

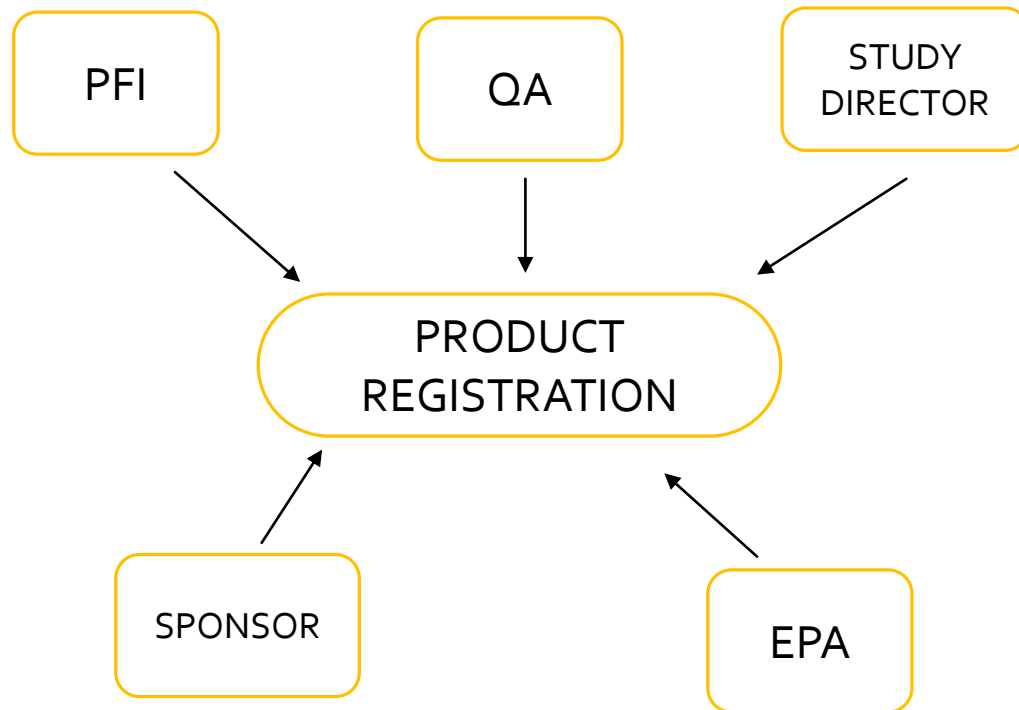
QA Perspective on GLP Field Notebooks

Makin' Sure It's Real

Carla M. Knipp

Knipp Consulting, LLC





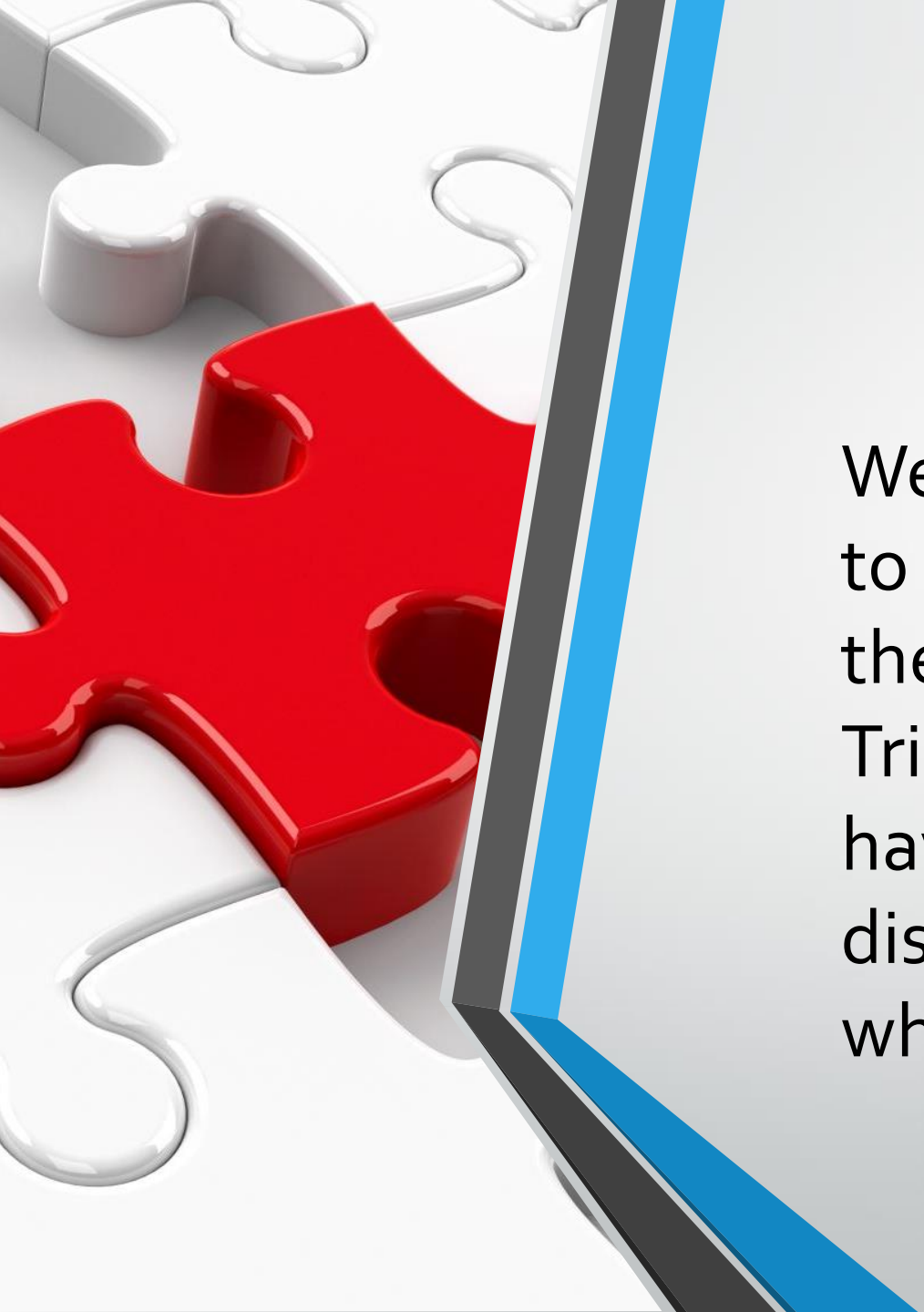
GOAL OF FIELD TRIAL STUDIES





Makin' Sure It's Real

The job of QA is to ensure that the field trial notebooks accurately reflect what happened in the field and that the facility's SOP's, protocol and GLP guidelines are followed.



We work with the PFI and Study Director to ensure everything that is required by the protocol is documented in the Field Trial Notebook. It is important that we have an open line of communication and discuss with the PFI and Study Director when there are potential issues.



How to Prepare for the Study

- Read the entire protocol for the field section
- Highlight important procedures
 - Concentration of the test substance
 - Plot design/information
 - Soil Characterization
 - Application
 - Sampling Procedure/timing
 - Weather Data
- Compare tables at end of protocol with text sections.



Test Substance

- Typically, nominal concentration is used.
- Compare text of protocol with table to ensure both have the same amounts.
- Storage – temperature monitored
- Certificate of Analysis
- Receipt Information/Tracking
- Documentation of amount used
- Safety Data Sheet



Plot

- Plot layout
- Ensure plot description and plot layout match
- UTC – upwind and up-slope of treated plots



SOIL CHARACTERIZATION

- Include in FTN
- Can you use one already completed or is it time for a new soil sample to be taken?



Application

- Amount of test substance – please verify
- How many applications
- Timing – is there any +/- days that can be used
- Wind speed and direction
- Calibration – day before/day of application
- Application Conditions that are needed to be documented
- Pass Time and Calculations – have someone verify calculations



SAMPLING

- Timing +/- days, BBCH, etc
- Number of samples for UTC and TRT
- Procedure on collection of sampling
- Timing to dislodge sample if applicable
- Timing from sample collection to freezer
- Check sample numbers on form with sample label and protocol

WEATHER DATA



- Celsius or Fahrenheit
- Absolute or Average min/max
- Time of Collection – Application to last sampling
- Historical weather – how many years 10, 20, etc.
- Source of weather data – distance from trial site, GLP or non-GLP

Some days do not go as planned.

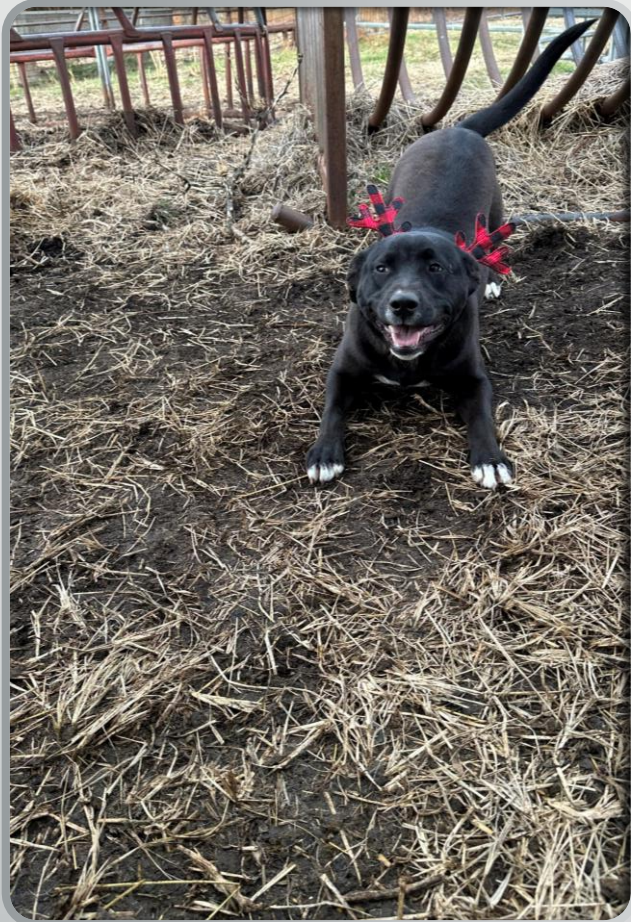
- What do you do?
- Document!
- Take pictures
- Call the Study Director



Review FTN

- Each day a form is completed – review and make sure any entry errors are documented, date/initial, sign form
- Calculations – please have someone review the calculations
- Review protocol to ensure all criteria has been documented
- No form –create one
- Better idea for a form – talk to the Study Director





We are all in this together to help each other to turn in an accurate and complete FTN to the Study Director. We each have our job and it is very important to communicate with one another. The study director then uses the data to create a report that is submitted to EPA for product registration. It is a team effort.