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2026 US Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION



Around the Data DOSE-y Doe, How Much Fun Can Your Data Can Be!

Using DOSExx Variables within ADaM Datasets

Inka Leprince, InkaStat Solutions; Richann Jean Watson, DataRich Consulting

Introducing…



Richann Watson is an independent statistical programmer and CDISC consultant based in Ohio who loves to code and is very active in the SAS User Group community. She loves spending time with her family and cute but psycho puppy, Loki, or doing some of her favorite crafts such as crocheting or sewing.

Inka Leprince is a independent biostatistician and statistical programmer with over five years of experience consulting with start-up pharmaceutical companies. In her free time, she likes to cross stitch, talk to her succulent collection, and walk through Costco.

Further Introducing…



Loki

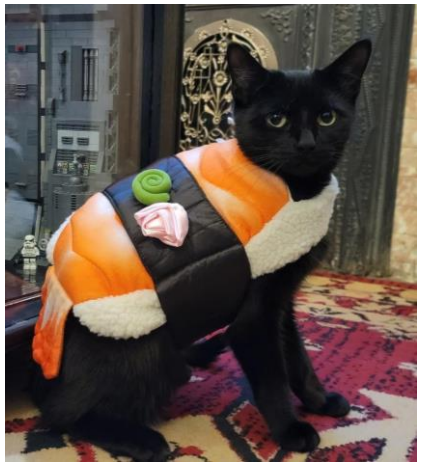
Handsome mama's boy Dog of Mischief.

Gets into things he should not. Never a dull moment.



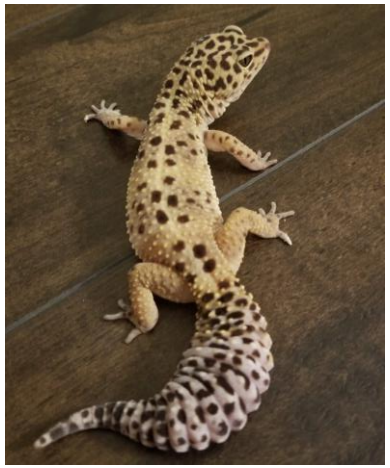
Chewy

The greatest of all time. Always up for an adventure and loves his clothes.



Lilith

Catistician and mother of four. Her hobbies include sleeping and yelling for chicken.

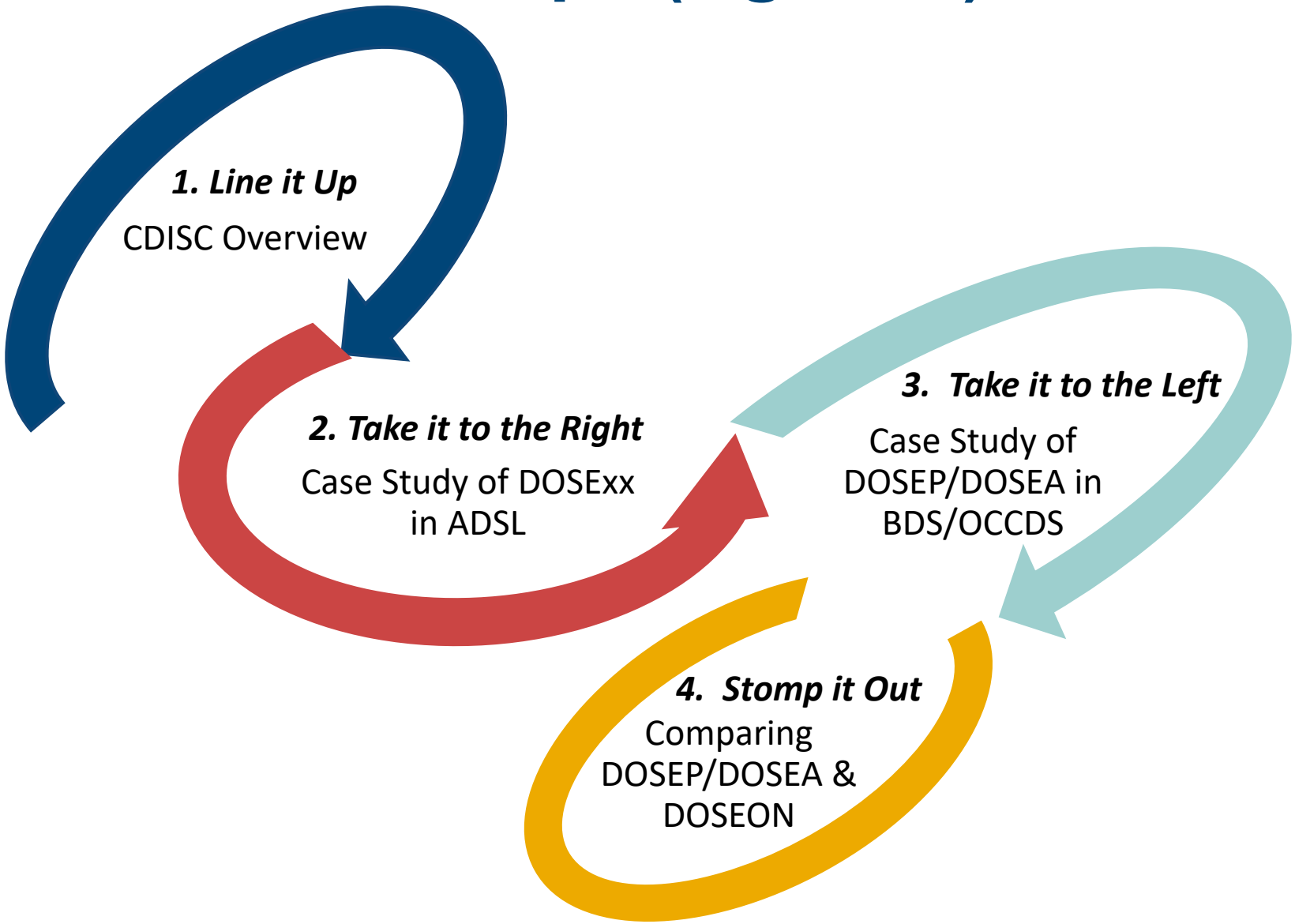


Dot

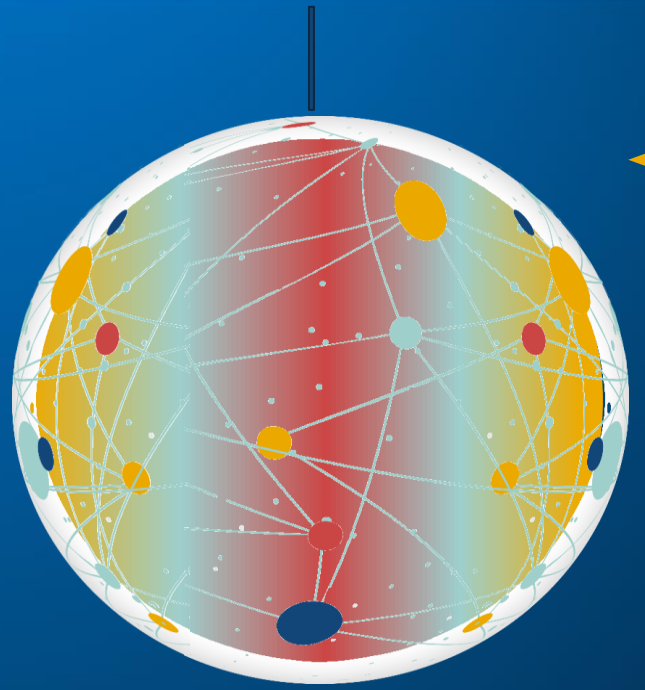
Talented leopard gecko whose crowning achievement was accidentally doing a backflip while trying to catch a cricket.

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DOSE-y DOE Dance Steps (Agenda)



CDISC Overview



What is CDISC

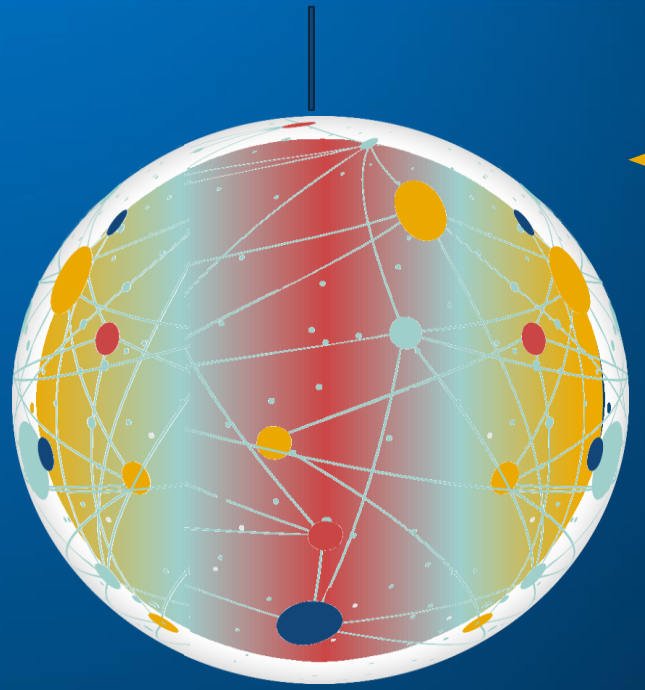
- Clinical Data Interchange Standards Consortium (CDISC) develops and promotes data standards that facilitate the collection, organization, and analysis of data in the clinical and health research (CDISC Website, 2024)
- Analysis Data Model (ADaM) is optimized to support data derivation and analysis. A framework that enables analysis of the data, while at the same time providing traceability from collection to analysis to results (ADaM v2.1, 2009).

Fundamental ADaM Principles of CDISC

1. Traceability
   - Facilitate clear and unambiguous path between an analysis result all the way to the source data
2. Analysis-Ready
   - Should be “one procedure” away from producing analysis results
3. Metadata
   - Descriptions of analysis datasets, variables, and parameters (as applicable)
4. Readily Usable Software
   - Analysis datasets must be readily usable by commonly available software tools (no proprietary software)

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Case Study



Case Study: SPIN

Study of Pediatric Ingestion of Norteño: A Randomized Trial

A Single-Center, Randomized, Phase 2 Study to evaluate the efficacy and safety of 28 days of treatment with Norteño in pediatric subjects with *"two left feet"*.

The dose assignment for a pediatric population is based on three adult equivalent doses of study drug.

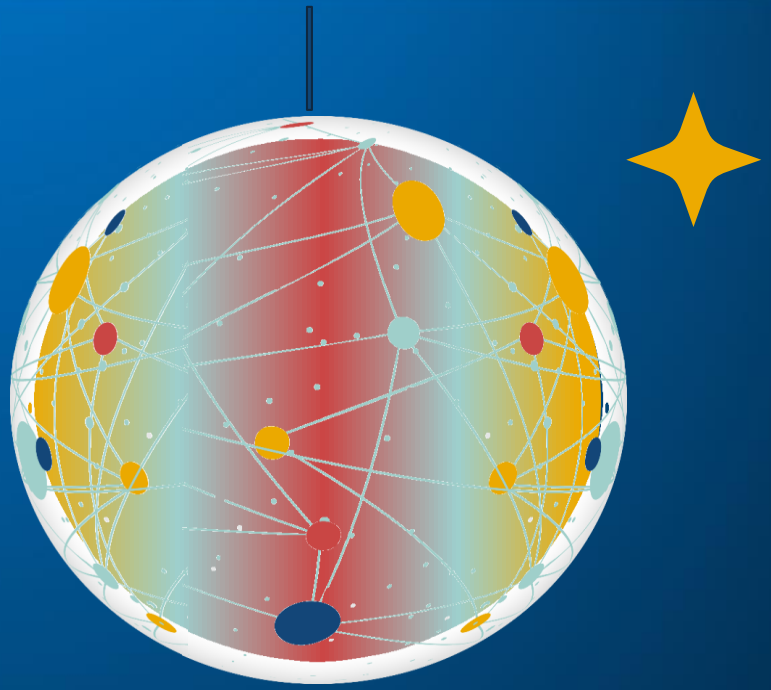
	Adult Equivalent Dose of Norteño		
Weight Class	**5 mg QD**	**10 mg QD**	**20 mg QD**
20 –< 35 kg	1 mg	2.5 mg	5 mg
35 –< 50 kg	2.5 mg	5 mg	10 mg
50 + kg	5 mg	10 mg	20 mg

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Summary Table Shell, Annotated

	Adult Equivalent Dose of Norteño				
	5 mg QD (N=xx)	10 mg QD (N=xx)	20 mg QD (N=xx)	Total (N=xxx)	ADSL.TRT01A
Sex, n (%)					ADSL.SEX
Male	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	
Female	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	
Race, n (%)					ADSL.RACE
White	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	
Asian	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	
Black or African American	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	
…	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	
Age (years)					ADSL.AGE
n	xx	xx	xx	xx	
mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	
min, max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	

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ADSL Example

Subject-Level Analysis Dataset

ADSL TRTxxP/A Metadata

VARIABLE NAME	VARIABLE LABEL	TYPE	CODELIST/ CT	CORE	CDISC NOTES
TRTxxP	Planned Treatment for Period xx	Char		Req	Subject-level identifier that represents the planned treatment for period xx. In a one-period randomized trial, TRT01P would be the treatment to which the subject was randomized. TRTxxP might be derived from the SDTM DM variable ARM. At least TRT01P is required.
TRTxxA	Actual Treatment for Period xx	Char		Cond	Subject-level identifier that represents the actual treatment for the subject for period xx. Required when actual treatment does not match planned and there is an analysis of the data as treated.

Source: ADaMIG v1.3 Table 3.2.4 ADSL Treatment Variables

VARIABLE NAME	VARIABLE LABEL	TYPE	LENGTH	SOURCE	DERIVATION
TRT01P	Planned Treatment for Period 01	Char	16	DM.ARM	
TRT01A	Actual Treatment for Period 01	Char	16	Derived	Select the first record in EX per subject. Concatenate EX.DOSE, EX.EXDOSU, EX.EXTRT, and EX.DOSFRQ, delimited by a space.

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Incomplete ADSL Data

SUBJID	WTBL	STRATAR	ARM	TRT01P	TRT01A
Subject ID	Baseline Weight (kg)	Strata Used for Randomization	Description of Planned Arm	Planned Treatment for Period 01	Actual Treatment for Period 01
Chewy	40	35 –< 50 kg	20 MG NORTEÑO QD	20 MG NORTEÑO QD	20 MG NORTEÑO QD
Dot	53	50+ kg	10 MG NORTEÑO QD	10 MG NORTEÑO QD	10 MG NORTEÑO QD
Lilith	25	20 –< 35 kg	10 MG NORTEÑO QD	10 MG NORTEÑO QD	20 MG NORTEÑO QD
Loki	30	20 –< 35 kg	5 MG NORTEÑO QD	5 MG NORTEÑO QD	5 MG NORTEÑO QD

	Adult Equivalent Dose of Norteño				
	5 mg QD (N=xx)	10 mg QD (N=xx)	20 mg QD (N=xx)	Total (N=xxx)	**ADSL.TRT01A**
Sex, n (%)					**ADSL.SEX**
Male	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	
Female	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	
Race, n (%)					**ADSL.RACE**
White	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	

Incomplete ADSL Data

SUBJID	WTBL	STRATAR	ARM	TRT01P	TRT01A
Subject ID	Baseline Weight (kg)	Strata Used for Randomization	Description of Planned Arm	Planned Treatment for Period 01	Actual Treatment for Period 01
Chewy	40	35 –< 50 kg	20 MG NORTEÑO QD	20 MG NORTEÑO QD	20 MG NORTEÑO QD
Dot	53	50+ kg	10 MG NORTEÑO QD	10 MG NORTEÑO QD	10 MG NORTEÑO QD
Lilith	25	20 –< 35 kg	10 MG NORTEÑO QD	10 MG NORTEÑO QD	20 MG NORTEÑO QD
Loki	30	20 –< 35 kg	5 MG NORTEÑO QD	5 MG NORTEÑO QD	5 MG NORTEÑO QD

	Adult Equivalent Dose		
Weight Class	**5 mg QD**	**10 mg QD**	**20 mg QD**
20 –< 35 kg	1 mg	2.5 mg	5 mg
35 -< 50 kg	2.5 mg	5 mg	10 mg
50 + kg	5 mg	10 mg	20 mg

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Incomplete ADSL Data

SUBJID	WTBL	STRATAR	ARM	TRT01P	TRT01A
Subject ID	Baseline Weight (kg)	Strata Used for Randomization	Description of Planned Arm	Planned Treatment for Period 01	Actual Treatment for Period 01
Chewy	40	35 –< 50 kg	20 MG NORTEÑO QD	20 MG NORTEÑO QD	20 MG NORTEÑO QD
Dot	53	50+ kg	10 MG NORTEÑO QD	10 MG NORTEÑO QD	10 MG NORTEÑO QD
Lilith	25	20 –< 35 kg	10 MG NORTEÑO QD	10 MG NORTEÑO QD	20 MG NORTEÑO QD
Loki	30	20 –< 35 kg	5 MG NORTEÑO QD	5 MG NORTEÑO QD	5 MG NORTEÑO QD

???	???	???
Planned Pediatric, Weight-Based Treatment Dose for Period 01	Actual Pediatric, Weight-Based Treatment Dose for Period 01	Units for Pediatric, Weight-Based Treatment Dose for Period 01

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Introducing DOSExx Variables!

VARIABLE NAME	VARIABLE LABEL	TYPE	CODELIST/ CT	CORE	CDISC NOTES
DOSExxP	Planned Treatment Dose for Period xx	Num		Perm	Subject-level identifier that represents the planned treatment dosage for period xx.
DOSExxA	Actual Treatment Dose for Period	Num		Perm	Subject-level identifier that represents the actual treatment dosage for period xx.
DOSExxU	Units for Dose for Period xx	Char		Perm	The units for DOSExxP and DOSExxA. It is permissible to use suffixes such as "P" and "A" if needed, with labels modified accordingly.

Source: ADAMIG v1.3 Table 3.2.5 ADSL Dose Variables

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It’s Time to DOSE-Y DOE!

ADSL Metadata

VARIABLE NAME	VARIABLE LABEL	TYPE	LENGTH	SOURCE	DERIVATION
DOSE01P	Planned Treatment Dose for Period 01	Num	8	Derived	Set to the numeric value of the pediatric dose level as mapped out in Table for Weight-Based Pediatric Doses, subject's weight used for randomization (DM.STRATAR) and the planned treatment (DM.ARM): If DM.STRATAR = '20 –< 35 kg' perform the following: Set to 1 if
DOSE01A	Actual Treatment Dose for Period 01	Num	8	Derived	records by USUBJID and ECSEQ
DOSE01U	Units for Dose for Period 01	Char	2	Assigned	Set to EC.ECDOSU

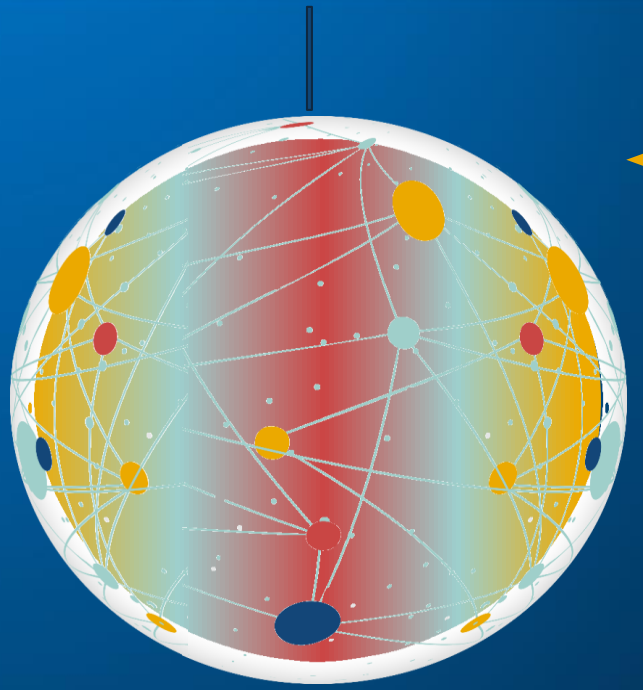
	Adult Equivalent Dose of Norteño		
Weight Class	**5 mg QD**	**10 mg QD**	**20 mg QD**
20 –< 35 kg	1 mg	2.5 mg	5 mg
35 –< 50 kg	2.5 mg	5 mg	10 mg
50 + kg	5 mg	10 mg	20 mg

ADSL Data

SUBJID	WTBL	STRATAR	ARM	TRT01P	TRT01A
Subject ID	Baseline Weight (kg)	Strata Used for Randomization	Description of Planned Arm	Planned Treatment for Period 01	Actual Treatment for Period 01
Chewy	40	35 –< 50 kg	20 MG NORTEÑO QD	20 MG NORTEÑO QD	20 MG NORTEÑO QD
Dot	53	50+ kg	10 MG NORTEÑO QD	10 MG NORTEÑO QD	10 MG NORTEÑO QD
Lilith	25	20 –< 35 kg	10 MG NORTEÑO QD	10 MG NORTEÑO QD	20 MG NORTEÑO QD
Loki	30	20 –< 35 kg	5 MG NORTEÑO QD	5 MG NORTEÑO QD	5 MG NORTEÑO QD

DOSE01P	DOSE01A	DOSE01U
Planned Treatment Dose for Period 01	Actual Treatment Dose for Period 01	Units for Dose for Period 01
10	10	MG
10	10	MG

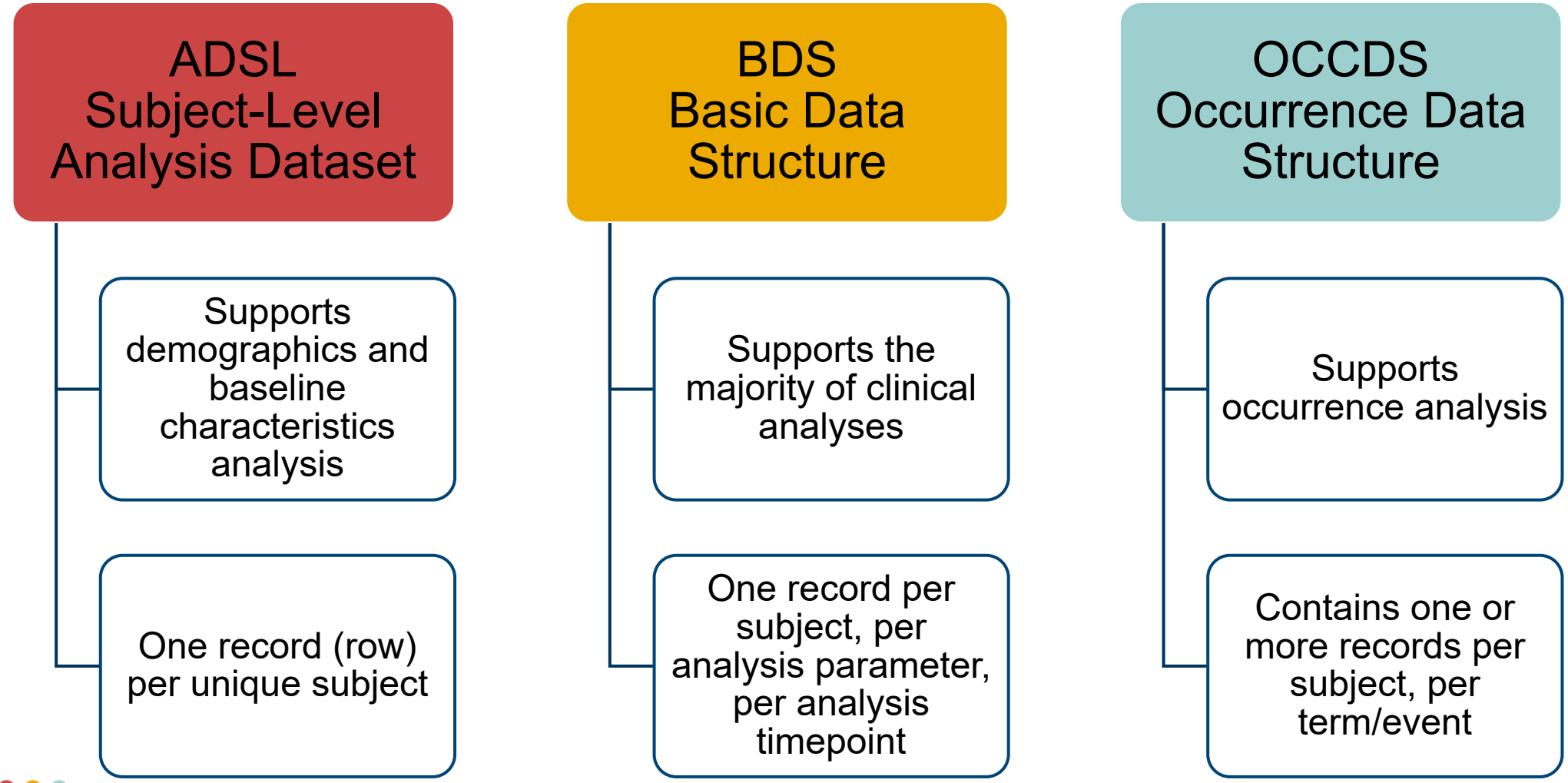
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BDS/OCCDS Example

Basic Data Structure / Occurrence Data Structure

CDISC ADaM Data Structures



Summary Table Shell, Annotated

	Adult Equivalent Dose of Norteño				
	5 mg QD (N=xx)	10 mg QD (N=xx)	20 mg QD (N=xx)	Total (N=xxx)	**ADAE.TRTA**
Subjects reporting at least one treatment-emergent adverse event, n (%)					**ADAE.AEDECOD**
Restless leg syndrome	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	
Dance fever	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	
Polka dots	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	
Electrically sliding	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	
…	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	

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BDS (and OCCDS) TRTP/A Metadata

VARIABLE NAME	VARIABLE LABEL	TYPE	CODELIST/ CT	CORE	CDISC NOTES
TRTP	Planned Treatment	Char		Req	TRTP is a record-level identifier that represents the planned treatment attributed to a record for analysis purposes. TRTP indicates how treatment varies by record within a subject and enables analysis of crossover and other designs. Though there is no requirement that TRTP will correspond to the TRTxxP as defined by the record's value of APERIOD, if populated, TRTP must match at least one value of the character planned treatment variables in ADSL (e.g., TRTxxP, TRTSEQP, TRxxPGy).
TRTA	Actual Treatment	Char		Cond	TRTA is a record-level identifier that represents the actual treatment attributed to a record for analysis purposes. TRTA indicates how treatment varies by record within a subject and enables analysis of crossover and other multi-period designs. Though there is no requirement that TRTA will correspond to the TRTxxA as defined by the record's value of APERIOD, TRTA must match at least one value of the character actual treatment variables in ADSL (e.g., TRTxxA, TRTSEQA, TRxxAGy).

Source: ADaMIG v1.3 Table 3.3.2.1 Record-Level Treatment Variables for BDS Datasets

VARIABLE NAME	VARIABLE LABEL	TYPE	LENGTH	SOURCE	DERIVATION
TRTP	Planned Treatment	Char	16	DM.ARM	Set to ADSL.TRT01P if TRTSDT <= ASTDT <= TRTEDT + 1 day. Otherwise leave null.
TRTA	Actual Treatment	Char	16	Derived	Set to ADSL.TRT01A if TRTSDT <= ASTDT <= TRTEDT + 1 day. Otherwise leave null.

Incomplete ADAE Data

#	USUBJID	TRTSDT	TRTEDT	TRTP	TRTA	ASTDT	AENDT	AEDECOD
	Subject ID	Date of First Exposure to Treatment	Date of Last Exposure to Treatment	Planned Treatment	Actual Treatment	Analysis Start Date	Analysis End Date	Dictionary-Derived Term
1	Chewy	2024-02-01	2024-02-28	20 MG NORTEÑO QD	20 MG NORTEÑO QD	2024-02-01	2024-02-09	RESTLESS LEG SYNDROME
2	Chewy	2024-02-01	2024-02-28			2024-03-02	2024-03-31	ELECTRICALLY SLIDING
3	Dot	2024-02-01	2024-02-28	10 MG NORTEÑO QD	10 MG NORTEÑO QD	2024-02-03	2024-12-31	POLKA DOTS
4	Dot	2024-02-01	2024-02-28	10 MG NORTEÑO QD	10 MG NORTEÑO QD	2024-02-04	2024-02-05	TWISTING AND SHOUTING
5	Dot	2024-02-01	2024-02-28	10 MG NORTEÑO QD	10 MG NORTEÑO QD	2024-02-05	2024-02-12	TWINKLE TOES
6	Lilith	2024-02-01	2024-02-28	10 MG NORTEÑO QD	20 MG NORTEÑO QD	2024-02-01	2024-02-03	JAZZ HANDS
7	Lilith	2024-02-01	2024-02-28	10 MG NORTEÑO QD	20 MG NORTEÑO QD	2024-02-23	2024-02-26	HUSTLING
8	Loki	2024-02-01	2024-02-28	5 MG NORTEÑO QD	5 MG NORTEÑO QD	2024-02-01	2024-02-29	DANCE FEVER
9	Loki	2024-02-01	2024-02-28	5 MG NORTEÑO QD	5 MG NORTEÑO QD	2024-02-06	2024-02-08	A LITTLE BOOGIE

Incomplete ADAE Data

#	USUBJID	TRTSDT	TRTEDT	TRTP	TRTA	ASTDT	AENDT	AEDECOD
	Subject ID	Date of First Exposure to Treatment	Date of Last Exposure to Treatment	Planned Treatment	Actual Treatment	Analysis Start Date	Analysis End Date	Dictionary-Derived Term
1	Chewy	2024-02-01	2024-02-28	20 MG NORTEÑO QD	20 MG NORTEÑO QD	2024-02-01	2024-02-09	RESTLESS LEG SYNDROME
2	Chewy	2024-02-01	2024-02-28			2024-03-02	2024-03-31	ELECTRICALLY SLIDING
3	Dot	2024-02-01	2024-02-28	10 MG NORTEÑO QD	10 MG NORTEÑO QD	2024-02-03	2024-12-31	POLKA DOTS
4	Dot	2024-02-01	2024-02-28	10 MG NORTEÑO QD	10 MG NORTEÑO QD	2024-02-04	2024-02-05	TWISTING AND SHOUTING
5	Dot	2024-02-01	2024-02-28	10 MG NORTEÑO QD	10 MG NORTEÑO QD	2024-02-05	2024-02-12	TWINKLE TOES
6	Lilith	2024-02-01	2024-02-28	10 MG NORTEÑO QD	20 MG NORTEÑO QD	2024-02-01	2024-02-03	JAZZ HANDS
7	Lilith	2024-02-01	2024-02-28	10 MG	20 MG	2024-02-23	2024-02-26	HUSTLING
8	Loki							
9	Loki							

VARIABLE NAME	VARIABLE LABEL	TYPE	LENGTH	SOURCE	DERIVATION
TRTP	Planned Treatment	Char	16	DM.ARM	Set to ADSL.TRT01P if TRTSDT <= ASTDT <= TRTEDT + 1 day. Otherwise leave null.
TRTA	Actual Treatment	Char	16	Derived	Set to ADSL.TRT01A if TRTSDT <= ASTDT <= TRTEDT + 1 day. Otherwise leave null.

Incomplete ADAE Data

#	USUBJID	TRTSDT	TRTEDT	TRTP	TRTA	ASTDT	AENDT	AETERM
	Subject ID	Date of First Exposure to Treatment	Date of Last Exposure to Treatment	Planned Treatment	Actual Treatment	Analysis Start Date	Analysis End Date	Dictionary-Derived Term
1	Chewy	2024-02-01	2024-02-28	20 MG NORTEÑO QD	20 MG NORTEÑO QD	2024-02-01	2024-02-09	RESTLESS LEG SYNDROME
2	Chewy	2024-02-01	2024-02-28			2024-03-02	2024-03-31	ELECTRICALLY SLIDING
3	Dot	2024-02-01	2024-02-28	10 MG NORTEÑO QD	10 MG NORTEÑO QD	2024-02-03	2024-12-31	POLKA DOTS
4	Dot	2024-02-01	2024-02-28	10 MG	10 MG	2024-02-04	2024-02-05	TWISTING AND SHOUTING

	Adult Equivalent Dose of Norteño				
5	5 mg QD	10 mg QD	20 mg QD	Total	**ADAE.TRTA**
6	(N=xx)	(N=xx)	(N=xx)	(N=xxx)	
7					
8	Subjects reporting at least one treatment-emergent adverse event, n (%)				**ADAE.AEDECOD**
9					
	Restless leg syndrome	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Dance fever	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Introducing DOSing Variables!

VARIABLE NAME	VARIABLE LABEL	TYPE	CODELIST/ CT	CORE	CDISC NOTES
DOSEP	Planned Treatment Dose	Num		Perm	DOSEP represents the planned treatment dosage associated with the record.
DOSCUMP	Cumulative Planned Treatment Dose	Num		Perm	Cumulative planned dosage of treatment for the subject at the point in time of the record (e.g., ADT).
DOSEA	Actual Treatment Dose	Num		Perm	DOSEA represents the actual treatment dosage associated with the record.
DOSCUMA	Cumulative Actual Treatment Dose	Num		Perm	Cumulative actual dosage of treatment for the subject at the point in time of the record (e.g., ADT).
DOSEU	Treatment Dose Units	Char		Perm	The units for DOSEP, DOSCUMP, DOSEA, and DOSCUMA. It is permissible to use suffixes such as "P" and "A" if needed, with labels modified accordingly.

Source: ADAMIG v1.3 Table 3.3.2.2. Record-Level Dose Variables for BDS Data Sets

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ADAE Metadata

VARIABLE NAME	VARIABLE LABEL	TYPE	LENGTH	SOURCE	DERIVATION
TRTP	Planned Treatment	Char	16	Derived	Set to ADSL.TRT01P if TRTSDT <= ASTDT <= TRTEDT + 1 day.
TRTA	Actual Treatment	Char	16	Derived	Set to ADSL.TRT01A if TRTSDT <= ASTDT <= TRTEDT + 1 day.
DOSEP	Planned Treatment Dose	Num	8	Derived	Set to ADSL.DOSE01P if TRTSDT <= ASTDT <= TRTEDT + 1 day.
DOSEA	Actual Treatment Dose	Num	8	Derived	Set to ADSL.DOSE01A if TRTSDT <= ASTDT <= TRTEDT + 1 day.
DOSEU	Units for Dose	Char	2	Assigned	Set to ADSL.DOSE01U if TRTSDT <= ASTDT <= TRTEDT + 1 day.

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ADAE Metadata, with multiple treatment periods

VARIABLE NAME	VARIABLE LABEL	TYPE	LENGTH	SOURCE	DERIVATION
APERIOD	Period	Num	8	Derived	Set to 1 if AP01SDT <= ASTDT <= AP01EDT; else set to 2 if AP02SDT <= ASTDT <= AP02EDT; else set to 3 if AP03SDT <= ASTDT <= AP03EDT. Otherwise leave null.
TRTP	Planned Treatment	Char	16	Derived	Set to ADSL.TRTxxP, where xx is defined by the value of APERIOD.
TRTA	Actual Treatment	Char	16	Derived	Set to ADSL.TRTxxA, where xx is defined by the value of APERIOD.
DOSEP	Planned Treatment Dose	Num	8	Derived	Set to ADSL.DOSExxP, where xx is defined by the value of APERIOD.
DOSEA	Actual Treatment Dose	Num	8	Derived	Set to ADSL.DOSExxA, where xx is defined by the value of APERIOD.
DOSEU	Treatment Dose Units	Char	2	Assigned	Set to ADSL.DOSExxU, where xx is defined by the value of APERIOD.

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ADAE Data

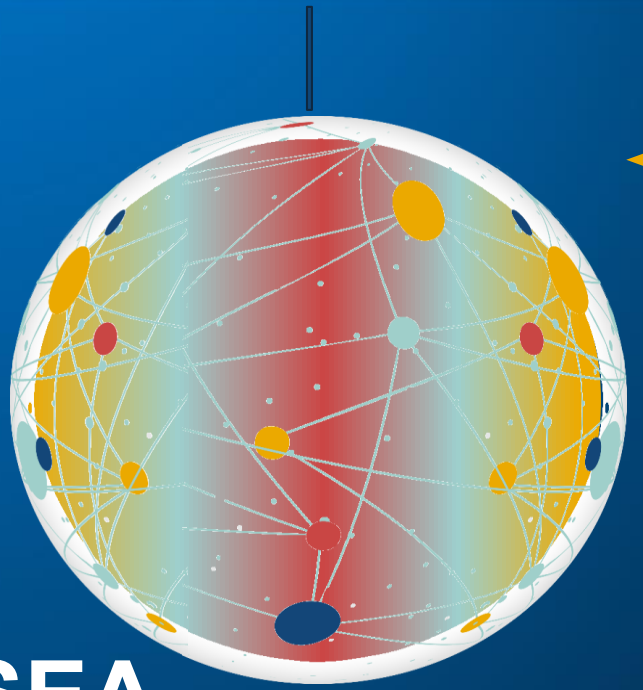
#	USUBJID	DOSEP	DOSEA	DOSEU	ASTDT	AENDT	AETERM
	Subject ID	Planned Treatment Dose	Actual Treatment Dose	Treatment Dose Units	Analysis Start Date	Analysis End Date	Dictionary-Derived Term
1	Chewy	10	10	MG	2024-02-01	2024-02-09	RESTLESS LEG SYNDROME
2	Chewy				2024-03-02	2024-03-31	ELECTRICALLY SLIDING
3	Dot	10	10	MG	2024-02-03	2024-12-31	POLKA DOTS
4	Dot	10	10	MG	2024-02-04	2024-02-05	TWISTING AND SHOUTING
5	Dot	10	10	MG	2024-02-05	2024-02-12	TWINKLE TOES
6	Lilith	2.5	5	MG	2024-02-01	2024-02-03	JAZZ HANDS
7	Lilith	2.5	5	MG	2024-02-23	2024-02-26	HUSTLING
8	Loki	1	1	MG	2024-02-01	2024-02-29	DANCE FEVER
9	Loki	1	1	MG	2024-02-06	2024-02-08	A LITTLE BOOGIE

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ADAE Data

#	USUBJID	DOSEP	DOSEA	DOSEU	ASTDT	AENDT	AETERM
	Subject ID	Planned Treatment Dose	Actual Treatment Dose	Treatment Dose Units	Analysis Start Date	Analysis End Date	Dictionary-Derived Term
1	Chewy	10	10	MG	2024-02-01	2024-02-09	RESTLESS LEG SYNDROME
2	Chewy				2024-03-02	2024-03-31	ELECTRICALLY SLIDING
3	Dot	10	10	MG	2024-02-03	2024-12-31	POLKA DOTS
4	Dot	10	10	MG	2024-02-04	2024-02-05	TWISTING AND SHOUTING
5	Dot	10	10	MG	2024-02-05	2024-02-12	TWINKLE TOES
6	Lilith	2.5	5	MG	2024-02-01	2024-02-03	JAZZ HANDS
7	Lilith	2.5	5	MG	2024-02-23	2024-02-26	HUSTLING
8	Loki	1	1	MG	2024-02-01	2024-02-29	DANCE FEVER
9	Loki	1	1	MG	2024-02-06	2024-02-08	A LITTLE BOOGIE

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Comparing DOSEP/DOSEA and DOSEON

Introducing DOSEON Variable!

VARIABLE NAME	VARIABLE LABEL	TYPE	CODELIST/ CT	CORE	CDISC NOTES
DOSEON	Treatment Dose at Record Start	Num		Perm	Dose received at the point in time of the record start date Example derivation: Obtained from EX.EXDOSE where --STDTC falls between the values of EX.EXSTDTC and EX.EXENDTC

Source: ADAM OCCDS v1.1 Table 3.2.7.1 Treatment/Dose Variables

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ADAE Metadata

VARIABLE NAME	VARIABLE LABEL	TYPE	LENGTH	SOURCE	DERIVATION
TRTP	Planned Treatment	Char	16	Derived	Set to ADSL.TRT01P if TRTSDT <= ASTDT <= TRTEDT + 1 day.
TRTA	Actual Treatment	Char	16	Derived	Set to ADSL.TRT01A if TRTSDT <= ASTDT <= TRTEDT + 1 day.
DOSEP	Planned Treatment Dose	Num	8	Derived	Set to ADSL.DOSE01P if TRTSDT <= ASTDT <= TRTEDT + 1 day.
DOSEA	Actual Treatment Dose	Num	8	Derived	Set to ADSL.DOSE01A if TRTSDT <= ASTDT <= TRTEDT + 1 day.
DOSEON	Treatment Dose at Record Start	Num	8	Derived	Obtained from EX.EXDOSE: if ASTDT falls between the values of EX.EXSTDTC and EX.EXENDTC then set to EX.EXDOSE (inclusive); otherwise set to last dose taken prior to ASTDT.
DOSEU	Units for Dose	Char	2	Assigned	Set to ADSL.DOSE01U if TRTSDT <= ASTDT <= TRTEDT + 1 day.

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ADAE Data

#	USUBJID	DOSEP	DOSEA	DOSEON	DOSEU	ASTDT	AENDT	AETERM
	Subject ID	Planned Treatment Dose	Actual Treatment Dose	Treatment Dose at Record Start	Treatment Dose Units	Analysis Start Date	Analysis End Date	Dictionary-Derived Term
1	Chewy	10	10	10	MG	2024-02-01	2024-02-09	RESTLESS LEG SYNDROME
2	Chewy			10		2024-03-02	2024-03-31	ELECTRICALLY SLIDING
3	Dot	10	10	10	MG	2024-02-03	2024-12-31	POLKA DOTS
4	Dot	10	10	10	MG	2024-02-04	2024-02-05	TWISTING AND SHOUTING
5	Dot	10	10	8	MG	2024-02-05	2024-02-12	TWINKLE TOES
6	Lilith	2.5	5	5	MG	2024-02-01	2024-02-03	JAZZ HANDS
7	Lilith	2.5	5	5	MG	2024-02-23	2024-02-26	HUSTLING
8	Loki	1	1	1	MG	2024-02-01	2024-02-29	DANCE FEVER
9	Loki	1	1	1	MG	2024-02-06	2024-02-08	A LITTLE BOOGIE



Thanks!

Questions?



Inka Leprince
InkaStat Solutions, LLC
leprince@inkastat.com

Richann Jean Watson
DataRich Consulting
richann.watson@datarichconsulting.com

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