

The JumpStart Flag Validator Tool

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Background

Flag variables found in ADaM datasets are commonly used in analyses; however frequently these flags are not consistently derived and may lengthen the review process. In order to provide reviewers confidence in using sponsor provided flags in analyses the Flag Validator Tool (FVT) was developed. The FVT is a R Shiny application that validates the accuracy of flags submitted in a product application. The tool currently supports the validation of the Safety Population Flag and Randomized Population Flag within the ADSL and the Treatment Emergent Flag within the ADAE. This poster highlights the tool's high-level methodology and provides examples of flag validations to help reviewers and sponsors understand the impact of confirming the accuracy of the flags submitted



Methodology

The JumpStart FVT is a customizable and flexible application that checks for consistency between the applicant's Define.xml file description of the flag derivation and what is reflected in the datasets. The tool which is customized to the application under review allows the user to input datasets, variables, and conditional statements that best align with the applicant's derivation of flags. The tool also allows for the user to select from a list of common derivations to more easily validate these derivations. A flag is then derived in the tool using the logic inputted by the user and compared to the applicant's flag. Users then can download the list of mismatches to investigate the source of the discrepancies. .

A high-level summary of the FVT process can be found in the figure below:



Treatment Emergent Flag

A common Treatment Emergent Flag derivation is:
'Set TRTEMFL = 'Y' when the Adverse Event Start

Date/Time occurs on or after the Treatment Start Date/Time.'

ADSL					ADAE					Flag Validator
USUBJID	ACTARM	TRTSDT	TRTSDTM	SAFFL	AESEQ	AEDECOD	ASTDT	ASTDTM	TRTEMFL	
ABC123	TRTA	04Feb2019	04Feb2019 11:30:00 AM	Y	1	Nausea	04Feb2019	04Feb2019 2:00:00 PM	N	Y

JumpStart: The FVT identifies records in the ADAE dataset in which the adverse event occurs after treatment start yet TRTEMFL is equal to 'N'. In the example above, the time of the event was *after* the time of treatment start, therefore the tool derived the flag to equal 'Y' and this event should be included in treatment emergent adverse event analyses. However, with the current flag provided by the applicant, this adverse event will be excluded from treatment emergent analyses and may warrant the flag to be re-derived.



Safety Population Flag

A common Safety Population Flag derivation is:
'Set SAFFL = 'Y' where TRTSDT is not missing.'

ADSL				EX					Flag Validator
USUBJID	TRT01A	TRTSDT	SAFFL	EXSEQ	EXTRT	EXDOSE	EXDOSEU	EXSTDTC	
ABC321	TRTB	13Mar2020	Y	1	TRTB	4	mg	13Mar2020	Y

Safety Population Flag		FVT Results	
SAFFL		Y	N
Y		549 (40.28%)	0 (0%)
N		0 (0%)	814 (59.72%)

JumpStart: The FVT derived Safety Population Flag and the applicant provided SAFFL match. The reviewer can confidently utilize the applicant's SAFFL in analyses, to include all subjects exposed to the treatment drug.



Randomized Population Flag

The tool also supports custom derivations such as:
'Set RANDFL to Y if ENRFL = 'Y' and SCRFL is not 'Y' and RANDDT is not missing; N otherwise.'

ADSL									Flag Validator
USUBJID	TRT01P	TRT01A	RANDDT	TRTSDT	RANDFL	ENRFL	SCRFL	SAFFL	
ABC321	TRTB	TRTB	10Mar2020	13Mar2020	Y	Y	N	Y	Y

Randomized Population Flag		FVT Results	
RANDFL		Y	N
Y		554 (40.65%)	0 (0%)
N		0 (0%)	809 (59.35%)

JumpStart: The FVT derived Randomized Population Flag and the sponsor provided RANDFL match. The reviewer can confidently utilize RANDFL to identify subjects who were randomized to a treatment.