The Effect of Protocol Requirements on Field Trial Costs

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What We Will Cover

• Cost is function of *effort* required
• Considerations when developing protocols
  – Business
  – Regulatory
  – Practical/logistical
  – Product/crop idiosyncrasies
Purpose of the Study?

- New registration
- Bridging
- Data call In
- Reregistration
- Label expansion
- Import tolerance
- Sponsor-identified data gaps
- Label changes = New GAP
- New product acquisition
- Environmental considerations
- Worker safety
Product Label or GAP

Does Label Exist?

How Many?

How Are They Different?

Protocol Design
Product Label or GAP

Does Label Exist?

NO

???
Regulatory Guidelines

• FIFRA GLPs
• EPA OPPTS Series Guidelines
• OECD Guidelines
• Canadian PMRA Guidelines
• USDA Guidelines
• Draft Guidelines

... Guidelines are evolving
Application Method

- Soil applications (drip, drench, infurrow)
- Broadcast at high/low volume
- Airblast for tree crops
- Seed treatment
- Aerial (simulated or real)
- Cover crop (rotational crop)
- Special cases (i.e., photosensitive products)
Numbers & Other Logistics

• Trial distribution
• Number of:
  – treatments
  – applications
  – samples to be collected
• Crop destruction
• Sample shipping
Data Requirements

Often sponsor or laboratory-driven

- QA requirements
- Data capture method
- Additional data requirements
Components of Effort & Cost

“while you’re at it…”
Components of Effort & Cost

- Non-GLP data capture
- Additional documentation
- Crop injury
- Large amount of work, small amount of time
Additional “Must Haves”
Requirements for Success
Trial Separation

Why?

“...to reflect the diversity of the growing region”

- Acceptable separation criteria
- Same crop/compound usually requires separation
- Weather
Restricted Chemistry

- Precaution to prevent analytical interference
- Control samples and analytical method performance
- May exclude field sites that have a history of test substance
- Less concern with more sensitive analytical methods
Takeaways

• Price is a function of effort
• Developing modern agricultural products within complex regulatory frameworks is demanding
• Details are important: communicate!
• Teamwork and professionalism is key
Together, we’re developing products to help feed the world.

Thank you.