

The Effect of Protocol Requirements on Field Trial Costs



**NAICC 2014 Annual Meeting
January 31, 2014**

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?**



YES

**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

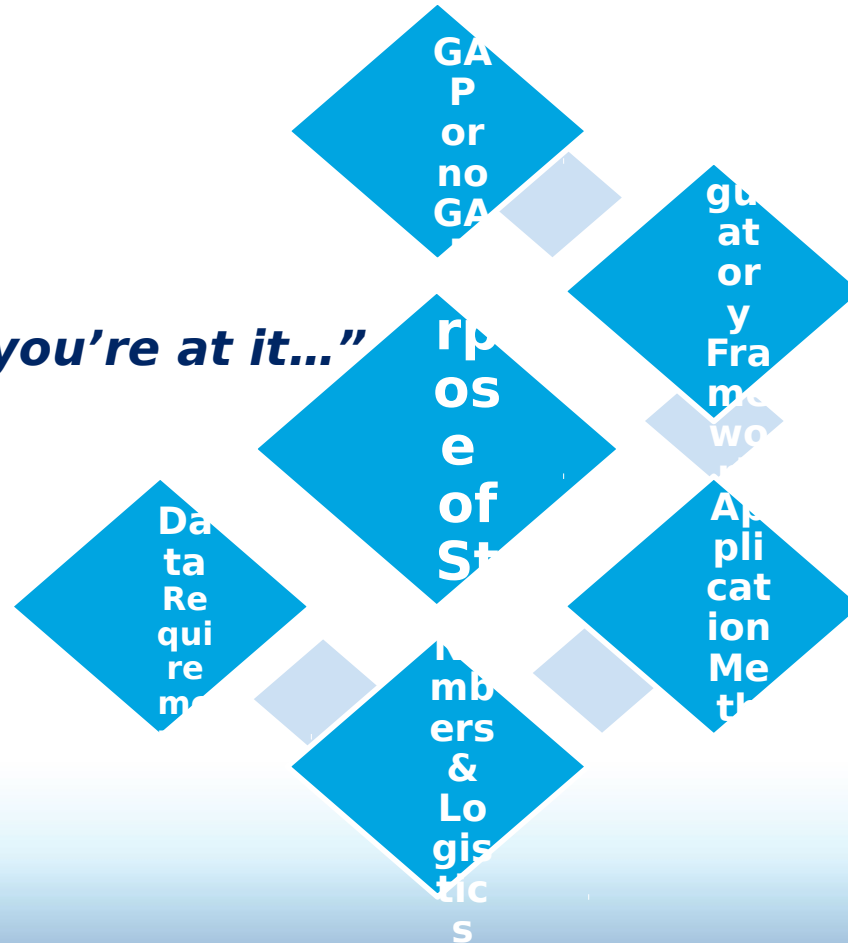
Data Requirements

Often sponsor or laboratory-driven

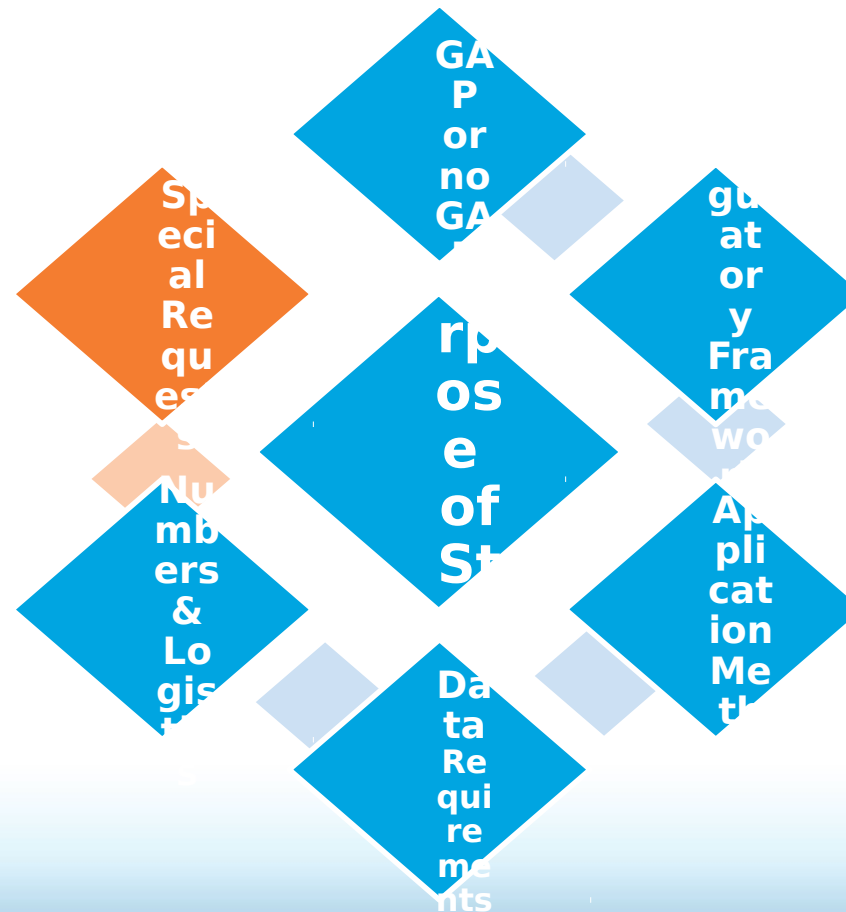
- QA requirements
- Data capture method
- Additional data requirements

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

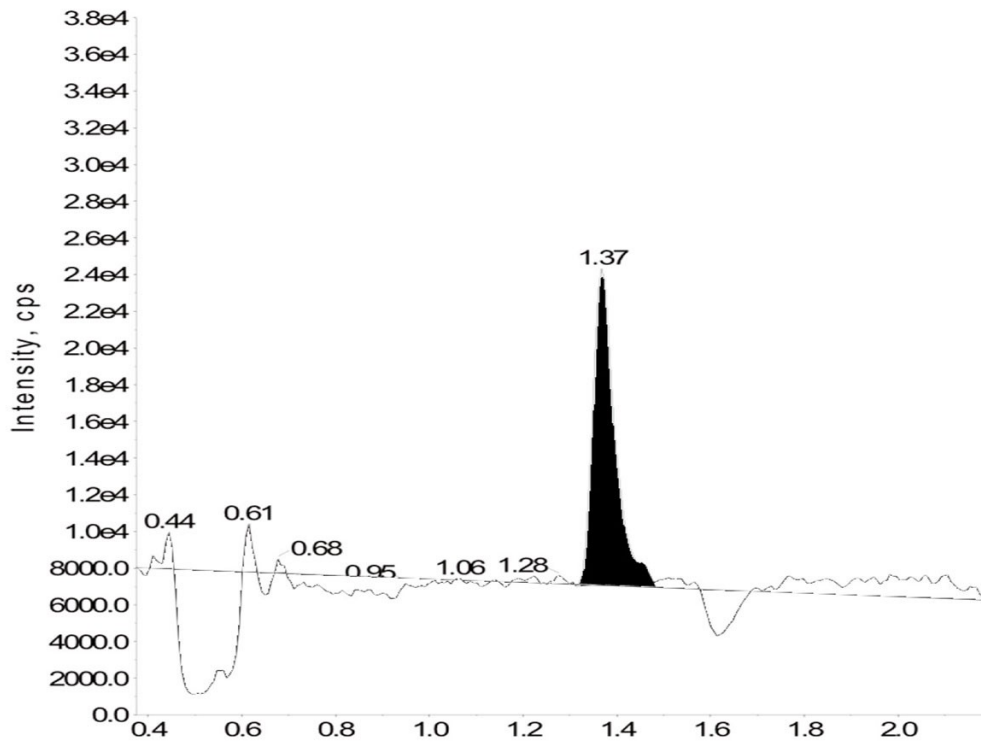
Trial Separation

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.