

Quick Checks for Quick Dataset Review

Gauri Khatu, Cytel, India



Obtain information of interest from **LARGE** datasets with minimum efforts and time



Gather
Inputs

Select
Domain

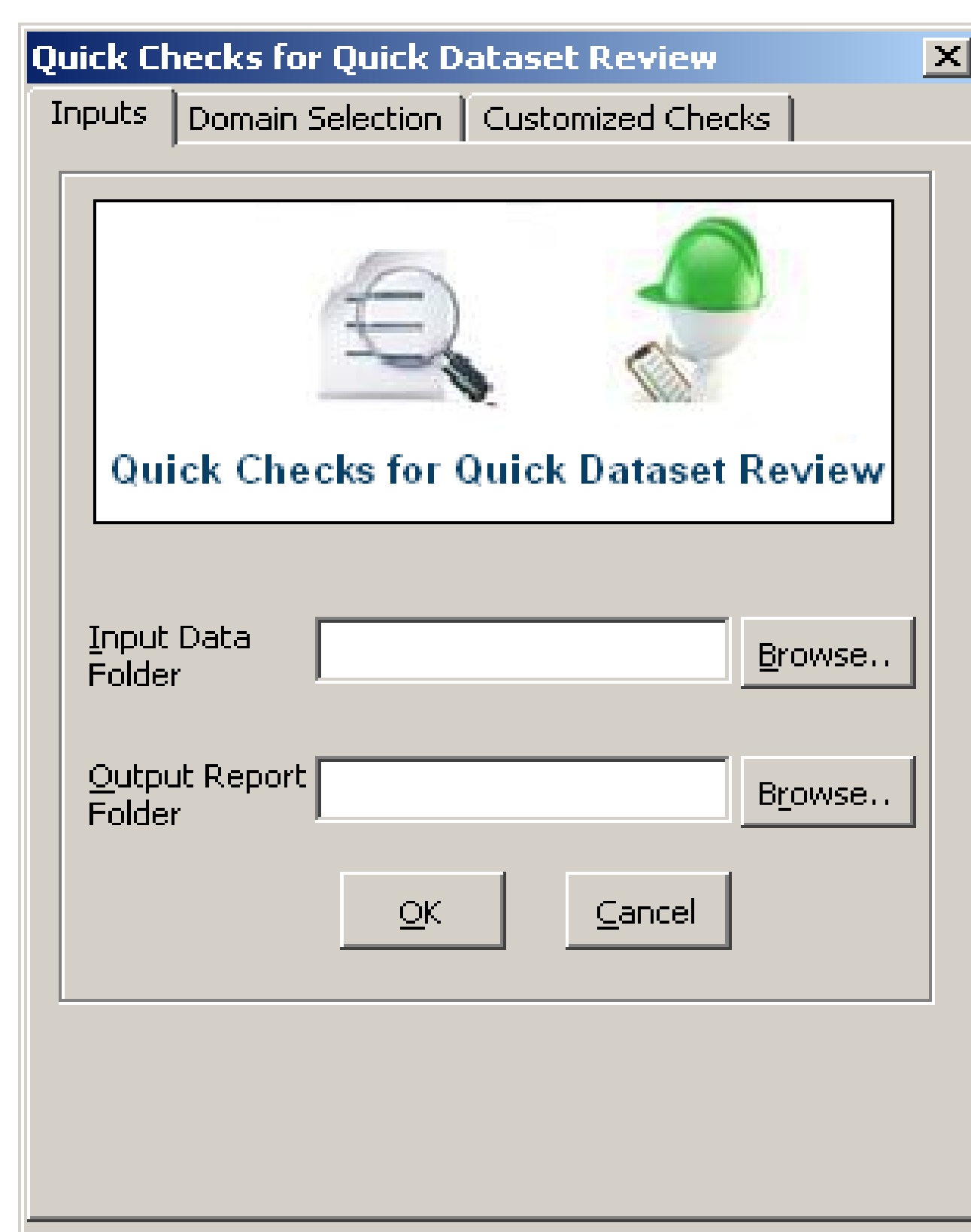
Select Checks
to perform

Define Custom
Checks

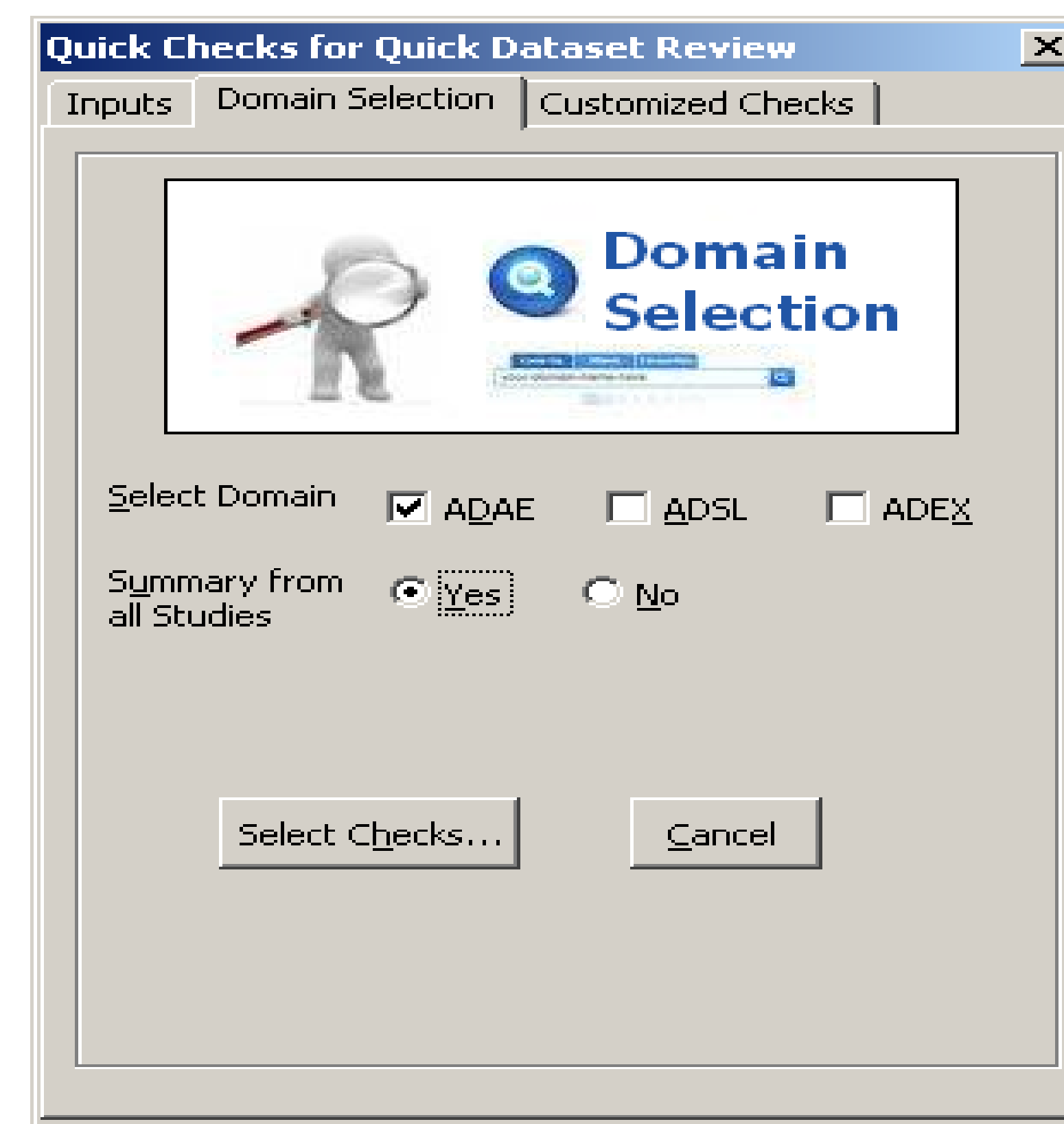
Generate
Report

Input Path

Output Path



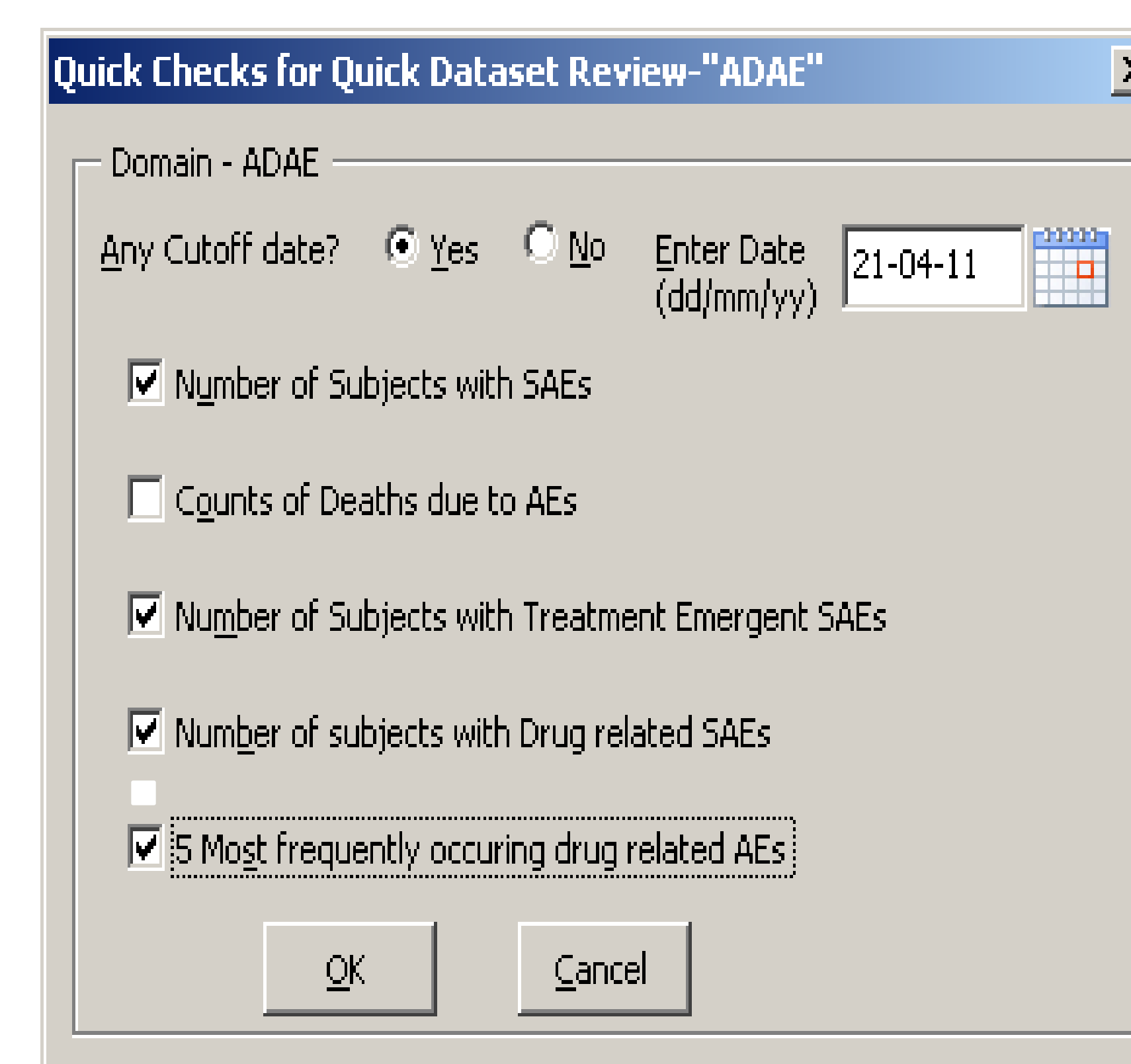
ADSL ADAE ADEX



Subjects with differing
planned and actual treatment

5 most frequent drug related AEs

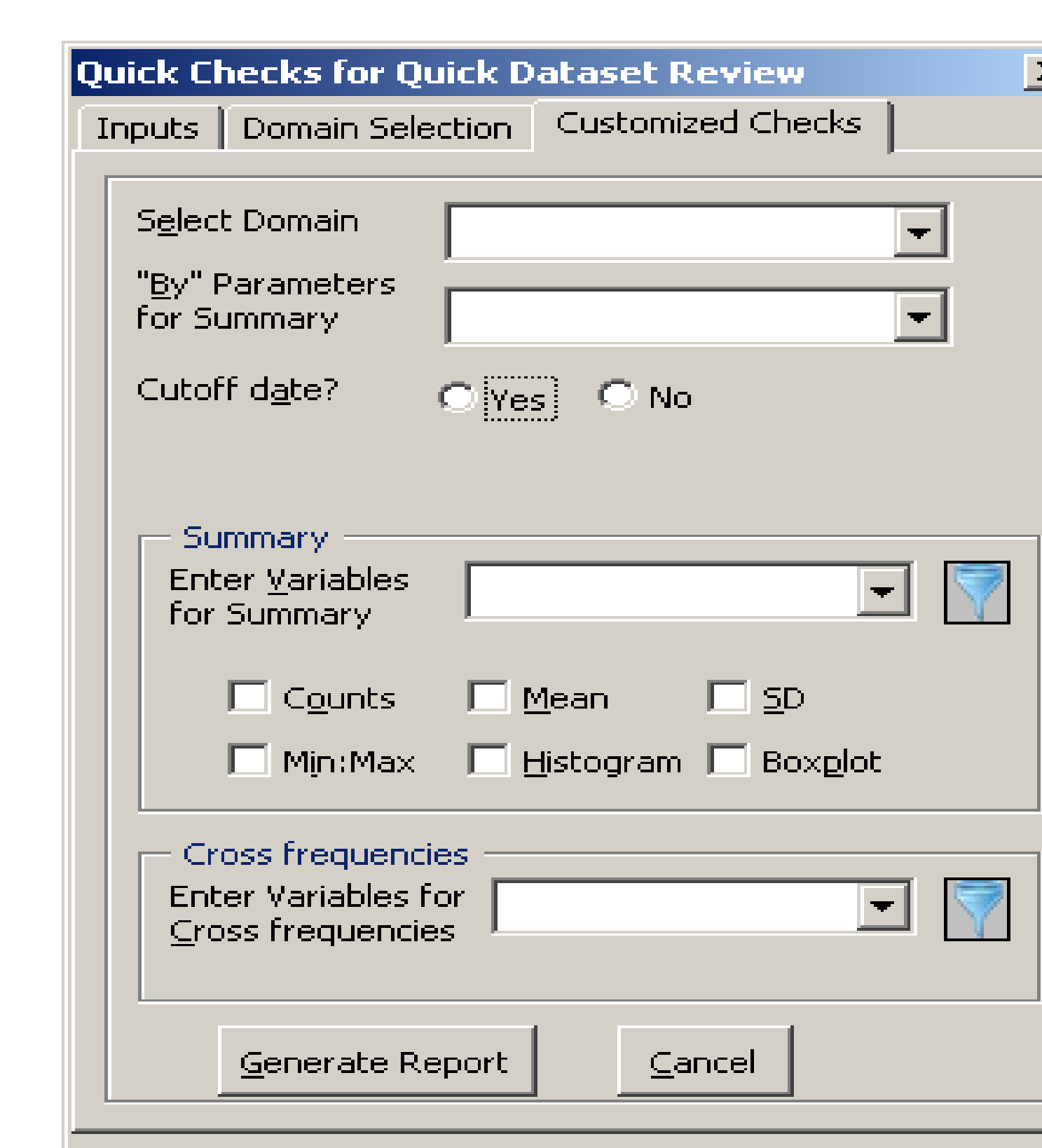
Subjects with dose reductions



Summary Statistics

Cross frequencies

Box plots



ADSL
.doc

ADAE
.doc

ADEX
.doc

Custom
.doc

Snapshot of ADAE.doc 06:45 Tuesday, October 01, 2013 1

Number of Subjects with SAEs

Analysis excludes observations beyond the cutoff date: 21 April 2011

STUDY=ABC-003

Obs	Treatment	Frequency Count	Percent of Total Frequency
1	Treatment 1	1	16.6667
2	Treatment 2	5	83.3333

STUDY=ABC-004

Obs	Treatment	Frequency Count	Percent of Total Frequency
3	Treatment 3	1	50
4	Treatment 4	1	50

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5 Most Frequently Occurring Drug Related AEs

Analysis excludes observations beyond the cutoff date: 21 April 2011

Obs	AEBODSYS	AEDCOD	COUNT	PERCENT
1	Gastrointestinal disorders	Nausea	20	20.6186
2	Gastrointestinal disorders	Vomiting	17	17.5258
3	Gastrointestinal disorders	Diarrhoea	12	12.3711
4	Gastrointestinal disorders	Abdominal pain	8	8.2474
5	Gastrointestinal disorders	Abdominal pain upper	5	5.1546
6	Nervous system disorders	Headache	5	5.1546

Benefits

- Increase in productivity
- No pre-requisite of SAS® programming knowledge

- Reusability
- Checks on important study numbers

Enhancements

- Add checks for other domains
- Flexibility for non-ADaM compliant inputs

- Shift tables
- AEs on or after one day of the infusion date.