



Raw Data and Data Management

Debi Garvin, RQAP-GLP, MS

Huvepharma, Inc.

K-State Data Management Seminar



Dilbert.com DilbertCartoonist@gmail.com



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Food for Thought

- Managing bad data is like putting lipstick on a pig
- Key components of quality data
 - People – equine DOB; rescues; cattle BRD enrollment
 - Protocols that are user friendly and easy to understand
 - Good Forms (whether paper or electronic)
 - Flexibility
- One size doesn't fit all
 - Toxicology; Target Animal Safety; other GLP studies
 - Clinical – Production vs. Companion animal

Types of Data

- RAW or SOURCE
 - Paper
 - Electronic
 - Instrumentation (minimal user interface)
 - Web-based EDCs
- DERIVED (calculations, etc. must be validated)
 - Average Daily Gain
 - All Statistical values
 - Drug Blood levels (ng/ml)

Raw Data Rules

- Results of original observations and activities
 - Accurate – proper significant figures
 - Legible – readable (not an issue with EDCs)
 - Contemporaneous – recorded when it happens
 - Original – first observation
 - Attributable – who recorded the data; who was involved in activities
- All data must be signed and dated on the day of entry
- Changes must not obscure the original
 - Some EDCs allow for changes before the page is “saved”
 - Changes include reason, signed and dated

Study No.: XXXXXXXXXX

Date: (mm/dd/yy) 07/26/2008

Temperature of Oven: 60 °C °F

Drying Time: 54 hours

| Pen Number or Feed Ingredient | Pan Weight (g) | Weight of Pan + Wet Feed Sample (g) | Weight of Pan + Dry Feed Sample (g) | % Dry Matter of Feed Sample | Initials |
|-------------------------------|----------------|-------------------------------------|-------------------------------------|-----------------------------|----------|
| West 1 | 13.7 | 414.1 | 346.6 | 83.14 | PJG |
| West 2 | 13.6 | 433.0 | 375.4 | 81.97 | PJG |
| West 3 | 13.7 | 434.1 | 355.6 | 81.27 | PJG |
| West 4 | 13.7 | 375.0 | 302.8 | 79.99 | PJG |
| West 5 | 13.7 | 440.8 | 356.2 | 80.19 | PJG |
| West 6 | 13.6 | 425.3 | 347.4 | 81.08 | PJG |
| West 7 | 13.5 | 400.3 | 329.2 | 81.62 | PJG |
| West 8 | 13.6 | 422.8 | 348.6 | 81.87 | PJG |
| West 9 | 13.6 | 433.3 | 355.0 | 81.34 | PJG |
| West 10 | 13.6 | 413.8 | 333.2 | 79.86 | PJG |
| West 11 | 13.8 | 419.9 | 340.4 | 80.42 | PJG |
| West 12 | 13.7 | 436.5 | 359.0 | 81.67 | PJG |
| West 13 | 13.7 | 412.8 | 335.9 | 80.73 | PJG |
| West 14 | 13.7 | 402.2 | 324.6 | 80.03 | PJG |
| West 15 | 13.6 | 436.1 | 363.0 | 82.70 | PJG |
| West 16 | 13.8 | 417.4 | 343.7 | 81.74 | PJG |
| East 22 | 13.7 | 426.2 | 344.3 | 80.15 | PJG |
| East 23 | 13.7 | 403.1 | 328.5 | 80.84 | PJG |
| East 24 | 13.7 | 417.8 | 340.6 | 80.90 | PJG |
| | | | | | |
| | | | | | |

*RE
C

Data Collection Forms

- Developed for the user NOT data entry folks
 - Batch data vs. individual data
- Follow flow of procedures and logical
- Completely document ACTIVITY, not just the data
- Have room for narratives
- Must be easy to change if they don't work
- Get PI's/SDs input before protocol finalization
- For EDCs, program limits and flags

Managing studies (not just about the data)

- Telling the story so someone who does not live in your house can understand it
- Accurately and completely documenting what is happening
- Finding issues in time to fix them so they don't compromise data integrity
- Being truthful and bringing problems and mitigation to the forefront
- Providing QA for GLP and GCP PROACTIVELY to find issues when they can still be fixed
- Assess workload, personnel and logic of study events
 - Tired and overworked people make mistakes

BLOOD COLLECTION FORM - Date 3-Feb-2017
Study # 23578

Time point: 60 minutes (+/- 2 min) Study Day 14

| Animal # | Theoretical time | Collection site (circle) | Actual time | Time on Ice |
|----------|------------------|--------------------------|-------------|-------------|
| 1243 | 8:01 | R L J C S | 8:01 | 8:01 |
| 1356 | 8:02 | R L J C S | 8:02 | 8:02 |
| 1367 | 8:03 | R L J C S | 8:03 | 8:03 |
| 1245 | 8:04 | R L J C S | 8:04 | 8:04 |
| 1134 | 8:05 | R L J C S | 8:05 | 8:05 |
| 1563 | 8:06 | R L J C S | 8:06 | 8:06 |
| 1325 | 8:07 | R L J C S | 8:07 | 8:07 |
| 1242 | 8:08 | R L J C S | 8:08 | 8:08 |
| 1358 | 8:09 | R L J C S | 8:09 | 8:09 |
| 1369 | 8:10 | R L J C S | 8:10 | 8:10 |
| 1247 | 8:11 | R L J C S | 8:11 | 8:11 |
| 1139 | 8:12 | R L J C S | 8:12 | 8:12 |
| 1561 | 8:13 | R L J C S | 8:13 | 8:13 |
| 1329 | 8:14 | R L J C S | 8:14 | 8:14 |

R = Right L = Left J = Jugular C = Cephalic S = Saphenous

Gene Jones Feb 3, 2017
Gene Jones Date

BLOOD COLLECTION FORM - Date 3-Feb-2017
Study # 23578

Time point: 60 minutes (+/- 2 min) Study Day 14

| Animal # | Theoretical time | Collection site (circle) | Actual time | Collected BY (Team) | Placed on wet ice * |
|----------|------------------|--------------------------|-------------|---------------------|---------------------|
| 1243 | 8:01 | R L J C S | 8:01 | A | ✓ |
| 1356 | 8:02 | R L J C S | 8:02 | B | ✓ |
| 1367 | 8:03 | R L J C S | 8:03 | C | ✓ |
| 1245 | 8:04 | R L J C S | 8:04 | A | ✓ |
| 1134 | 8:05 | R L J C S | 8:05 | B | ✓ |
| 1563 | 8:06 | R L J C S | 8:06 | C | ✓ |
| 1325 | 8:07 | R L J C S | 8:07 | A | ✓ |
| 1242 | 8:08 | R L J C S | 8:08 | B | ✓ |
| 1358 | 8:09 | R L J C S | 8:09 | C | ✓ |
| 1369 | 8:10 | R L J C S | 8:10 | A | ✓ |
| 1247 | 8:11 | R L J C S | 8:11 | B | ✓ |
| 1139 | 8:12 | R L J C S | 8:12 | C | ✓ |
| 1561 | 8:13 | R L J C S | 8:13 | A | ✓ |
| 1329 | 8:14 | R L J C S | 8:14 | B | ✓ |

R = Right L = Left J = Jugular C = Cephalic S = Saphenous
* Y indicates placed on wet ice immediately after collection

Animals were equipped with catheters to facilitate blood collection. Three teams were involved in Blood Collection, each with a holder and collector as follows:

Team A - Holder Ann Jones; Collector Ryan Smith AS 3 Feb 2017
Team B - Holder Joe Daniels; Collector Cassie Hamman CH 3 Feb 2017
Team C - Holder Bill Barney; Collector Jill Johnson JB 3 Feb 2017

Date Recorded By: Sammy Simpson 3 February 2017
Sammy Simpson Date

Comments:

none

Helpful Hints

- Have QA/DM review forms prior to use (yes even for GCP)
- Make sure spaces are available to document all protocol requirements
- Try them out if possible and change when needed
- Review, QC, QA and then add Sponsor oversight
 - Monitor, QA
- Don't collect data that you don't need
- Challenge regulators on unreasonable designs and demands with scientific rationales

Helpful Hints

- Use Notes to File to explain processes when needed
- Organize data to allow for easy review by reviewers
- Include a “Reviewer’s Notes” (Roadmap) with each study
- Bring issues tl the forefront and don’t bury them in the data



Take Home Message

- If you don't have time to do things right, you probably don't have time to do them over
- Sponsors should provide QA and monitoring for all studies
 - Use Sponsor QA oversight for all GLP studies; use GLP QA for clinical studies
 - Monitor all studies - for GLP, monitor all phases equally
 - Don't assume all QA and contractors are equal
- The cost of increased QA/monitoring is miniscule compared to repeating a study or delayed registration
- Data management starts before the protocol is signed; the more invested upfront, the less issues you will find
- Bad data (and studies) cannot be QA'd into quality; quality is a culture not a department
- You get what you pay for - some contractors are cheap for a reason
- As an industry we have to ensure our studies are adequate and well controlled and that our products are safe and efficacious in the target population

Questions????

