## Challenges in Legacy Data Mapping to SDTM Exposure Domains for Topical Drug Studies

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DDPD, ODE3, CDER, FDA, Silver Spring, MD 20993

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### Results (Continued)

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### Results

- Upon the scenario of photo-irritation study, SDTM EX domain was converted as shown below. To resolve the incomplete presentation of exposure data in EX domain, UV light exposure as a treatment was presented under EXTRT, with EXCSTM0U distinguishing the several treatment categories. EXLOC was used for sub-sites of the applications. The standard patch test provided adequate dosage for each application for the EXDOSE and EXDOSU.

- In the example of HPA axis suppression study, there is an important time factor in the injection of the stimulant in relation to blood draw (cortisol levels before and 30 minutes after administration of a stimulant, ACTH (cosyntropin)). To complete EX domain conversion, cosyntropin should be counted as a treatment under EXTRT and captured under EXCAT as stimulant. The EC domain is not shown since it would be exact duplicate of EX domain (shown as below).

- The study involved ACH (cosyntropin) Stimulation Test to measure how well adrenal glands respond to adrenocorticotrophic hormone (ACTH) after treatments.

- The study involved clinical trial for a topical therapy for 14 consecutive days. At the Week 1 and 2 visits, study professionals reviewed the subject’s daily diary and collected all used and unused containers. Each container of study medication dispensed to the subjects was weighed before dispensing and again upon return: weights were recorded in the CRF.

### Conclusions

- We have presented the challenges and proposed solutions in converting legacy data into SDTM EX and EC domains in topical drug studies. It may require sponsors additional considerations when mapping collected drug exposure data to 20TM EX and EC domains according to CDISC SDTMv3.2.

- The remedies for deficiencies in data collection and data management can be addressed up front, in the design of protocol and the CRF. This will ensure that one obtains the most accurate picture of study drug exposure.

- Experience gained in conversion here may be helpful in the consideration of therapeutic area standards and industry EX domain submissions for dermatologic conditions.

### Acknowledgements

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