Contraceptive Research

Perspectives on Laboratory and Field Research Considerations

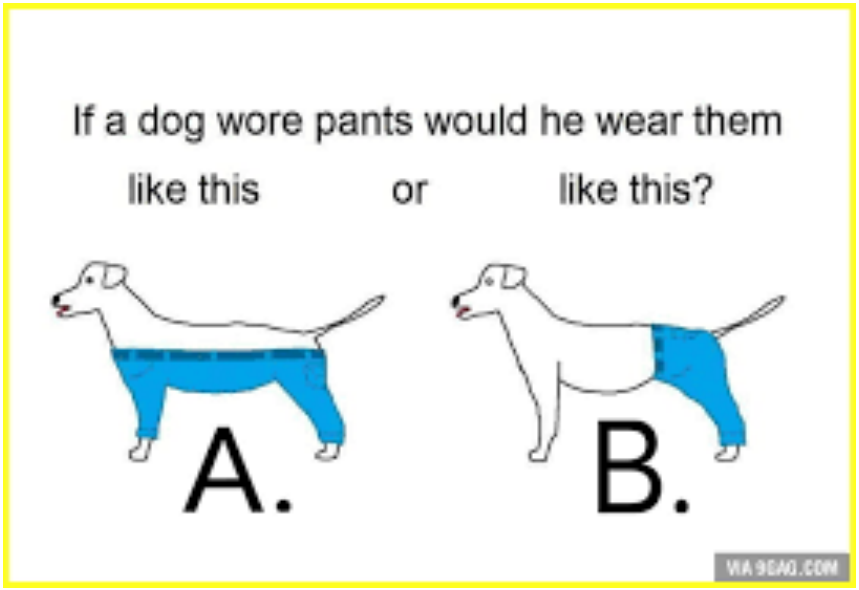
Linda Rhodes, VMD,PhD
Independent Consultant, Animal Health
ACC&D Board of Directors

Clinical Research for Regulatory Submissions

- What is “clinical” research?

Clinical Research for Regulatory Submissions

- Why is clinical research done?
  - SAFETY
  - EFFECTIVENESS



Academic vs Regulatory

Academic

1. Smaller sample sizes
2. Limited clinical sites
3. Retrospective or Prospective
4. Oversight may be limited
5. Submitted for peer review

Regulatory

1. 150 cases minimum, may be much higher
2. 6-10 clinical sites minimum
3. Prospective
4. Significant oversight (GCP)
5. Submitted to regulatory agencies

Who Does the Study?

- Sponsor
  - Writes the protocol, in consultation with regulatory authorities, finds and trains the site personnel, supplies the drug, study oversight, statistical analysis and report
- Veterinarian
  - Follows the protocol, recruits the patients, collects and reports the data
- Pet Owner
  - Owner consent
  - Pet observation and reporting of any adverse events

Study Design

- Placebo controlled
- Randomized
- Masked
- Owner consent
- Long term
- Must use the final commercial formulation of the drug

Study Population

Attribute	Protocol
Age	>2 months, pre-pubertal male dogs
Breed	Any breed
Fertility Status	Not previously treated with contraceptive or surgically sterilized; not intended for breeding
Health	Generally healthy, no evidence of disease that could interfere with data collection
Medications	No treatments that might interfere with the implant activity, common flea/tick, and heartworm prevention drugs allowed.

Long Term Trial Challenges

- To prove that an implant will last 5 years…..