Bringing Pet Health Innovation to Market

10 Lessons from a First-in-Class Approval



BY TAMMIE WAHAUS
Co-Founder & CEO, ELIAS Animal Health

PET INDUSTRY RISING 2026

AI and new diagnostics are helping find cancer in pets earlier. Early detection matters most when there is an effective, approved treatment to act on. That's why ELIAS Animal Health was founded in 2014: to change the way cancer is treated in dogs. In 2025, ELIAS Cancer Immunotherapy (ECI®) earned USDA approval as a first-in-class therapy, and it is currently the only USDA-approved treatment for canine osteosarcoma. Along the way, we've treated more than 300 dogs, navigated changing regulations, built manufacturing, distribution and customer service for a personalized therapy, and earned the trust of veterinary oncologists. Here are 10 lessons I've learned leading ELIAS, from our first study to approval.

1 Let patient outcomes fuel your conviction

Dakota and Roscoe were enrolled in the ECI® pilot study in canine osteosarcoma. They both have incredible stories, but seeing how much it meant to their families to get more than two years after diagnosis with their furry companions was the spark that told us we had to fight for this therapy. What ECI® gave Roscoe and Dakota, along with others in that pilot study, affirmed to us what it could mean for every family facing this diagnosis.

TAKEAWAY *Real outcomes for real patients sustain a team through a long development path.*

2 Identify your regulatory pathway early

It's a common misconception that companies can choose their regulatory path. In reality, federal regulations and established precedents define the types of products the FDA CVM (primarily drugs) and USDA CVB (primarily biologics) oversees, and you must consider the nature of your product, mechanism of action, and manufacturing methods to determine which category your product best fits. Then you need to confirm it with that regulatory agency before you commit to that path.

TAKEAWAY *Determine early which regulatory agency has jurisdiction, and confirm they agree.*

3 Expect the rules to change

Regulations naturally evolve as new technologies emerge. Regulators can't write rules for what doesn't exist yet, so as innovations develop, they monitor it closely, and then decide if that technology needs regulation. AI is a current example: few rules govern it today but the regulators are paying attention. Additionally, complying with regulation builds a moat. Companies that won't invest the time and money to comply don't get to compete.

TAKEAWAY *Treat regulatory change as a constant, and compliance as a competitive advantage.*

4 Evidence is the currency of credibility

Veterinarians make evidence-based clinical decisions, so companies must provide sufficient evidence of a product's risks and benefits. Credibility also comes from being transparent about what worked and what didn't. Early on, several oncologists told us they appreciated that we were doing this "the right way" by being open about how we were developing our therapy and the results we were observing.

TAKEAWAY *Rigorous, transparent data earns trust that marketing can't.*

5 Manufacturing is strategy

Scalability and quality must be built in up front. That may take more time and money, but changing a manufacturing process later costs even more. Depending on the nature of those changes, it could be necessary to repeat studies to prove that a new process produces the same product.

TAKEAWAY *Diligence the manufacturing plan as closely as the science.*

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6 Know where the finish line is

Our key milestones were establishing the product's safety and efficacy, while building relationships with veterinary oncologists. Those trusted relationships were critical to reaching each milestone, and to the real finish line: commercialization.

TAKEAWAY *Approval is a milestone. Build the relationships you'll need to reach the market.*

7 Approval is not adoption

The day we received approval from the USDA was cause for celebration, but it wasn't the final podium. The relationships we nurtured during our clinical trials established a base of experts in the field, and many of them have become vocal advocates during commercialization.

TAKEAWAY *Adoption starts long before approval. The stakeholders in your development process can become your strongest advocates.*

8 Plan with conviction, adjust with awareness

Projections are what you plan to achieve. They tell you what actions to take, on what timeline and at what cost. But you must watch your surroundings and adjust when the environment changes, whether that is regulation, the economy or the competitive landscape. As an example, we finished our first study and then the requirements for product approval changed. So, we leaned in and adjusted our strategy and budget quickly.

TAKEAWAY *A plan tells you what to do; watching your surroundings tells you when to pivot.*

9 Learn from human health

ELIAS began in 2014 as a spin-off of TVAX Biomedical, which was developing an immunotherapy for glioblastoma, an aggressive human brain cancer. We brought that technology to dogs, along with human medicine's evidence-based approach and its lessons in clinical trial design, manufacturing, distribution and commercialization. The value of this collaboration runs both ways. Human and canine cancers share similarities, and safety and efficacy data from our canine osteosarcoma study was an important part of the application that earned TVAX FDA Fast Track Designation in 2020. Collaboration can advance medicine in both species faster.

TAKEAWAY *A plan tells you what to do; watching your surroundings tells you when to pivot.*

10 Partners complete the care pathway

The best partnerships share an underlying culture. For us, that means being patient-centric and data-driven. We're excited about the current innovation in pet wellness and disease detection, and the potential it brings in creating more efficient care journeys for our pets. With ECI®, the decision must be made before surgery occurs, and for dogs diagnosed with osteosarcoma at a later stage, that decision sometimes must be made in the moment. Pet owners have more options when cancer is found earlier in the course of the disease and veterinary consultations about available treatments are had upfront.

TAKEAWAY *Detection and treatment create the most value together.*

"Make a plan you believe in but be ready to adapt, because regulations, markets and science will keep moving. The companies that endure see change as an opportunity, and build on evidence and relationships that hold up when the rules shift."

TAMMIE WAHAUS, CO-FOUNDER & CEO, ELIAS ANIMAL HEALTH

BUILDING IN PET HEALTH? Here's how ELIAS works with partners and veterinarians. ⟶

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ELIAS ANIMAL HEALTH

From Early Detection to Treatment



ABOUT ELIAS ANIMAL HEALTH

ELIAS Animal Health is a medical biotechnology company advancing its novel therapies for the treatment of cancer in pets. Its first product, ELIAS Cancer Immunotherapy (ECI®), is a first-in-class, personalized immunotherapy for canine osteosarcoma, and currently the only USDA-approved treatment for the disease.

ECI® AT A GLANCE

2025
USDA approval

300+
Dogs treated

100+
Authorized treatment centers in the U.S.

ECI-trained
Veterinarians administer every treatment

HOW ECI® WORKS

ECI® uses each dog's own immune system to fight its cancer:

1. Tumor tissue is collected during amputation surgery and used to create a series of personalized vaccines that trigger the dog's immune response against its cancer.
2. The dog's T cells are collected, then activated and multiplied in a USDA-licensed manufacturing facility.
3. The activated T cells are returned to the dog to target the cancer.

WHY TIMING MATTERS

Because ECI® is made from the dog's own tumor, the treatment decision must be made before surgery or other treatments. Dogs that have already had surgery to remove the primary tumor cannot receive ECI®. Earlier detection gives families and veterinarians time to evaluate every option.

OUR PIPELINE

ELIAS is also developing ELI352, an oncolytic virotherapy licensed from Genelux Corporation. ELI352 is a vaccinia viral strain that selectively replicates in cancer cells, causing cell death. ELIAS plans to evaluate it in cancers in companion animals (dogs and cats), including osteosarcoma, oral melanoma, lymphoma and mast cell tumors.

PARTNER WITH ELIAS

We work with organizations that share our patient-centric, data-driven culture, including diagnostics companies, treating veterinarians, research institutions and strategic investors.

Talk to us to explore a partnership or investment →

FOR VETERINARIANS

The best candidates for ECI® are dogs with newly diagnosed appendicular osteosarcoma and no signs of metastatic disease. Refer a patient to an authorized treatment center: eliasanimalhealth.com/locations.

Or, become an authorized treatment center →

"Understanding treatment options early keeps the door open for families seeking innovative therapies like ECI®. ELIAS supports veterinarians from that first conversation onward, so they can focus on what matters most: their patients and the families who love them."

NOE REYES, DVM · Chief Medical Officer, ELIAS Animal Health

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Early Warning Signs of Cancer in Dogs



One in four dogs will develop cancer in their lifetime. Finding it early gives families and veterinarians more options for treatment. Share this checklist with your customers, partners and community.

TALK TO YOUR VETERINARIAN IF YOUR DOG HAS ANY OF THESE SYMPTOMS

- ☐ A lump or swelling that persists or keeps growing
- ☐ A sore that doesn't heal
- ☐ Unexplained weight loss
- ☐ Change in appetite, or reduced water intake
- ☐ Bleeding or discharge from the mouth, nose or any other body opening
- ☐ Changes in breathing, urination or bowel movements
- ☐ Reluctance to play
- ☐ Persistent lameness or stiffness
- ☐ Difficulty eating or swallowing
- ☐ Unusual or offensive odor

Many of these symptoms can have causes other than cancer. Only a veterinarian can tell the difference, so don't wait to see if it goes away on its own.

COMMON SYMPTOMS OF BONE CANCER (OSTEOSARCOMA)

Osteosarcoma is common in large and giant breeds, such as Rottweilers, Great Danes, St. Bernards and Golden Retrievers, often around seven years of age. Watch for:

- Persistent limping or reluctance to bear weight
- Firm lump or swelling on a leg
- Pain when the leg is touched
- Loss of muscle in one leg

IF YOUR DOG IS DIAGNOSED, ASK YOUR VETERINARIAN

- What type of cancer is it, and has it spread?
- What are all my treatment options, including immunotherapy?
- Do any options need to be decided before surgery?
- Should we see a veterinary oncologist?
- What will each option mean for my dog's quality of life?

Reviewed by Noe Reyes, DVM · Shared by ELIAS Animal Health · eliasanimalhealth.com

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