Ensuring Quality in Animal Health Studies
Clinical Investigator and Study Monitor Perspectives

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March 6, 2018
Where the data starts
Bradford Park Veterinary Clinic (BPVH)
Lack of Quality / Detail

BPVH

Dry Cleaner
Lack of attention to detail
Good Team
Why Investigators go into Clinical Research

• Supplement practice income
• Cutting edge medicine at a subsidized cost
• Treating patients for those clients who desire good care for their animals, but don't have the funds
• Helping young farmers who are undercapitalized, but have the time and are willing to learn the skills necessary for observations and recording
• Interest in research and science
How do Investigator motivations for going into research translate into quality data?
What makes a good Investigator?
Where can we find more good Investigators?

• Investigators
  – How does an Investigator get started?
  – Where is the formal GCP training?
  – How do we retain them in the industry?
Quality of the support staff

• Staff selection and training
• Challenges of a new Investigator and one technician
  – Masking
  – Drug allocation
  – Dispensing
Quality of the Clients

• Owner recruitment
• Patient recruitment
  – Established patients
  – Advertising
  – Shelters
• Incentives to
  – Clinic for recruitment
  – Owners
Conflicting expectations
118K veterinarians in the US

74K in private practice

Private clinics large enough for clinical research

Vets interested in clinical research

Vets attracting attention of a pharmaceutical company

Not very many

Number of veterinarians in private practice involved in clinical research
Competing priorities

**Investigators**
- Practicing medicine
- Clinic growth
- Retaining clients
- Helping people
- Clinical study

**Sponsors**
- Clinical study
- Timelines
- Shareholders

**Monitors**
Site selection

• Confirm a strong “house” was built
• Education for Investigator and Staff
• Align “must haves” (and reinforce)
• Set *real* expectations
• Select the right sites
  – How the site functions
  – How the site is motivated
  – Relationship of the site to its patients
  – Site obstacles
Quality of the tools
Protocol

• Good protocol and data collection method
• Identify protocol priorities
• Identify and mitigate risks to data
• Monitor feedback in protocol design
• Investigator feedback in protocol design
• Practical fit for the clinic
• Addressing grey areas of the protocol
• Communicating the non-anticipated
Quality of the Monitoring

• Detail-oriented, organized
• Monitor Training
  – Formal *animal health* GCP training
  – Formal mentoring
• Strong site relationships
• Clear, realistic expectations
• Create a plan pre-study
• Standardization across monitors
• Continued training

Don’t become the site enemy
Quality of the training

• Clear understanding of protocol objectives
• Translating the “mission”
• Providing the right tools
• Translating protocol to daily work flow
• Amount of time
• Understanding the major protocol risks
Data oversight

• Oversight over the data
  – Be early
  – Be vigilant

• Check in

• Give prompt answers

• Good communication
Any questions?