Evaluating new product on the farm - approaches to field trials

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Designing scientific field trials

- ***Most problems in studies are due to poor design (not poor analysis)***

Develop Written and Precise Trial Protocol

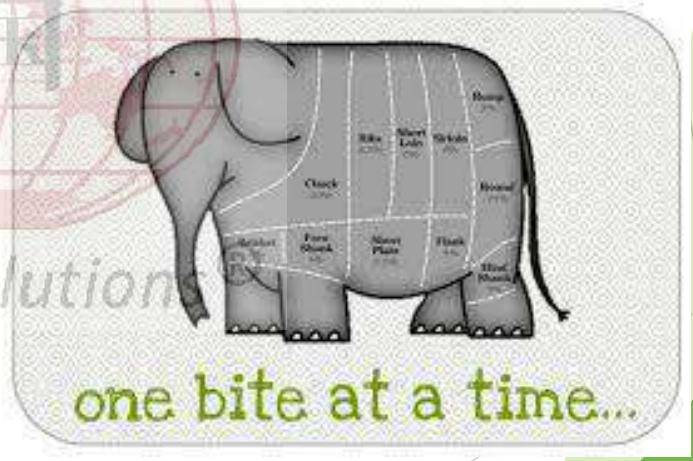
1. Study Name
2. Study Contacts
3. System, Flow, and Farm Sites in study
4. Objectives
5. Justification
6. Study Design
7. Assessment of Effectiveness and Statistics/Biometrics
    1. Primary Parameter
    2. Other Parameters
8. Diagnostic Details and Requirements
9. Schedule of Events

Develop Written and Precise Trial Protocol

10. Animal Selection and Identification
11. Inclusion/Exclusion and Post-Inclusion Removal Criteria
12. Animal Management and Housing
13. Description of Feed Composition
14. Use of Other Veterinary Product(s)
15. Study Animal Considerations
16. Biosecurity
17. Adverse Events
18. Changes to the Study Protocol
19. Data Ownership
20. Acknowledged Signatures

Setting Objectives

- Absolutely most important part of conducting research
- Be reasonable
  - How much can you accomplish in one trial?
- Be relevant and timely
  - What is most important to producer?
- Be courteous and conscientious
  - What will be impact on day-to-day operations?



Drives methodology

Defining and refining objectives

- Good objectives should:
  1. Be brief and concise
  2. Be in a logical sequence
  3. Be realistic /reasonable
     - *Time frames, budgets*
  4. Be phrased in operational terms
     - *Such that brings producer closer to their objectives… what is relevant to them?*
  5. Use action verbs
     - *For example: assess, determine, verify.*
  6. Be static once project begins
     - *No drifting!*

Study design and limitations

- Is there one, perfect design? NO!
  - Logistics
  - What can we accomplish
  - What producer can accomplish
  - Economics
  - Time

- Limitations… often chose “lesser of the evils”
  - Within barn/room
  - Between barns/room
  - Before and after

Trial development

- Don’t go alone!
- Biostatistician,
  - Early and often
  - Universities, genetics/pharmaceutical/feed companies, independent
- Study design, power calculation, data management/analysis
- Generously estimate your time…. Then DOUBLE it!

Study execution

-Data management

- Biostatistician
  - Clear understanding of what data is needed
- Pre-made collection forms
- Layout of electronic databases

Excel

Microsoft Access

Study execution
-INITIATION

- Helpers… generally better to have plenty of help!
- Right tools, right job

Study execution
-MANAGEMENT

- Protocol training
  - Implementation
  - Data collection
- Regular, scheduled time
  - Daily? Weekly? Monthly? Quarterly?
- Periodic summaries and updates

Study execution

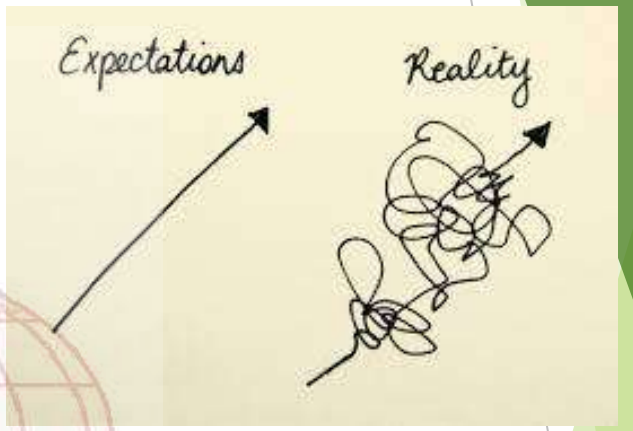
-COMPLETION

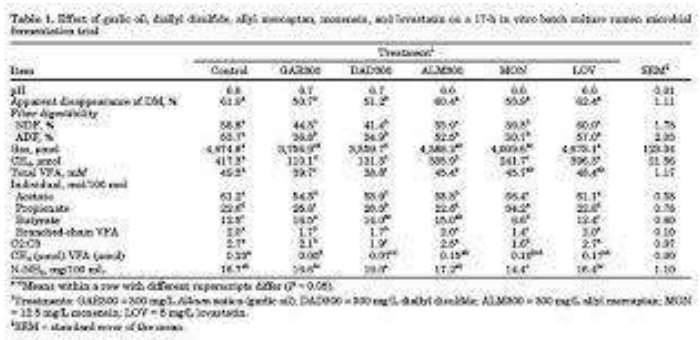
- On farm
  - ‘Leave no trace’
  - Expressions of gratitude/appreciation
- Data
  - Review promptly
  - Identify and correct errors
  - Document, document, document

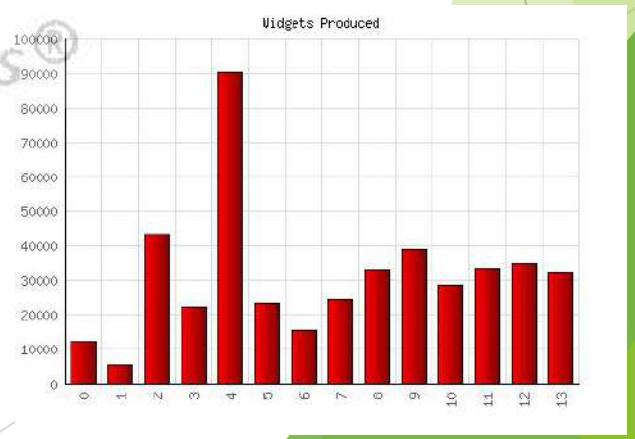
Study execution

-DATA ANALYSIS AND REPORTING

- Biostatistician
- Discuss analysis time lines
  - Generously estimate (then double it)
- Set expectations
  - Tables? Graphs? Manuscript?







Final thoughts

- Plan, but expect the unexpected
- Be flexible and understanding
- Above all, be curious!

"I have no special talent. I am only passionately curious."

- Albert Einstein

What's in a sample size estimation?

I have not failed. I've just found 10,00 ways that won't work
- Thomas Edison

- Ethical obligations
  - Use fewest animals possible

- Trials are expensive
  - Weights, serum/fecal/nasal samples, feed, rent, etc.

- Help refine objectives

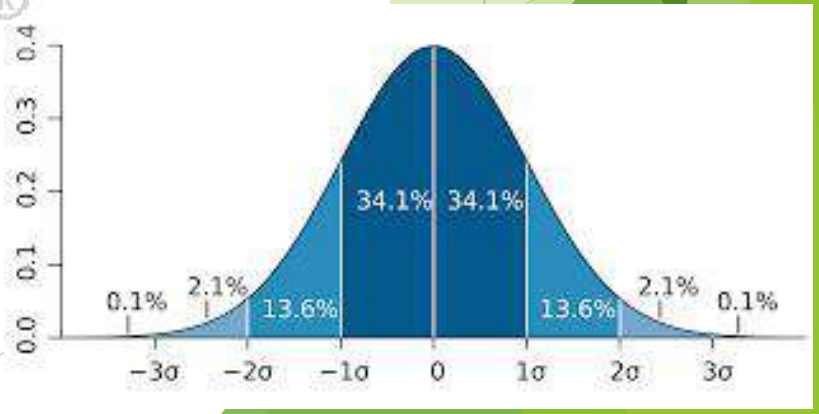
Why is this important questions?

- What do we want to be able to detect?
- ***Significance*** vs biological/economical significance?
- What amount of uncertainty are we OK with?
  - Generally look for a p value <0.05

Basic components

- Expected estimates of your outcome
  - How much will the experimental treatment change the outcome of our pigs?
    - Controls (population 1) vs treated (population 2)
    - 'Effect'
    - Mean of weight, ADG, ADFI, FG, body temperature

- Expected amount of variation
  - How much natural variation occurs within our pigs?
    - Standard Deviation (pilot study, records)



Philosophy of Vendor to Vet Relationship

- Excellent Products = Efficacy
- Product Availability
- Technical Support

- Let the vet be the vet

- Collaborate in generating new knowledge that benefits pigs and farmers

Background of PAR

- Pipestone Applied Research
- Animal Health and Genetic Performance Research Trials
- Generate relevant and applicable data = practical to the farmer
- P</= 0.05
- Transparency of results = “never bury the results”
- Share with the world

Boehringer Ingelheim/Pipestone Collaboration Topics

- PRRSv
- Mycoplasma hyopneumonia
- Lawsonia intracellularis
- The “Cost of Disease Project”

PRRSv

Farmer frustration with PRRSv challenges

Perception that MLV vaccines not efficacious

No clear plan by Pipestone veterinarians on how to effectively use MLV

Sows

Growing pigs

Hypothesis

- Application of a MLV vaccine can reduce viral shedding and improve performance in growing pigs previously infected with PRRSv

Effect of a modified-live PRRS virus vaccine on shedding of PRRS wild-type virus

Pipestone Applied Research

&

Dr. Tom Wetzell, Dr. Jean Paul Cano, Justin Rustvold,

Dr. Reíd Philips

Objectives

• Measure the effect of a PRRS modified-live virus vaccine (Ingelvac® PRRS MLV) on wild-type virus shedding in growing pigs vaccinated at weaning and challenged 4 weeks later

• Compare the performance to market weight of pigs vaccinated with Ingelvac® PRRS MLV versus non vaccinated pigs challenged with a PRRS field virus.

• Compare the performance of weaned pigs vaccinated with Ingelvac® PRRS MLV in the first 28 days post vaccination versus non vaccinated weaned pigs.

Conclusions

- PRRSv detection in air samples was significantly reduced:

	Frequency	Duration
Vaccinated pigs	5/120 samples	6 days
Non vaccinated pigs	27/120 samples	55 days

- Performance
  - The proportion of pigs culled was significantly lower in the vaccinated group than non vaccinated .
  - ADG from day 1 - day 147 was significantly higher for the vaccinates (1.65) than for non vaccinates (1.59).
  - On a subset of 300 individual pig weights per room, ADG from day-1 to day 28 (pre challenge) was significantly lower for vaccinated pigs (0.825) than for non vaccinated pigs (0.853).

Our Conclusions:

- Collaboration is key to scientific advancement
- Well designed and well funded projects are keys to getting good results
- When we work together, the pig and the farmer win

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