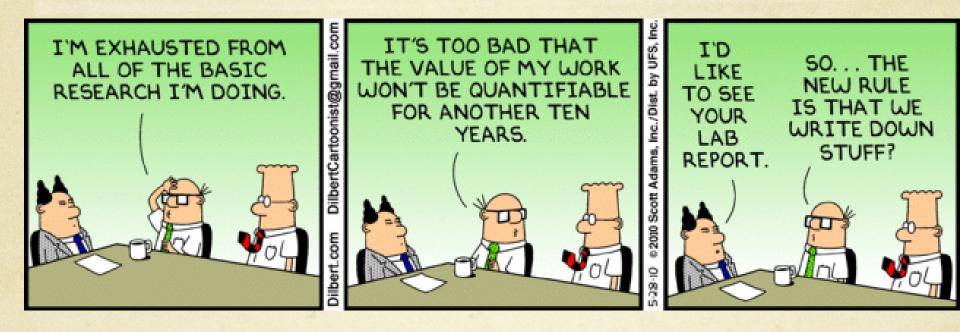


Raw Data and Data Management Debi Garvin, RQAP-GLP, MS Huvepharma, Inc. K-State Data Management Seminar

Debi Garvin - Huvepharma, Inc.



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.:		e de la companya de la	٦			
	and a clo	3 2 T		•		
Date: (mm/dd/yy)07 26 8 f Oven: 6 O	608				
Temperature of	f Oven: 60	℃ °F	Dryin	g Time: 5	1 hours	
Pen Number		Weight of Pan	Weight of Pan		T	
or Feed Ingredient	Weight	+ Wet Feed	+ Dry Feed	% Dry Matter		
West 1	(g)	Sample (g)	Sample (g)	of Feed Sample	Initials	
West Z	13.7	414.1	346.6	83.14	PTG	
	13.6	433.0	3751.4	81.97	PJG	*@
West 3	13.7	434.1	355.6	81.27	PJG	c
West 4	13.7	375.0	302.8	79.99	PJG	
West 5	13.7	440.8	3562	80,19	PJG	-
West 6	13.6	425.3	347.4	61.08	PJG	-
West 7	13.5	400.3	329.2	81.6Z	PJG	-
West B	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		
West 15	13.6	436.1	363.0	82.70	PJG PJG	
West 16	13.8	417.4	343.7	81.74		
East 22	13.7	426.2	344.3	80.15	PJG	
East 23	13.1	403,1	328.5		PJG	
East 24	13.7	417.8	340.6	80.84	PJG	
			51010	80.90	P56	
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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 - 2017Study # 23578 Time point: 60 minutes (+/- 2 min) Study Day $1^{4/2}$

Animal #	Theoretical time	Col	lection site (circle)	Actual time	Time on Ice	
1243	8:01	RL	JCS	5:01	8:01	
1356	8:02	RL	JCS	5:07	8:02	
1367	8:03	R L	J (C) S	8:03	8:03	
1245	8:04	RQ	JCA	8:09	8:04	
1134	8:05	RU	JCS	8:05	8:05	
1563	8:06	(R) L	JCS	8:06	8:06	
1325	8:07	RL	JC(S)	8:07	8:07	
1242	8:08	(R L	JCS	81.08	8:08	
1358	8:09	RL	JCS	8:09	8:09	
1369	8:10	RL	JOS	8:10	8:10	
1247	8:11	R (L)	J C (S)	8:11	8:11	
1139	8:12	R(L)	JCS	8:12	8:12	
1561	8:13	(R) L	J (C) S	8:13	8:13	
1329	8:14	R(D)	J C (S)	874	8:14	

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

Jule 3.2017 nes i Gene Jone Date

BLOOD COLLECTION FORM - Date <u>3-Feb-2017</u> Study # 23578

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

Animal #	Theoretic al time	Collection site (circle)		Actual time	Collected BY (Team)	Placed on wet ice *	
1243	8:01	(R) L	JOS	8:01	A	/	
1356	8:02	R L	J C S	5:00	B	1	
1367	8:03	R) L	JOS	8:03	C	1	
1245	8:04	RD	J C (S)	8:04	A	1	
1134	8:05	R (L)	JC(S)	8:05	B	V	
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	JC(S)	8:08	B	V	
1358	8:09	R L	J (C) S	8:09	C	1	
1369	8:10	RO	JCO	8:10	A	/	
1247	8:11	R(L)	J (C) S	8:11	B	1	
1139	8:12	(R) L	JCO	8:12	C	/	
1561	8:13	R (1)	JC(S)	8:13	A	-	
1329	8:14	(R) L	J(C) S	8:14	B	1	

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 <u>AS 3776</u> 2017 Team B – Holder Joe Daniels; Collector Cassie Hamman <u>CS 3776</u> 2017 Team C – Holder Bill Barney; Collector Jill Johnson <u>AS 36</u> 2017

5 Libruary 2017 Date Recorded By: Sammy Simpson

Comments:

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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

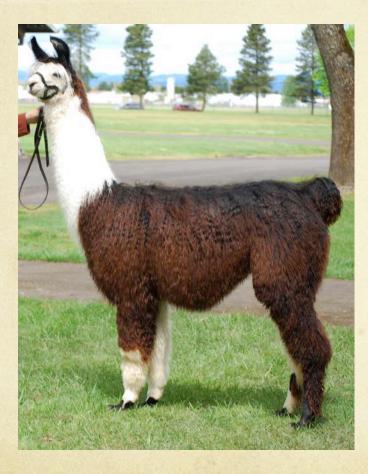
- Use Notes to File to explain processes when needed
- Organize data to allow for easy review by reviewers
- Include a "Reviewer's Notes" (Roadmap) with each study
- Bring issues tl the forefront and don't bury them in the data



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
 - O 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????





Debi Garvin - Huvepharma, Inc.