



2026 Europe Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION



MILAN, ITALY | MAIN CONFERENCE: 20-21 MAY | TRAININGS & WORKSHOPS: 18, 19, & 22 MAY

Diary Data: Cracking EC & EX Challenges

Soundharavalli Sekar, Biostatistician, Zifo RnD Solutions

Speaker



Soundharavalli Sekar
Biostatistician
Zifo RnD Solutions

Mrs. Soundharavalli Sekar is a seasoned Biostatistician with a strong background in statistical programming and clinical data standards. She started her career at Zifo as a Statistical Programmer, where she supported more than 30 clinical studies across varied therapeutic areas and developed extensive expertise in CDISC standards and output quality review. In her current role, she leads end-to-end study execution with core competencies in Statistical Analysis Plans, SDTM, ADaM, and CSR TLFs for regulatory submissions. She has successfully managed and mentored teams of over five professionals and overseen 10+ global studies for clients across the US, Australia, and India, ensuring alignment with regulatory requirements. Her experience includes hosting data surveillance meetings, serving as a randomization manager, and driving quality gating processes. She is widely recognized for her strong client partnerships, effective cross-functional collaboration, and leadership in developing abstracts and conference presentations, consistently delivering high-quality, compliant outcomes.

Agenda

1. Capturing dosing through Diaries
2. Challenges in Diary-Based Dosing
3. What the Standards Require
4. Handling Diary Data in SDTM
5. Practical Example
6. Conclusion

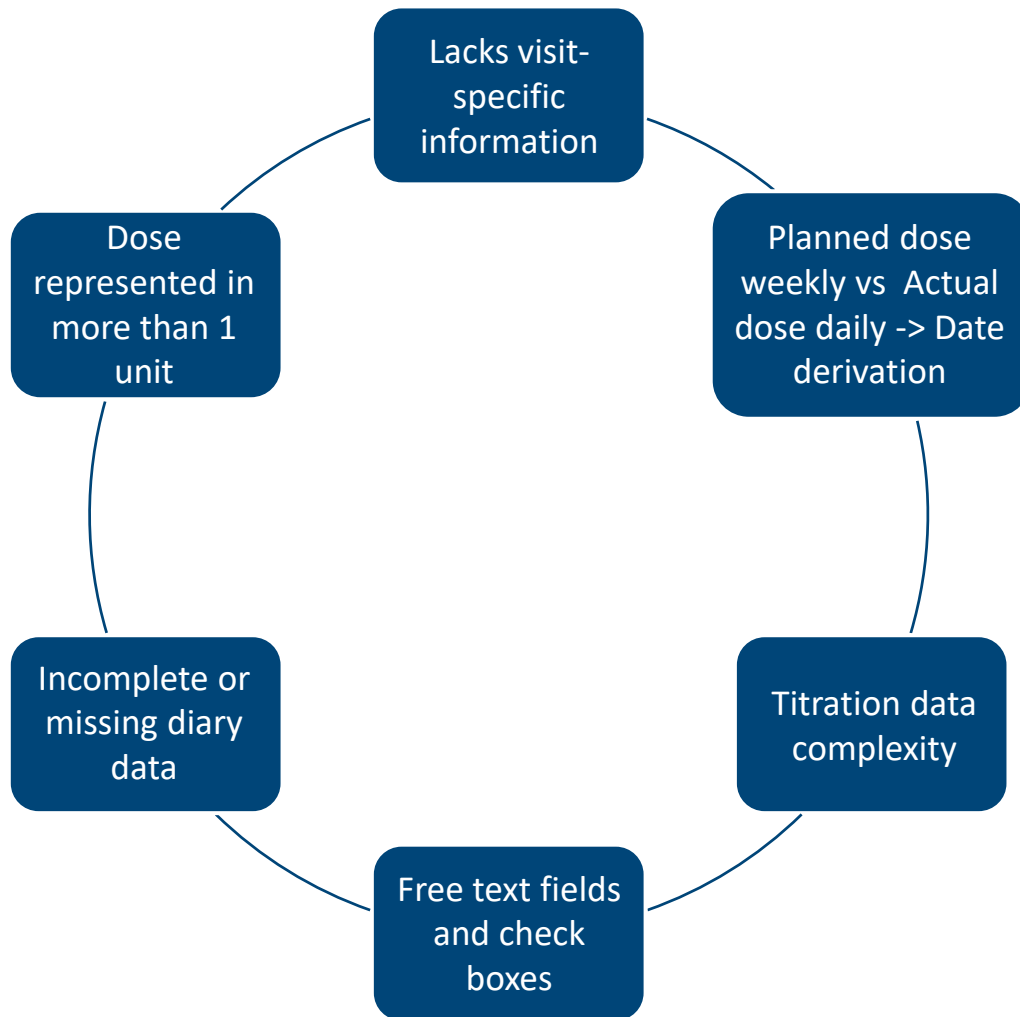


Capturing dosing through Diaries

- Dosing diaries capture real-world, daily medication intake beyond site visits, reflecting participant-recorded data.
- Participants record information as events happen
- Reduces recall bias compared to reporting during site visits



Challenges in Diary-Based Dosing





What the Standards Require?

Clear distinction between planned and performed dosing

Consistent and standardized dose representation

Accurate start and end dates for dosing records

Proper handling of missing or unconfirmed dosing

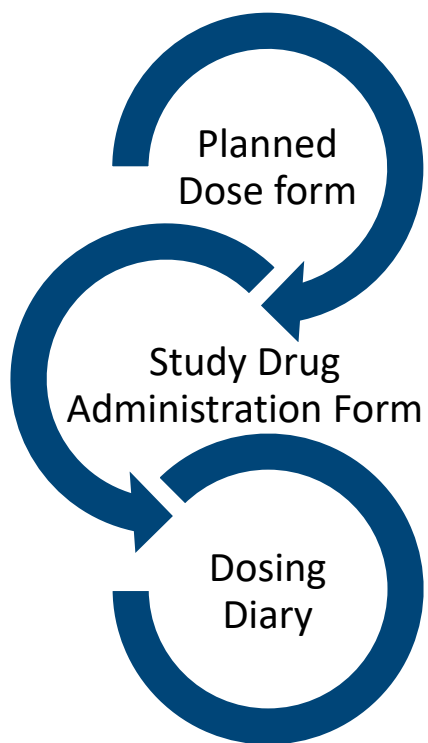




Handling Diary Data in SDTM



Consider a scenario where dosing data is collected from 3 sources: the drug is administered once during a clinic visit, while the remaining doses are taken at home and recorded in a patient diary. Additionally, the planned dose for each participant is maintained in a separate dataset.



Test scenario



Reason for Change	☐ Titration ☐ Tapering / Washout ☐ Other
If Other, Specify	_____
Dose Level (mg/kg)	_____ mg/kg
Planned Dose (mg)	_____ mg
Planned Dose Volume (mL)	_____ mL
Planned Start Date	___ / ___ / ____
Planned Administration Time Period	☐ Morning ☐ Evening

Planned Dose Form



Was the study drug administered?	☐ Yes ☐ No
If No, Reason Not Done	
Date of Administration	/ /
Time of Administration (HH:MM)	:
Administration Time Period	☐ Morning ☐ Evening
Dose Volume (mL)	mL
Were there any issues with administration?	☐ Yes ☐ No
If Yes, Specify Issue	

Study Drug Administration Form



Participant Information

- Participant ID: _____
- Study ID / Protocol No.: _____
- Site Number: _____
- Cohort Number: _____



Daily Dosing Record

Field	Day 1 – AM	Day 1 – PM	Day 2 – AM
Date			
Time			
Dose Taken ☐	☐	☐	☐
Dose Volume (mL)			

Dosing Diary

Planned
Dosing

- “SCHEDULED” records
- Planned start date sourced from PD form
- End date derived from subsequent planned start date

Performed
dosing

- Clinical visit dosing – with mapped visit info
- Dosing Diary records – without visit, differentiated using ECCAT = “DOSING DIARY”

Dosing Diary
not returned
or completed

- ECOCCUR = N
- ECREASOC = Diary Not Completed / Returned

Practical Strategies

Dose Level
Changes

- Titration → ECADJ
- Other reasons → ECADJOTH (SUPPEC)

Dose Units

Dose volume (mL) → ECDOSE / ECDOSU
Dose strength (mg) → ECPSTRG /
ECPSTRGU
Protocol dose (mg/kg) → SUPPEC

Practical Strategies



The final SDTM EC dataset

Test scenario

	USUBJID	ECSEQ	ECMOOD	ECCAT	ECPRESP	EOCCUR	ECREASOC	ECDOSE	ECDOSU	ECPSTRG	ECPSTRGU	ECADJ	VISIT	ECSTDTC	ECENDTC	ECTPT
1	ABC	1	SCHEDULED					6 mL		60 mg			Clinic Visit 1	2025-03-13	2025-03-19	
2	ABC	2	PERFORMED	CLINIC ADMINISTRATION	Y	Y		6 mL		.			Clinic Visit 1	2025-03-13T10:15	2025-03-13T10:15	MORNING
3	ABC	3	PERFORMED	DOSING DIARY	Y	Y		6 mL		.			Clinic Visit 1	2025-03-13T17:00	2025-03-13T17:00	EVENING
4	ABC	4	PERFORMED	DOSING DIARY	Y	Y		6 mL		.				2025-03-14T11:00	2025-03-14T11:00	MORNING
5	ABC	5	PERFORMED	DOSING DIARY	Y	N	Evening Dose Not Taken	.		.				2025-03-14	2025-03-14	EVENING
6	ABC	6	PERFORMED	DOSING DIARY	Y	N	Diary Not Completed / Returned	.		.				2025-03-15	2025-03-15	
7	ABC	7	PERFORMED	DOSING DIARY	Y	N	Diary Not Completed / Returned	.		.				2025-03-16	2025-03-16	
8	ABC	8	PERFORMED	DOSING DIARY	Y	N	Diary Not Completed / Returned	.		.				2025-03-17	2025-03-17	
9	ABC	9	PERFORMED	DOSING DIARY	Y	N	Diary Not Completed / Returned	.		.				2025-03-18	2025-03-18	
10	ABC	10	PERFORMED	DOSING DIARY	Y	Y		6 mL		.				2025-03-19T10:30	2025-03-19T10:30	MORNING
11	ABC	11	PERFORMED	DOSING DIARY	Y	Y		6 mL		.				2025-03-19T18:20	2025-03-19T18:20	EVENING
12	ABC	12	SCHEDULED					8.5 mL		85 mg		Titration	Clinic Visit 2	2025-03-20	2025-03-21	
13	ABC	13	PERFORMED	CLINIC ADMINISTRATION	Y	Y		8.5 mL		.			Clinic Visit 2	2025-03-20T10:20	2025-03-20T10:20	MORNING
14	ABC	14	PERFORMED	DOSING DIARY	Y	N	Evening Dose Not Taken	.		.			Clinic Visit 2	2025-03-20	2025-03-20	EVENING
15	ABC	15	PERFORMED	DOSING DIARY	Y	N	Diary Not Completed / Returned	.		.				2025-03-21	2025-03-21	
16	ABC	16	SCHEDULED					7.5 mL		75 mg		Other	Unscheduled 3.01	2025-03-22	2025-03-26	
17	ABC	17	PERFORMED	CLINIC ADMINISTRATION	Y	N		.		.			Unscheduled 3.01	2025-03-22	2025-03-22	MORNING
18	ABC	18	PERFORMED	DOSING DIARY	Y	Y		7.5 mL		.			Unscheduled 3.01	2025-03-22T18:15	2025-03-22T18:15	EVENING
19	ABC	19	PERFORMED	DOSING DIARY	Y	N	Diary Not Completed / Returned	.		.				2025-03-23	2025-03-23	
20	ABC	20	PERFORMED	DOSING DIARY	Y	N	Diary Not Completed / Returned	.		.				2025-03-24	2025-03-24	
21	ABC	21	PERFORMED	DOSING DIARY	Y	N	Diary Not Completed / Returned	.		.				2025-03-25	2025-03-25	
22	ABC	22	PERFORMED	DOSING DIARY	Y	Y		7.5 mL		.				2025-03-26T10:00	2025-03-26T10:00	MORNING
23	ABC	23	PERFORMED	DOSING DIARY	Y	Y		7.5 mL		.				2025-03-26T18:00	2025-03-26T18:00	EVENING
24	ABC	24	SCHEDULED					8 mL		80 mg		Titration	Clinic Visit 3	2025-03-27	2025-04-02	

The final SDTM
SUPPEC dataset

	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL
1	ABC	ECSEQ	1	ECDOSLVL	Planned Dose Level	0.68 mg/kg BID
2	ABC	ECSEQ	2	ECADI	Any issues with administration	N
3	ABC	ECSEQ	13	ECDOSLVL	Planned Dose Level	1.10 mg/kg BID
4	ABC	ECSEQ	14	ECADI	Any issues with administration	N
5	ABC	ECSEQ	16	ECADJOTH	If Other, Please Specify Adj Reason	IP reduced due to AE-1 and AE #3
6	ABC	ECSEQ	16	ECDOSLVL	Planned Dose Level	0.87 mg/kg BID
7	ABC	ECSEQ	17	ECADI	Any issues with administration	Y
8	ABC	ECSEQ	17	ECADISP	Administration issue specify	Dose was not administered due to sudden AE just before giving the drug

The final SDTM EX dataset

	USUBJID	EXSEQ	EXCAT	EXDOSE	EXDOSU	VISIT	EXSTDTC	EXENDTC	EXTPT
1	ABC	1	CLINIC ADMINISTRATION	6 mL		Clinic Visit 1	2025-03-13T10:15	2025-03-13T10:15	MORNING
2	ABC	2	DOSING DIARY	6 mL		Clinic Visit 1	2025-03-13T17:00	2025-03-13T17:00	EVENING
3	ABC	3	DOSING DIARY	6 mL			2025-03-14T11:00	2025-03-14T11:00	MORNING
4	ABC	4	DOSING DIARY	6 mL			2025-03-19T10:30	2025-03-19T10:30	MORNING
5	ABC	5	DOSING DIARY	6 mL			2025-03-19T18:20	2025-03-19T18:20	EVENING
6	ABC	6	CLINIC ADMINISTRATION	8.5 mL		Clinic Visit 2	2025-03-20T10:20	2025-03-20T10:20	MORNING
7	ABC	7	DOSING DIARY	7.5 mL		Unscheduled 3.01	2025-03-22T18:15	2025-03-22T18:15	EVENING
8	ABC	8	DOSING DIARY	7.5 mL			2025-03-26T10:00	2025-03-26T10:00	MORNING
9	ABC	9	DOSING DIARY	7.5 mL			2025-03-26T18:00	2025-03-26T18:00	EVENING



Conclusion

This example illustrates how diary-based dosing challenges were addressed and incorporated into SDTM while preserving clarity, traceability, and standards alignment.





Thank You!





Questions?

