

# COLLABORATIVE LEARNING CODEBOOK

**Form: Protocol Deviation**  
**(raw data)**

**DATE CREATED 22JUN18**

**Number of Observations: 17**

**Number of Variables: 10**

**Organization of file: One Record per Patient**

Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
Blind Subject ID	BLIND_ID			17(0)	53471.35(279.63)	53359.00(53272.00,53754.00)	53030.00-53835.00
Visit ID	VISITID	50	17(100.0)				
Days between Protocol Deviation and procedure	PD_D_DAY			13(4)	387.54(213.96)	313.00(250.00,621.00)	52.00-659.00
2a. Enrollment of a subject who did not meet all inclusion/exclusion criteria	INC_EXC	Yes	17(100.0)				
2b. Enrolling a subject after IRB approval expired	IRB_EXP	No	17(100.0)				
2c. Performing study procedure not approved by the IRB	NOT_APPRVD	No	17(100.0)				
2d. Failure to perform study procedure as outlined in protocol	STUDY_PROC	No	17(100.0)				
2e. Study procedures and/or assessments performed prior to obtaining or reaffirming written informed consent.	NO_CNST	No	17(100.0)				
2f. Obtaining informed consent with outdated / expired consent document	EXP_DOCUMENT	No	17(100.0)				

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2g. Other	OTHER	No	17(100.0)				