

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

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Where the data starts



Bradford Park Veterinary Clinic (BPVH)



Lack of Quality / Detail

BPVH



Dry Cleaner



Lack of attention to detail



BPVH



Good Team

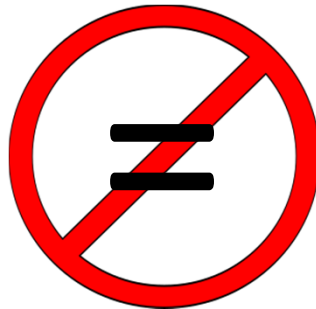


Why Investigators go into Clinical Research

- 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?



EXCELLENT



GOOD



AVERAGE

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

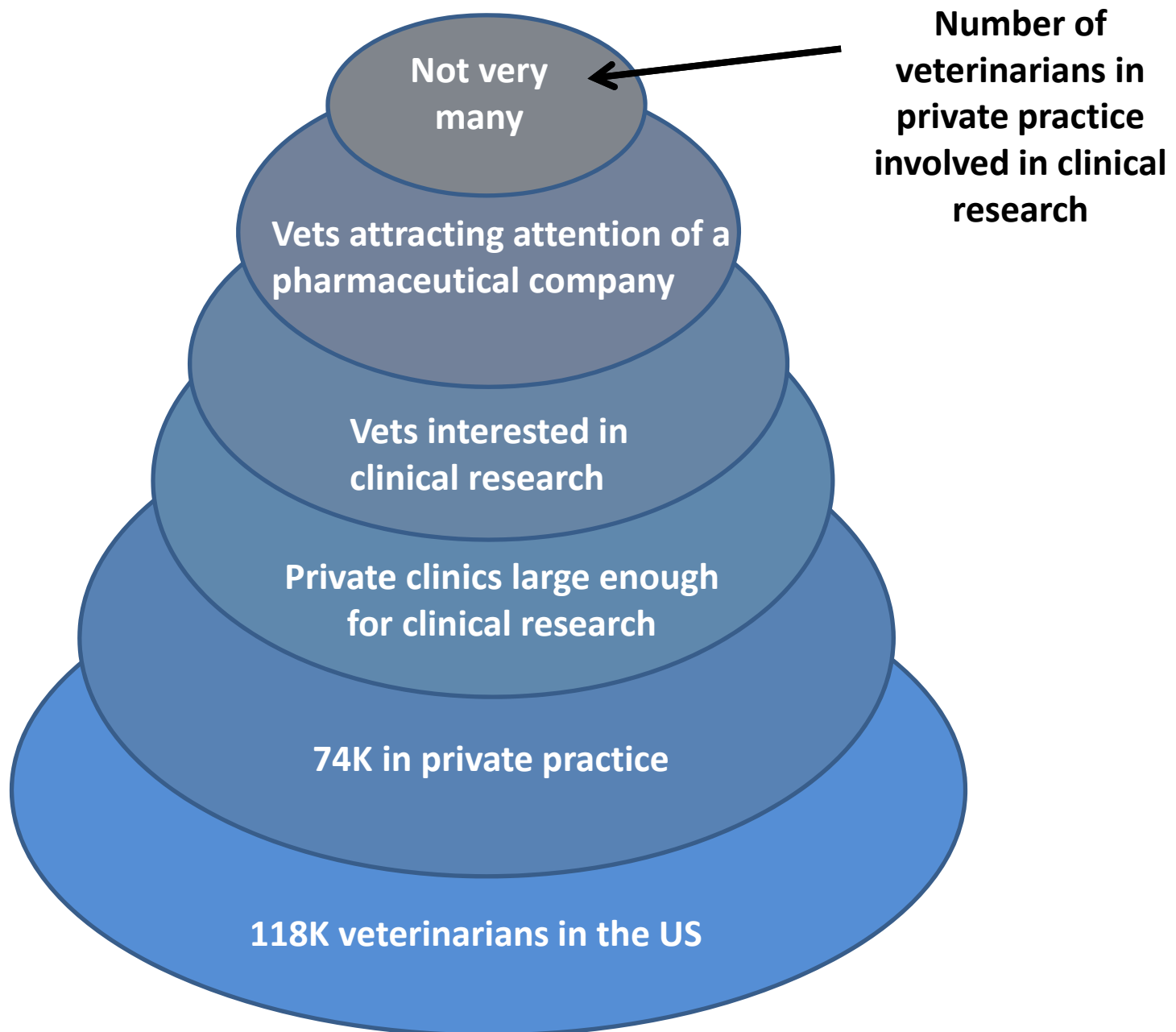
- Staff selection and training
- Challenges of a new Investigator and one technician
 - Masking
 - Drug allocation
 - Dispensing

Quality of the Clients

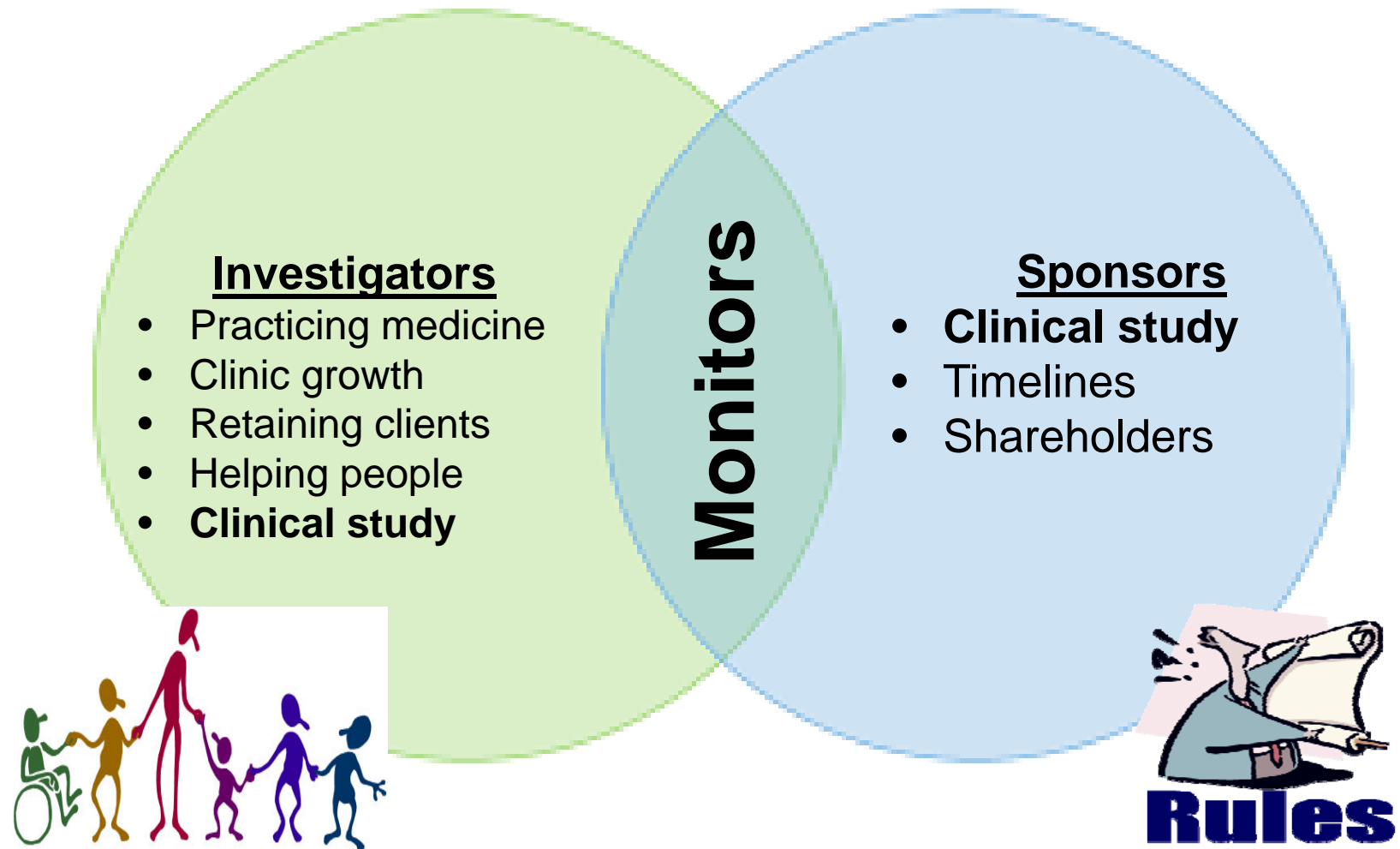
- Owner recruitment
- Patient recruitment
 - Established patients
 - Advertising
 - Shelters
- Incentives to
 - Clinic for recruitment
 - Owners

Conflicting expectations





Competing priorities



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?

