Contraceptive Research
Perspectives on Laboratory and Field Research Considerations

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Clinical Research for Regulatory Submissions

What is “clinical” research?
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

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

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