clients, teaching residents. Research is like a quiet child – one who deserves more attention but doesn’t always get it. The VCIC has helped change this reality for good – and for the common good.”

A DELICATE BALANCE
Without an integrated center such as VCIC to oversee and support these clinical trials, many of the activities underway would not take place.

“I first realized how difficult it is to find time for research when I began measuring and managing chronic pain in dogs,” says Dr. Dorothy Cimino Brown, the Center’s current director. “The research end of things always tends to suffer. That needed to change.”

Brown shared her perspective with Dean Hendricks, then Interim Chair of Clinical Studies, unaware that the latter was already in talks with Pfizer about building a
relationship with Penn Vet. The pharmaceutical giant embraced the novel concept and the nascent Center set up shop managing a small nucleus of Pfizer animal health studies.

These first trials provided useful primers in navigating regulations and managing the logistical side of studies. “For a canine osteosarcoma study – where our clinic normally encounters just one or two cases a month – we had to find 100 subjects. How do you do that?” Brown found herself asking. “We had to learn, practically overnight, how to creatively recruit participants.”

Connections to community vets, especially alumni, were tapped. Spots were aired on KYW News Radio. Over the course of the year, one by one, the 100 dogs came through the door.

Next followed the need for stronger human resources. The first hire was a nurse/clinical trial coordinator – there are four today – to gather robust data, keep protocols and support reporting. Brown herself went back to school, earning a Masters in Clinical Epidemiology from Penn to ensure greater in-house expertise about clinical trial design, implementation and analysis.

The Center readily tapped into Penn Vet’s own technological resources, from the latest in magnetic resonance imaging to digital and intra-oral radiology, and found an essential on-campus partner in the Investigational Drug Service at the Hospital of the University of Pennsylvania. A “research-only” pharmacy, it has the capacity to compound and dispense investigational drugs.

**CONTINUUM OF SUPPORT**

The Center staff, comprised entirely of veterinarians, nurses and vet technicians, quickly became expert at working with clients who enroll their companion animals for VCIC studies. At the heart of these relationships is a rigorous informed-consent process for each meticulously designed and peer-reviewed study.

“It’s so important to express the scope, risk and potential benefits accurately so owners and animals both feel protected,” says Brown. “You especially cannot mislead owners of terminal patients. They have to feel motivated to participate.”

One of VCIC’s current clients, George Heath, has embraced the opportunity to enroll Rocky, his beloved 11-year-old Rottweiler, in the osteosarcoma study.

“I found out about the study from my local veterinarian,” says Heath, who lives in Chester County, Pennsylvania — an hour-long drive from Ryan Veterinary Hospital in good traffic but a relatively short trip when measured against his companion’s welfare and happiness.

When Rocky arrived at Penn in March, a limp detected the previous September and first treated with a common anti-inflammatory drug, had turned into a debilitated gait that indicated a great deal of pain. With radiation and chemotherapy the only other options, the VCIC study, which focuses on pain management, was a welcome alternative.

“To me, being part of this study means a lot because Rocky is family. I’ve had him since he was a puppy,” Heath explains. “This study offers better options and Rocky’s doing better. He’s happy and he’s comfortable. If it helps other dogs and even humans, so much the better.”

Each month, Heath and Rocky make the trip to the Penn Vet campus for a physical and a data “dump” from the microchip tag on Rocky’s collar, which constantly tracks his vital signs and behavior.

Beyond these check-ups and information gathering, Heath appreciates VCIC’s human touch. In this case, Molly Love, CW’74, NU’81, GNU’84, is the nurse/clinical trial coordinator who oversees Rocky’s case. “Molly’s always there by telephone or e-mail if I need her,” he says. “She sends reports to my vet right away. I couldn’t ask for more.
“In fact, I was just telling Molly my vet diagnosed another Rottweiler with osteosarcoma. If that patient needs a reference, I said, call me. I’ll let them know what a great program this is.”

Like Heath, many participants see VCIC as a welcome lifeline, offering up-to-date information, access to novel drugs and techniques, more affordable costs, and, above all, the knowledge that they are helping future generations of companion animals — and now people.

On September 23, 2009, the National Institutes of Health treated the first human patient in its Phase 1 study of the pain management treatment given to Rocky. The study, designed for people with end-stage cancer, is highly restricted in its participation criteria. Early results indicate that the patient was free of debilitating daily pain. Truly, one — translational — medicine.

Burgeoning Potential

From alternative medications to nanotechnology, VCIC never stops seeking new ways to expand what can be accomplished through translational research.

Today, the Center is made possible through gifts, grants and clinical trials. Funding for new trials and advancing the Center’s mission are being sought.

“The first two quarters of 2009 saw more studies initiated than in all of 2008,” says Brown. “As investigators work with us, they realize how much better it is to take advantage of our infrastructure. Owners are happier to know they are advancing science for the future. For us, it’s better all around.”

The Center’s team is happy, too, knowing that, among those cubicles, they are indeed making history.

Do you have a dog with...

...well-regulated Diabetes Mellitus
...bone cancer in need of pain management
...diagnosed with splenic hemangiosarcoma
...mast cell tumors not amenable to surgery
...Or a Doberman Pincher who needs a free cardiac evaluation

Penn’s Veterinary Clinical Investigation Center (VCIC) is looking for you and your dog. Please call us to find out more about clinical trials. Your dog may be qualified to participate in a study at the University of Pennsylvania, Matthew J. Ryan Veterinary Hospital. For more information call 215-573-0302 or email VCIC@vet.upenn.edu. Please check our website for information about other ongoing studies in the VCIC at www.PennVCIC.org.