

PP11 - Implementation of a bespoke SDTM to facilitate analysis of pooled standardised datasets

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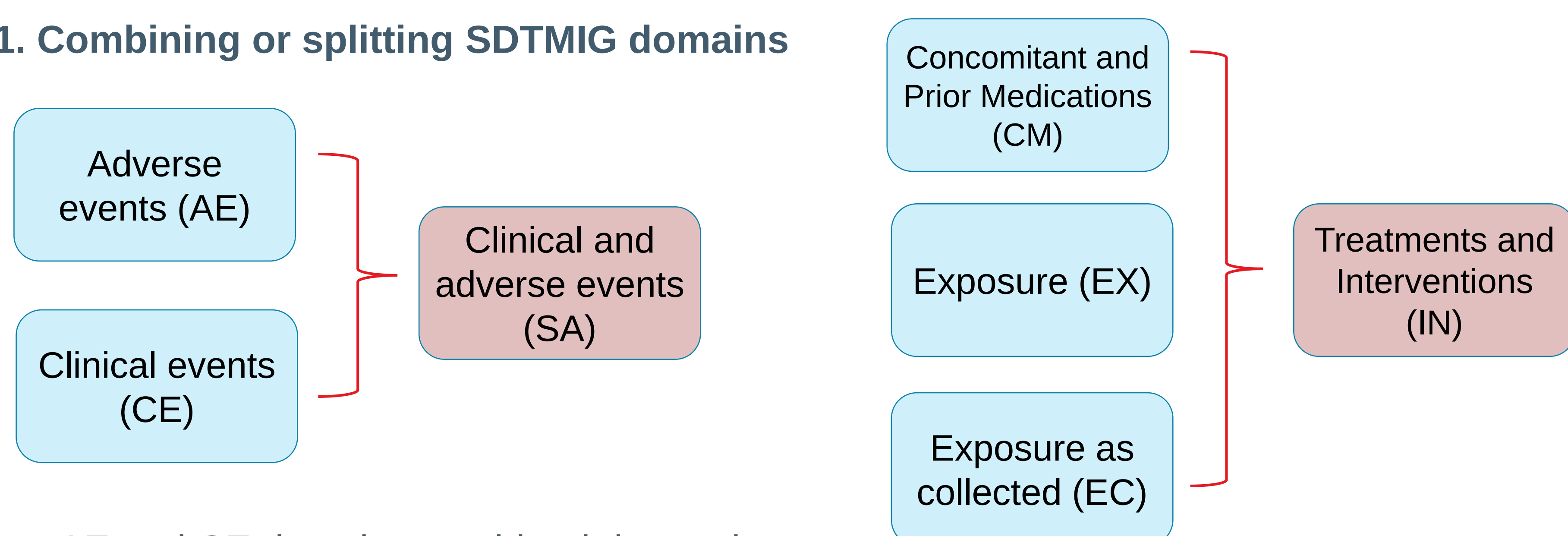
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Background

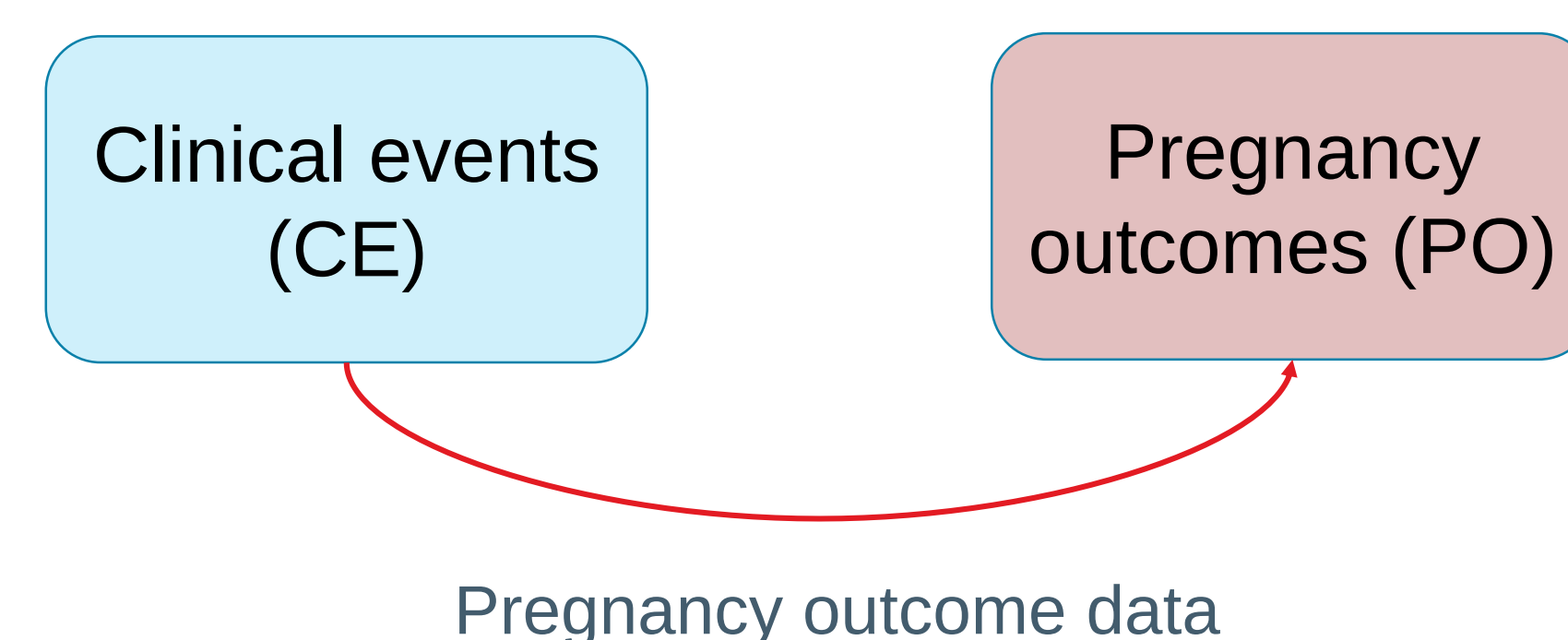
- IDDO standardises existing clinical trial and observational data from studies contributed globally, focusing on emerging and neglected infections.
- The contributed datasets are diverse in their design, structure, and format, requiring conversion to a single data standard to facilitate pooling and meta-analysis to answer questions only possible through collaborative analysis.

Results

1. Combining or splitting SDTMIG domains



- AE and CE domains combined due to the diversity and ambiguity of contributed data.
- Any events not in SDTM AE domain cannot be defined as definitely not adverse events.
- Domains are combined to avoid misinterpretation of data.
- CM, EX and EC domains are combined to facilitate analysis by using fewer linked tables.

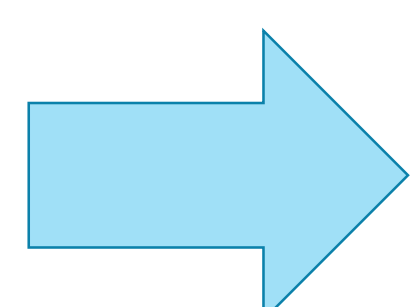


USUBJID	POTERM	POCAT	POSTDY	POENDY
A_B_1001	Live Birth	PREGNANCY OUTCOME	4	
A_B_1001	Pregnancy			4

- PO domain formed by extracting pregnancy outcome data from CE domain.
- Facilitate specific pregnancy-related analyses.

2. Creating timing variables

Patient_id	Day3_temp	Day7_temp	Day10_temp
1001	38.4	38.1	37.5
1002	37.9	36.8	36.9



USUBJID	VSTESTCD	VSORRES	VSORRESU	VSDY	VISIT	VSCDSTDY
A_A_1001	TEMP	38.4	C		Day 3	
A_A_1001	TEMP	38.1	C			7
A_A_1001	TEMP	37.5	C			10

- Contributed data does not always contain dates and may not be associated to a defined study visit from which we can derive timing variables (--DY, VISIT, VISITDY).
- Without timing variables, we have rows that appear duplicated with no indication of when a finding or event occurred.
- Day 3 is a defined planned study visit therefore VISIT, VISITNUM and VISITDY can be used.
- Day 7 and Day 10 are unplanned visits
- The variable --CDSTDY, the Contributor-Defined Study Day, was created to add timing to these unplanned visit findings where no dates have been provided.

3. Creating controlled terminology

- IDDO's SDTM Implementation Manual has expanded on the existing controlled terminology dictionaries to ensure consistency within the datasets.
- To cover the diversity of microorganisms reported in the contributed datasets, controlled terminology has been defined for MBTEST and MBTESTCD and submitted to NCI for approval.

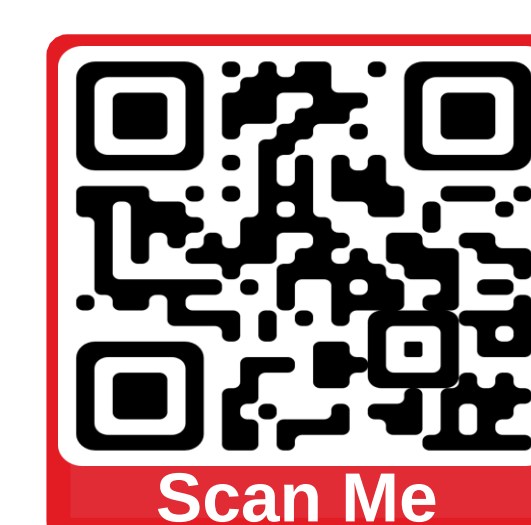
4. Combining variables from another domain

USUBJID	INTRT	FATGIVEN
A_B_1001	ARTEMETHER	Y
A_B_1002	ARTESUNATE	

- Antimalarial treatments are often given with a small snack to prevent adverse side effects.
- To prevent the need for using the MEALS domain to specifically capture this data, the FATGIVEN variable was created and added to the Treatments and Interventions (IN) domain.

Conclusion

- IDDO's bespoke use of CDISC SDTM has been tailored to meet the needs of our analysis partners, aiming to keep linkage across domain tables to a minimum whilst avoiding over-interpretation of the diverse datasets contributed to the data platform.
- Future analyses involving new disease themes or new study groups may require re-evaluation and further development of IDDO's SDTM Implementation Manual.
- A customisable checking tool is being developed to facilitate the application of IDDO's SDTM Implementation Manual.



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