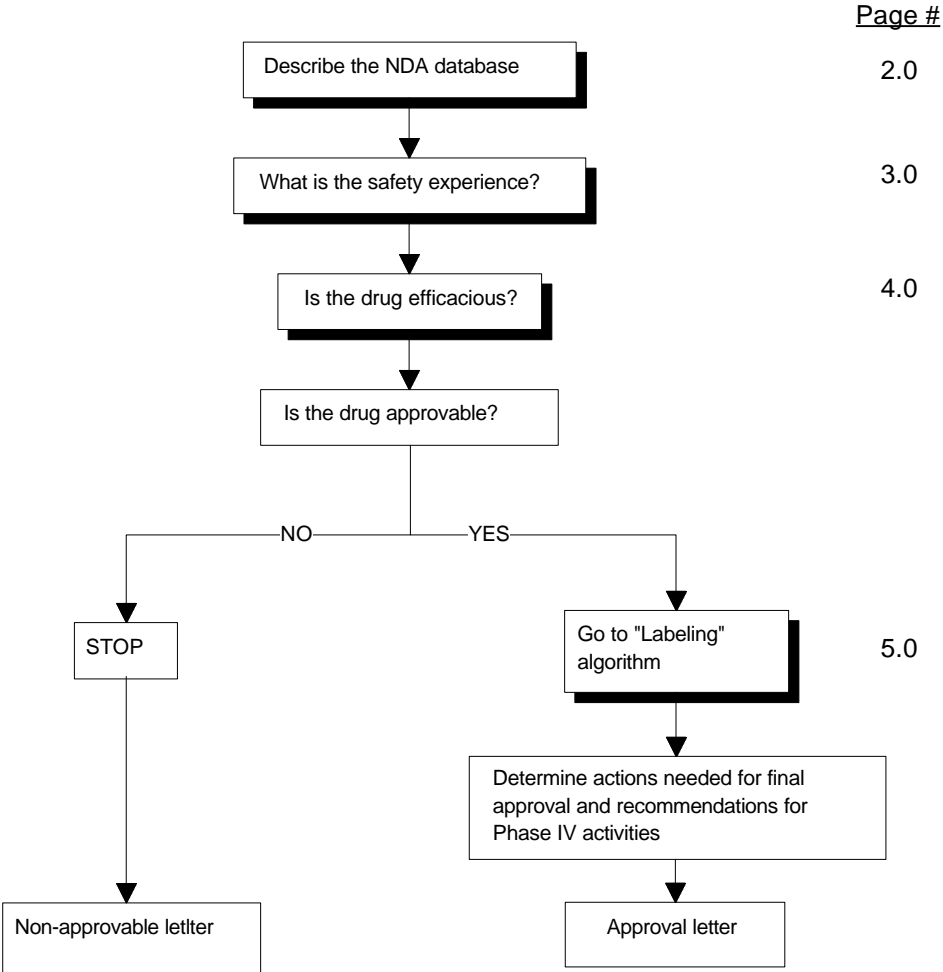


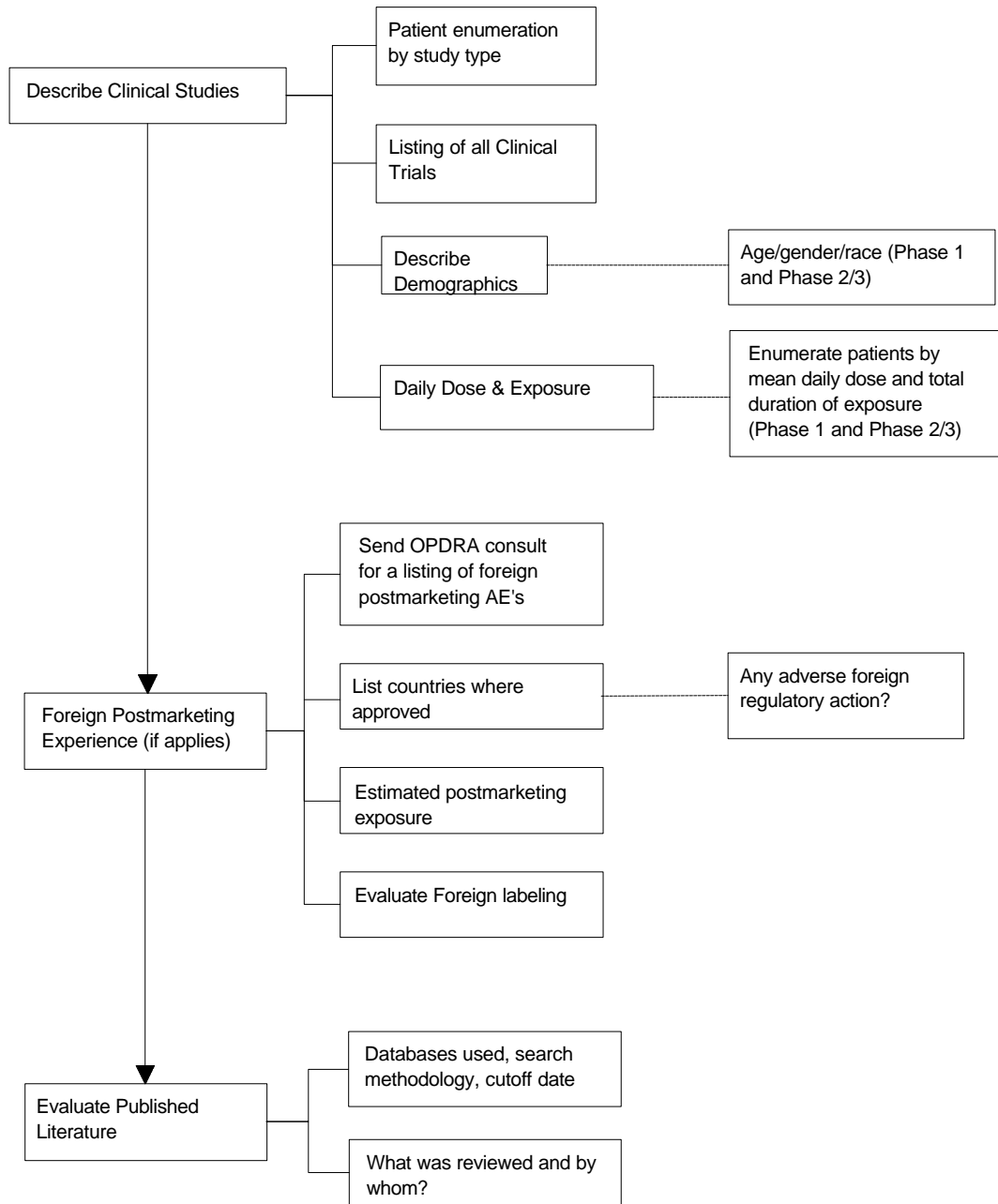
Outline for Performing NDA Review

Greg Dubitsky, MD, Division of Neuropharmacological Drug Products



4/22/99

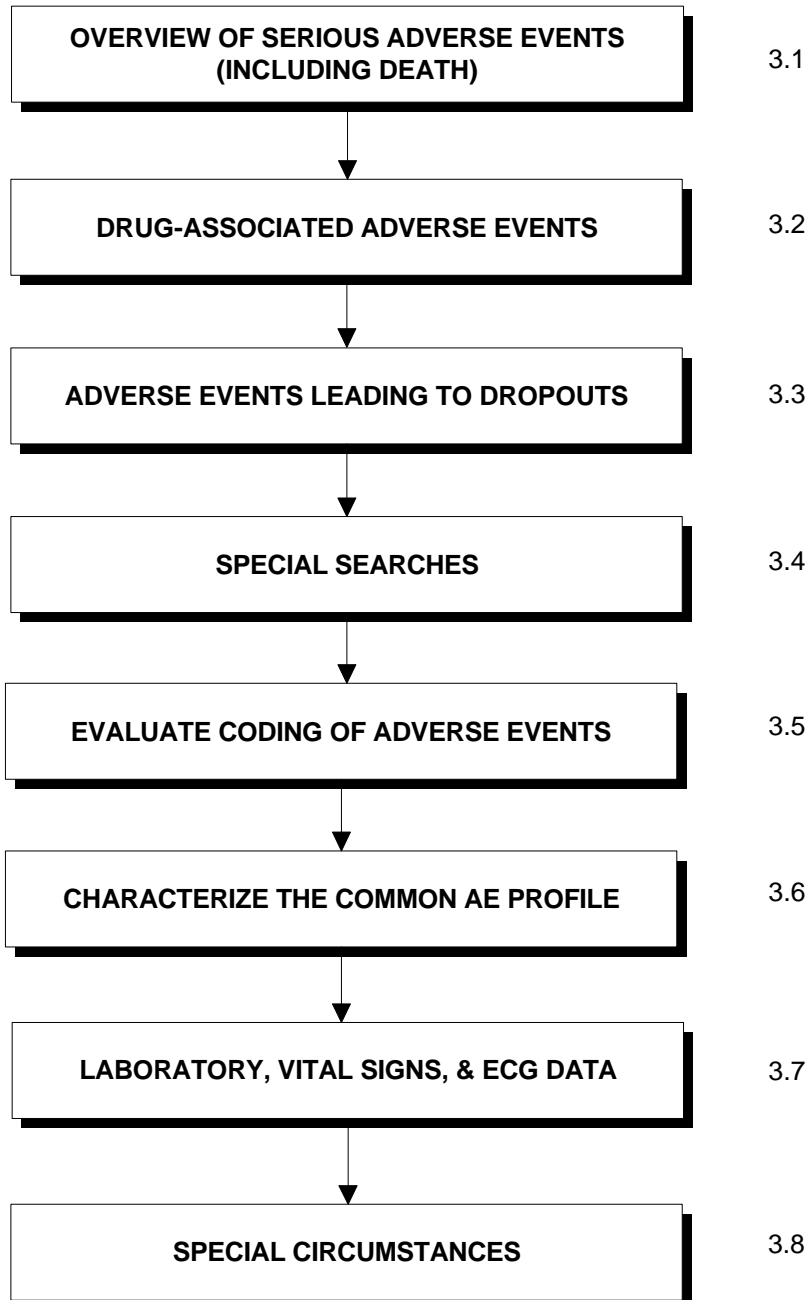
DESCRIBE THE DATABASE



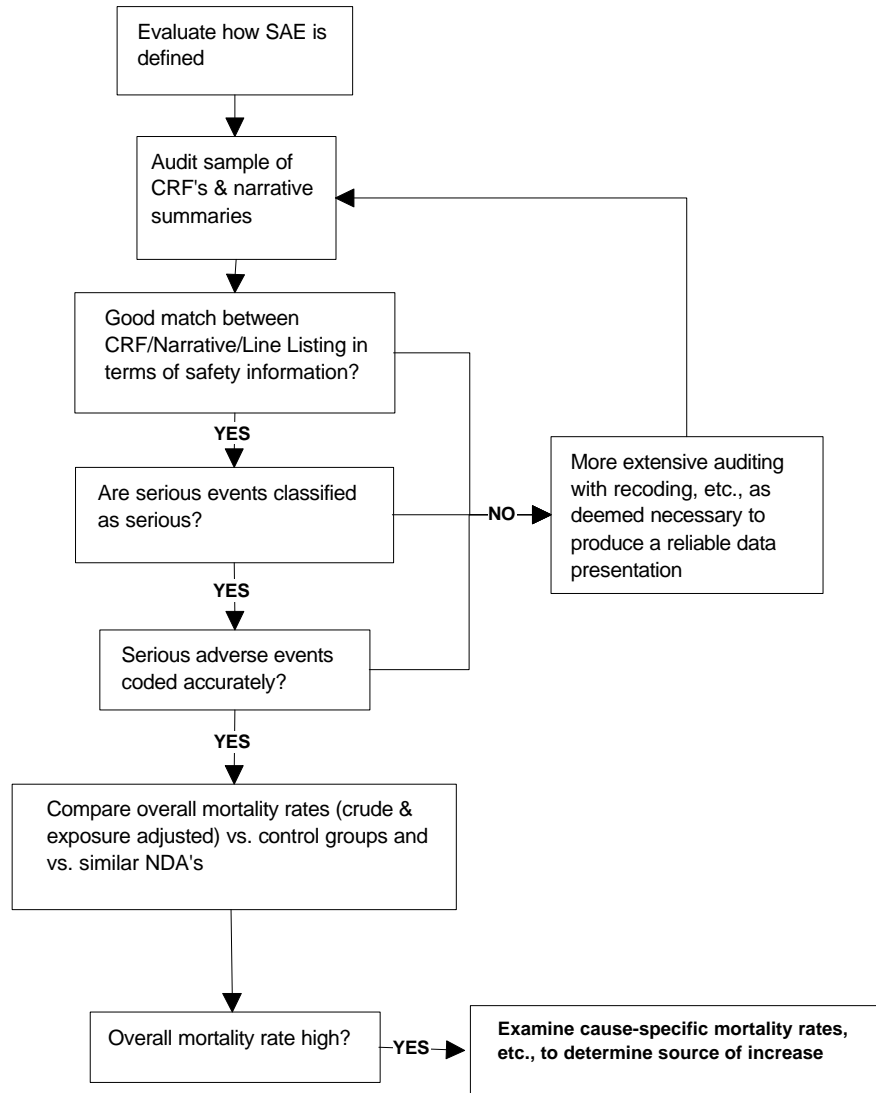
SAFETY REVIEW

p 3.0

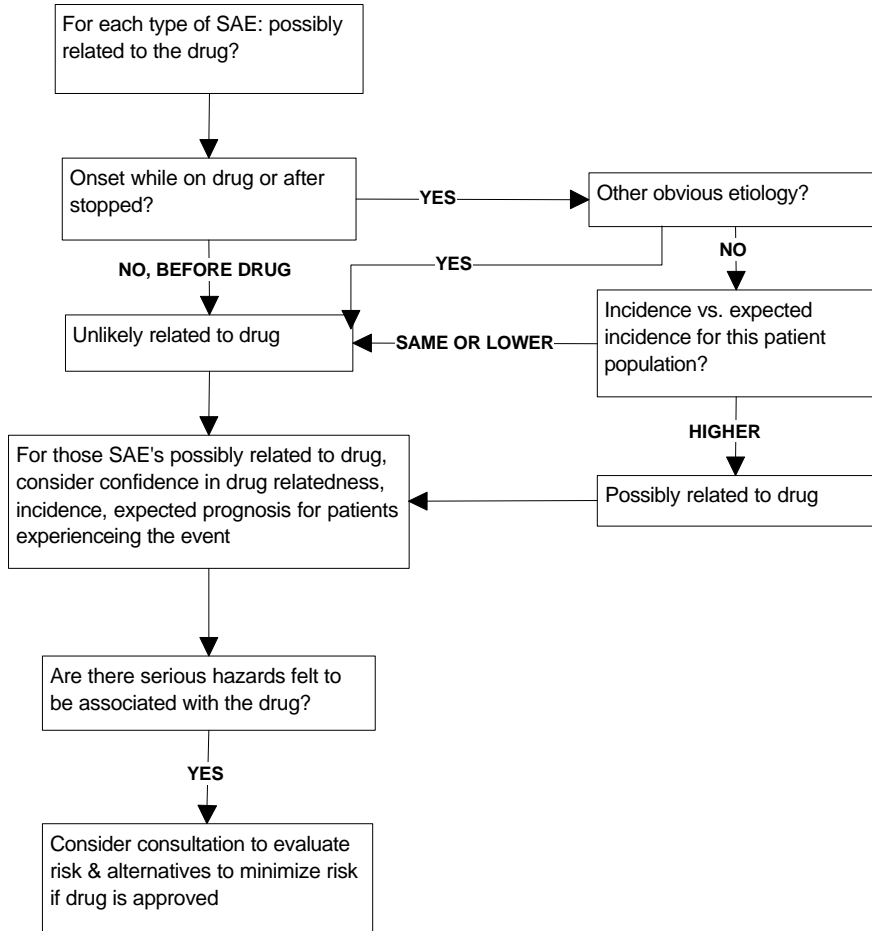
Page #



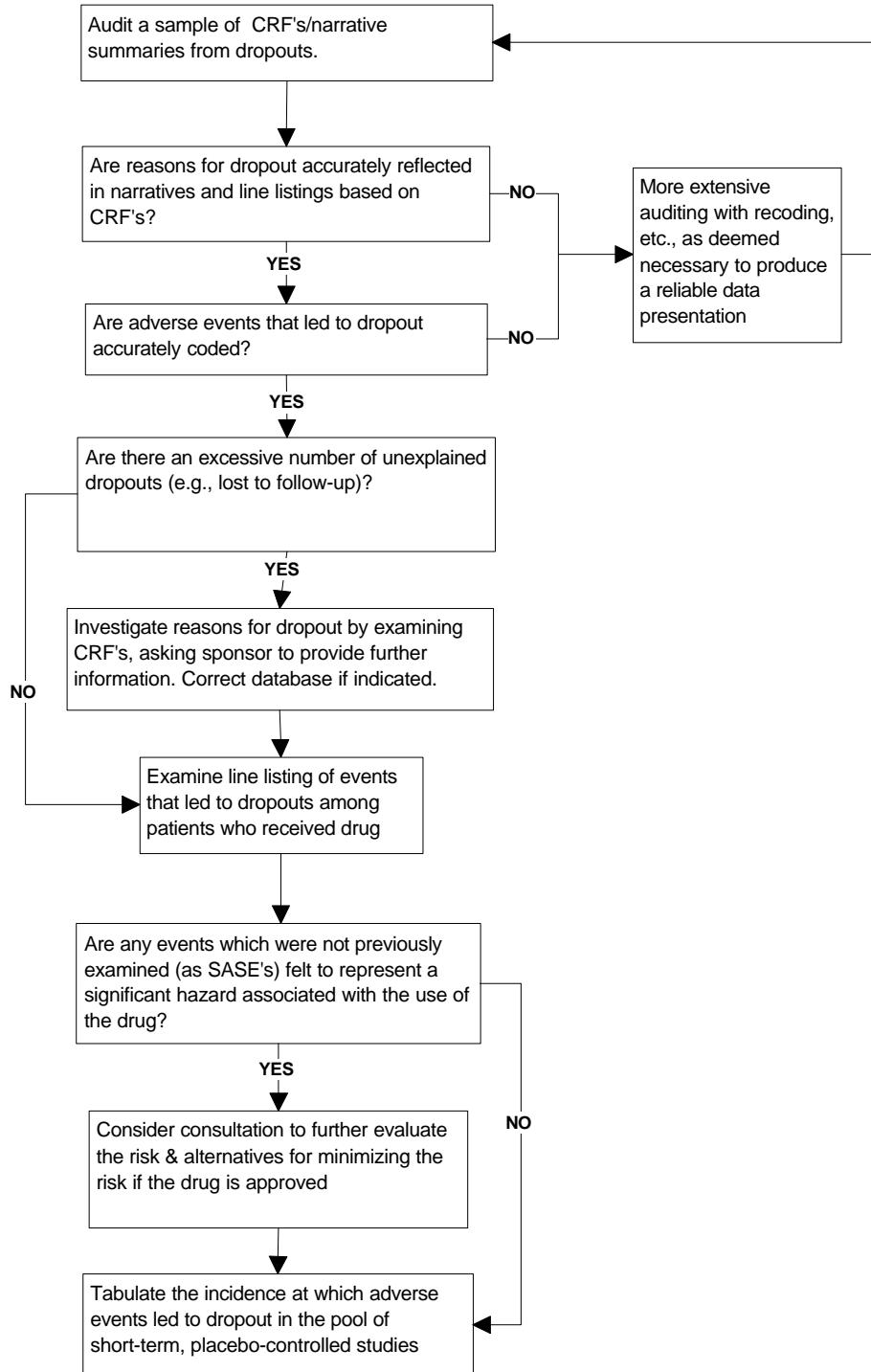
OVERVIEW OF SERIOUS ADVERSE EVENTS (INCLUDING DEATH)



DRUG-ASSOCIATED ADVERSE EVENTS



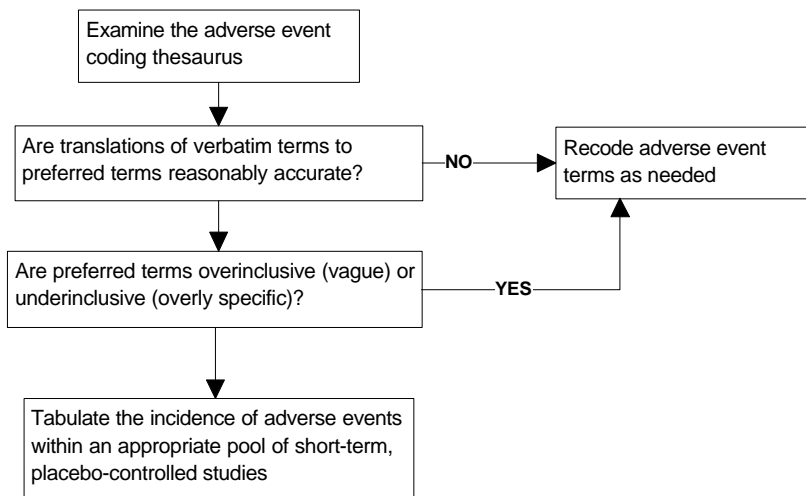
ADVERSE EVENTS LEADING TO DROPOUTS



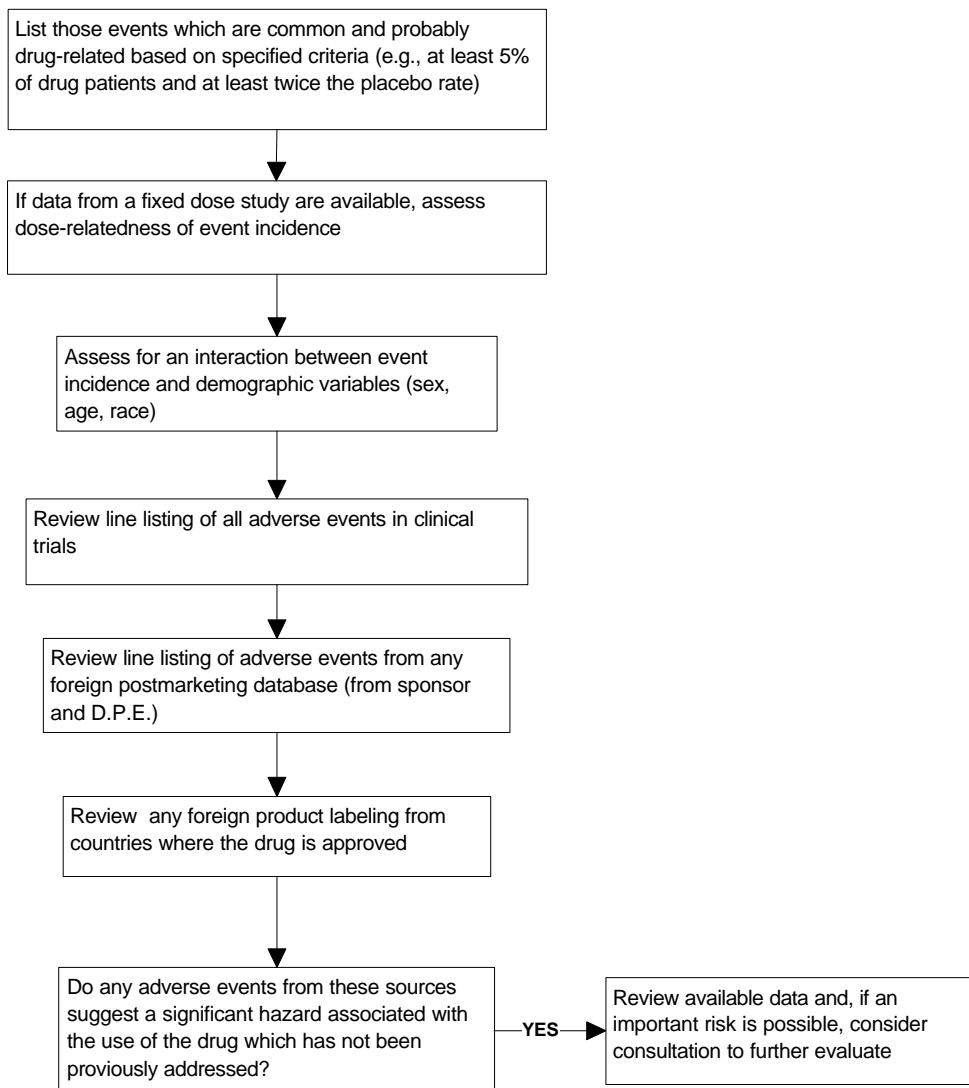
SPECIAL SEARCHES

Describe the methodology and results of any special searches or analyses to evaluate the occurrence of specific events or syndromes (e.g., emergence of suicidality, serotonin syndrome, allergic phenomena)

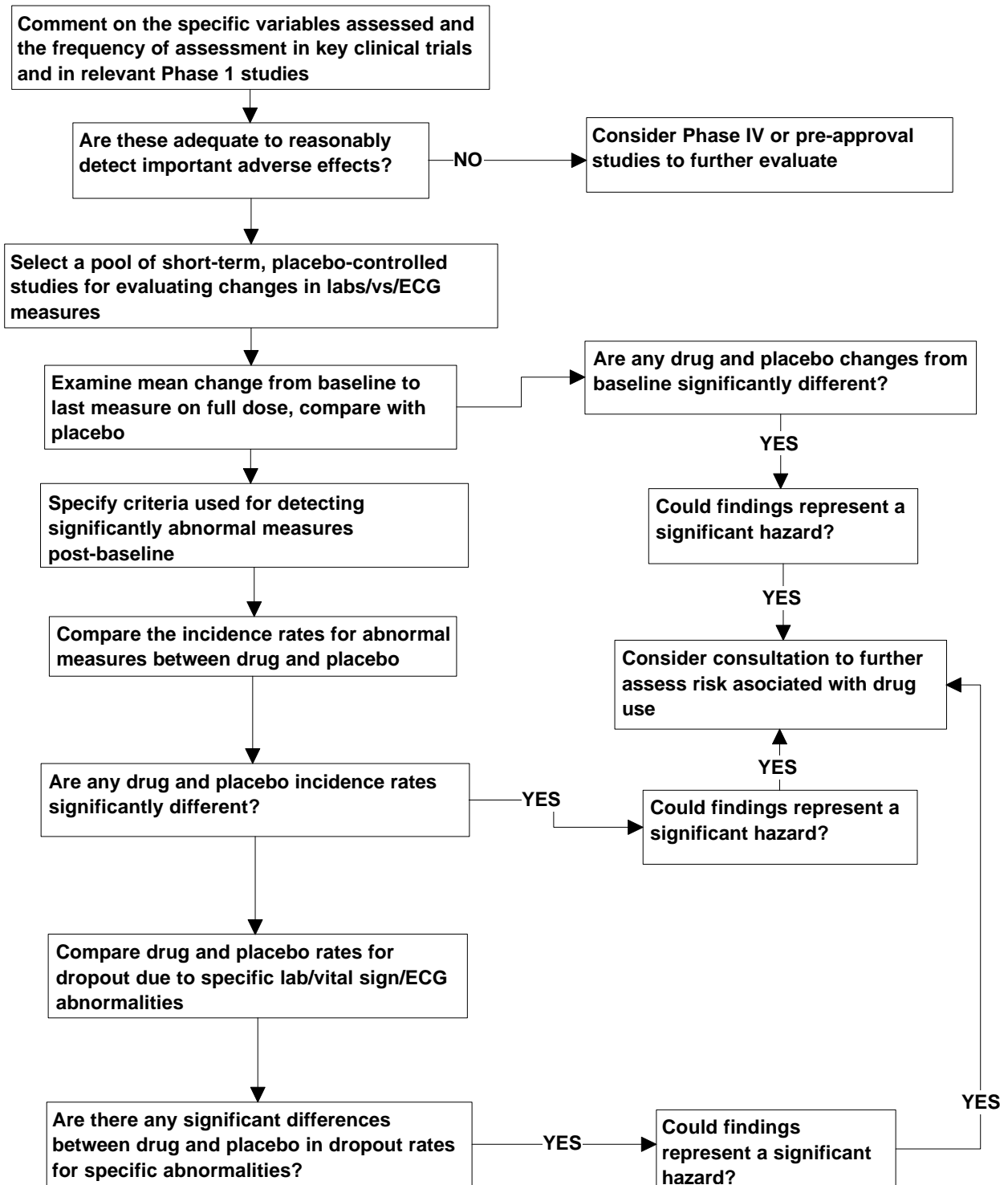
EVALUATE CODING OF ADVERSE EVENTS



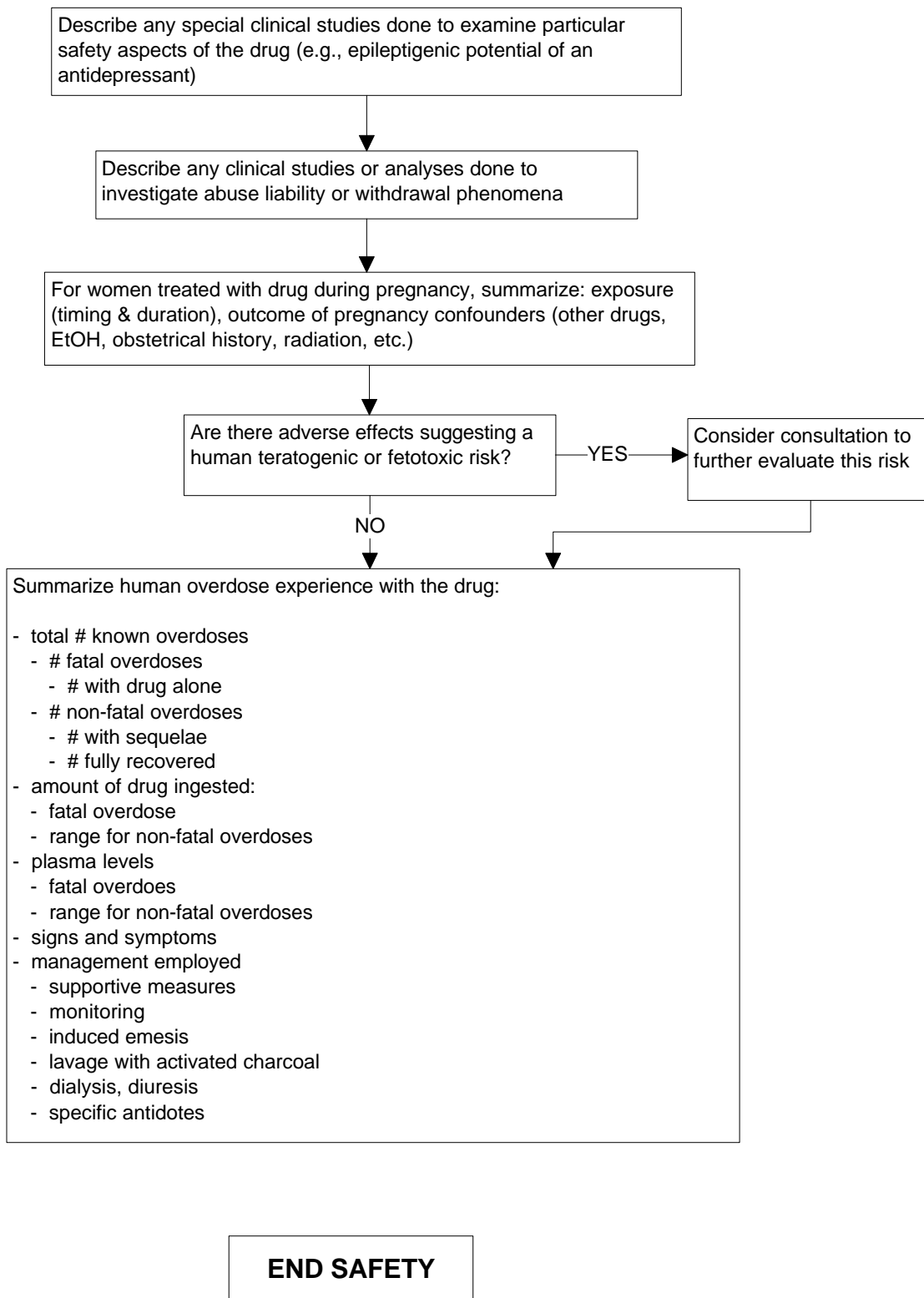
CHARACTERIZE THE COMMON AE PROFILE



LABORATORY, VITAL SIGNS, & ECG DATA

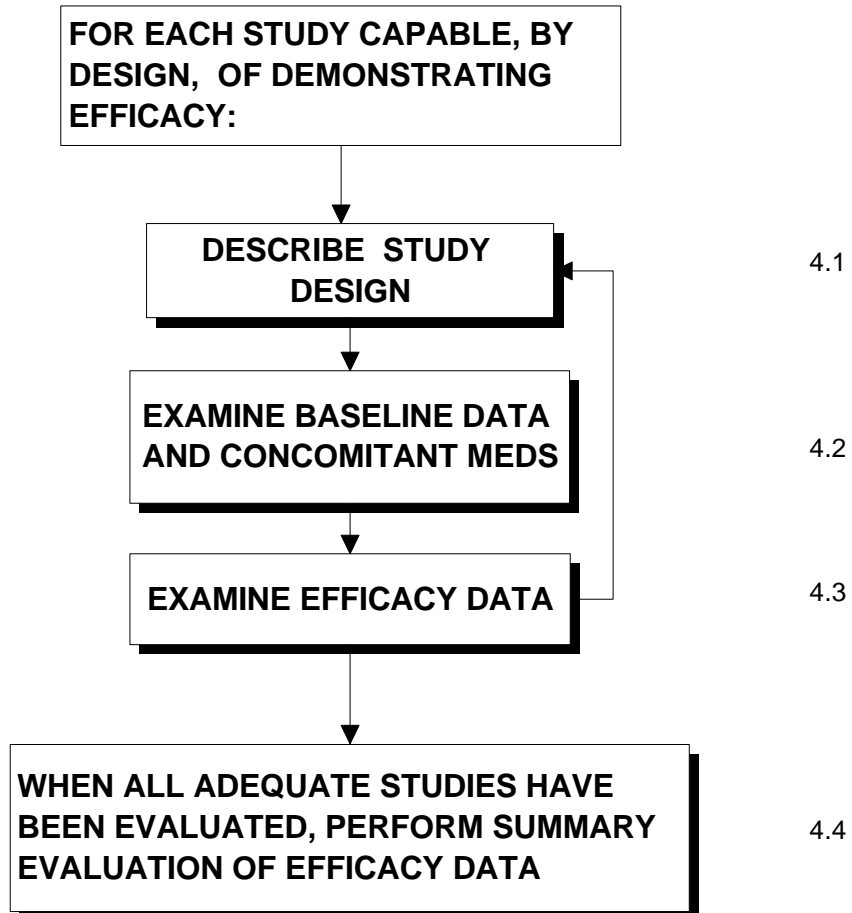


SPECIAL CIRCUMSTANCES

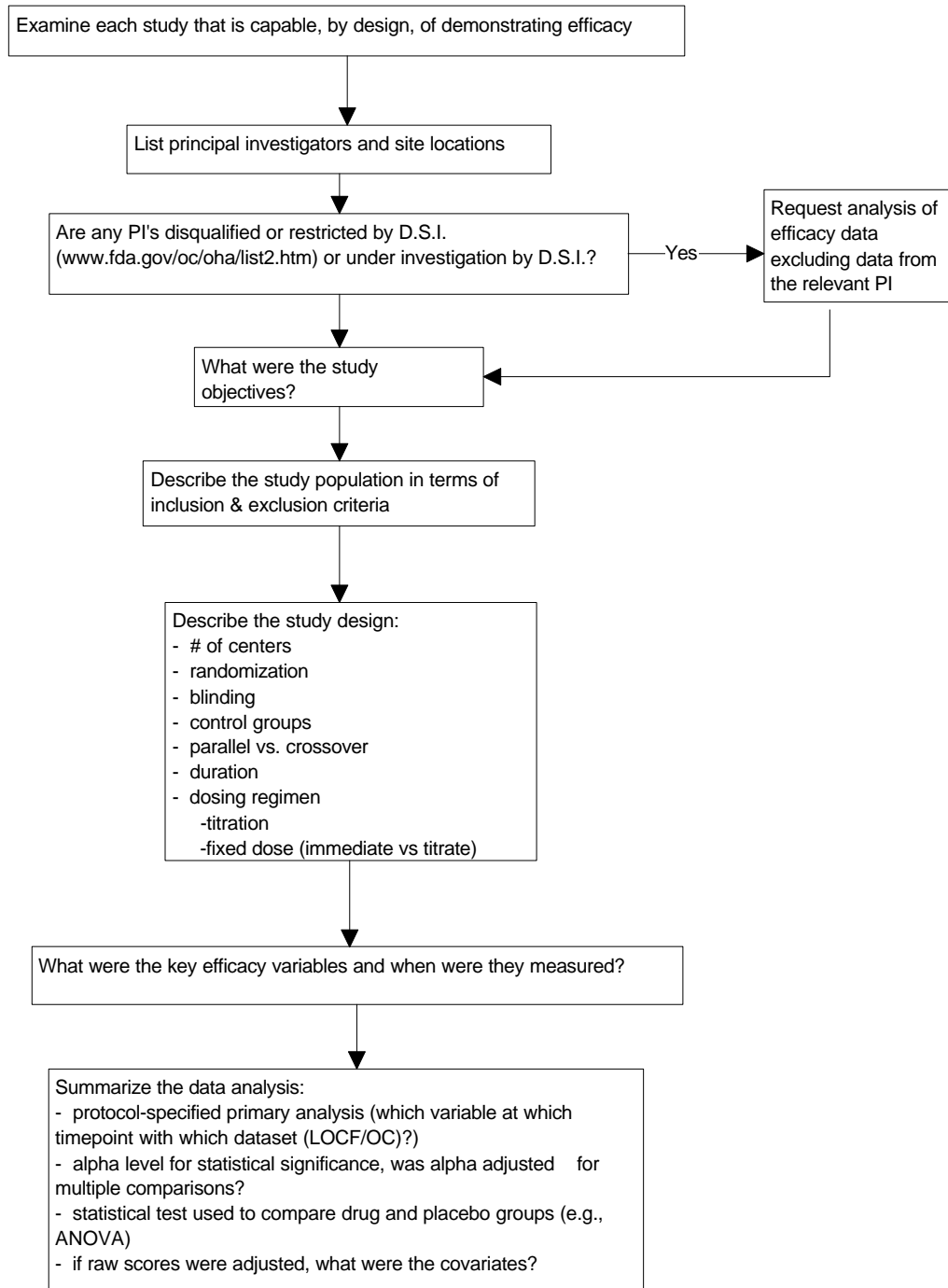


EFFICACY REVIEW

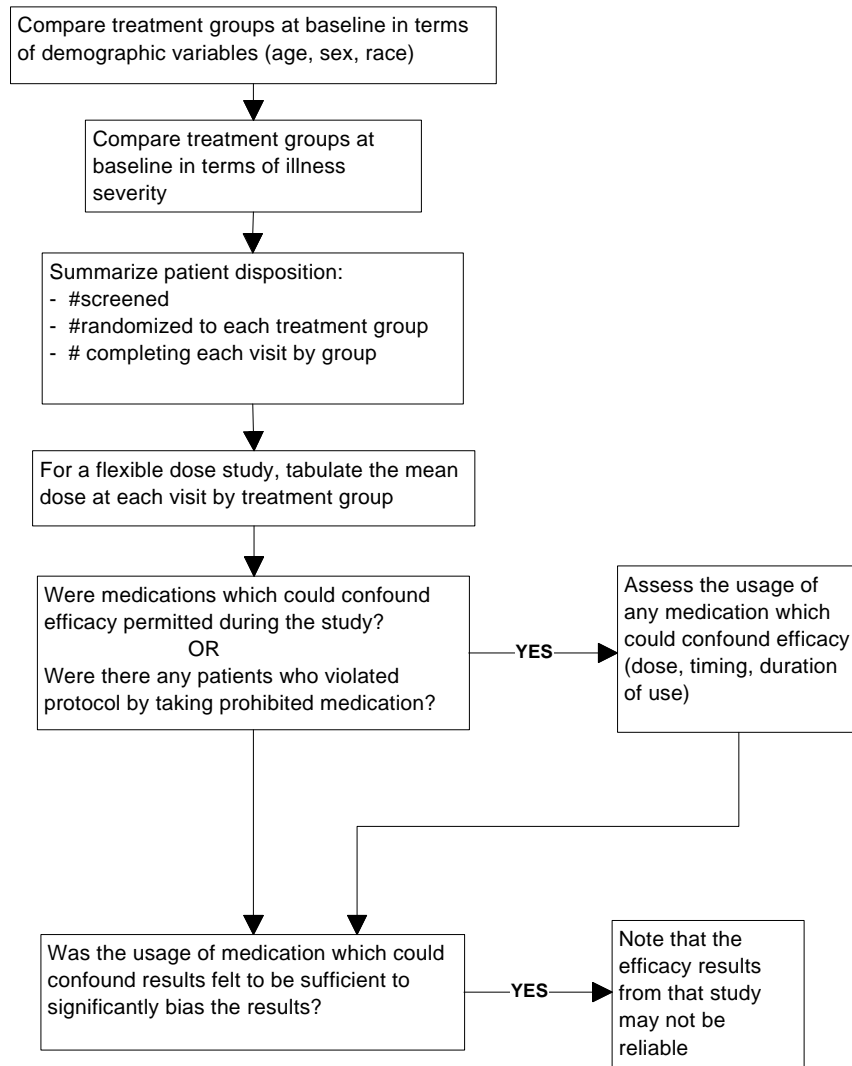
Page #



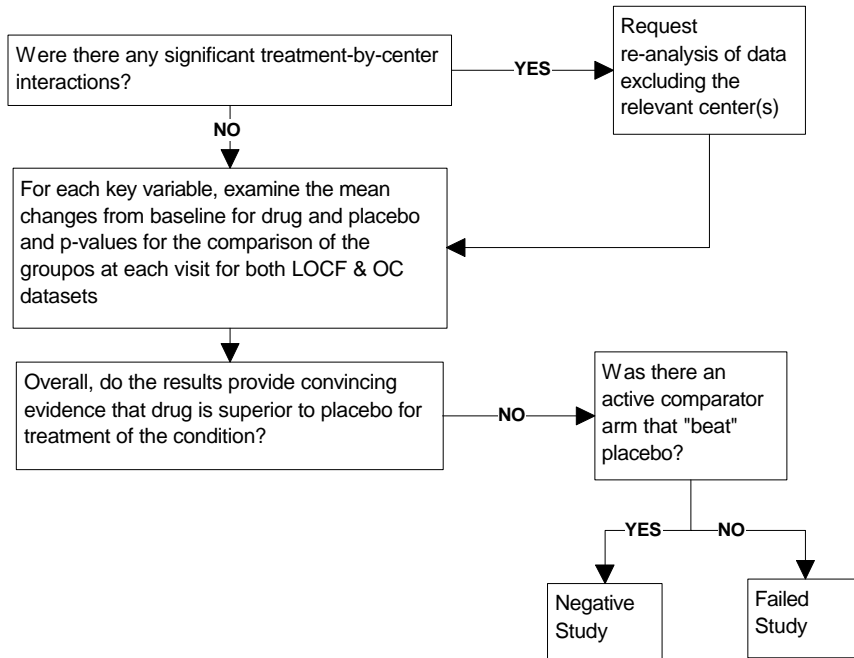
EVALUATE STUDY DESIGN



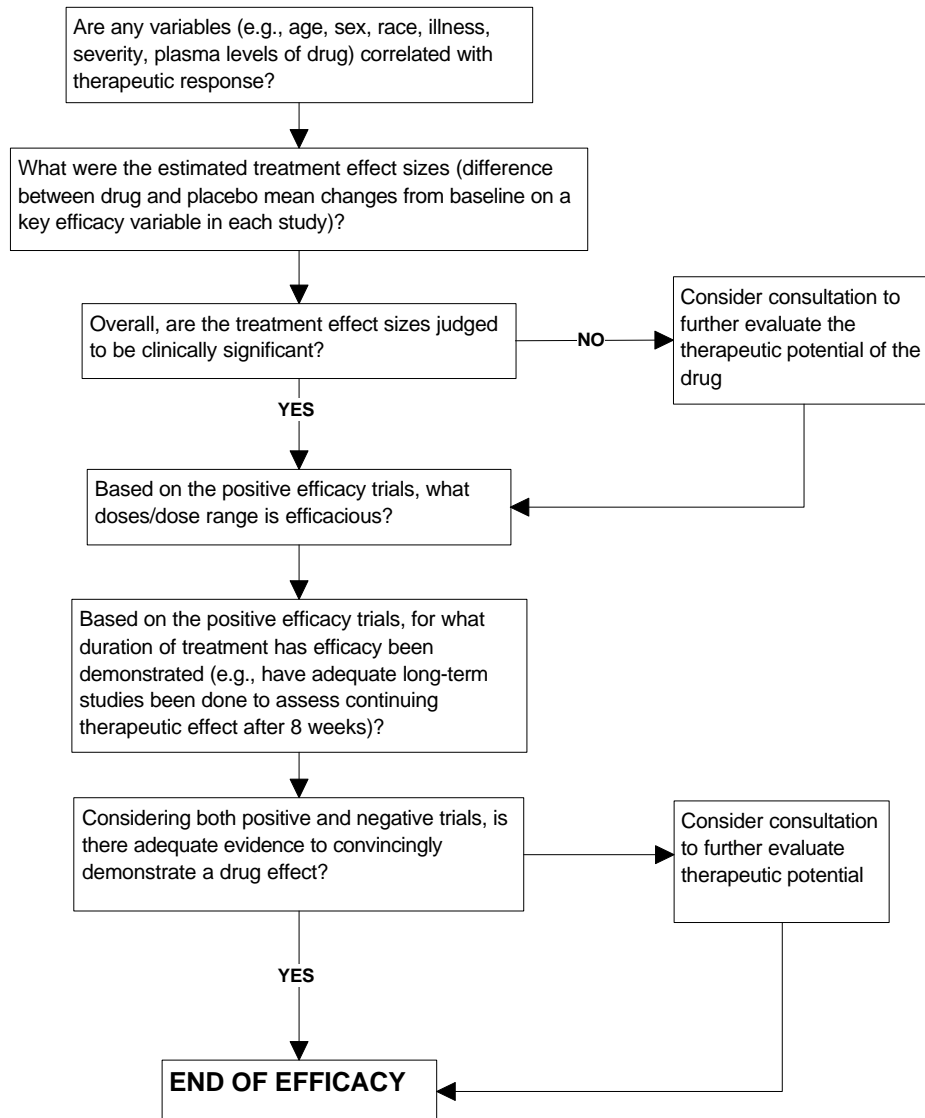
Baseline data and concomitant medications



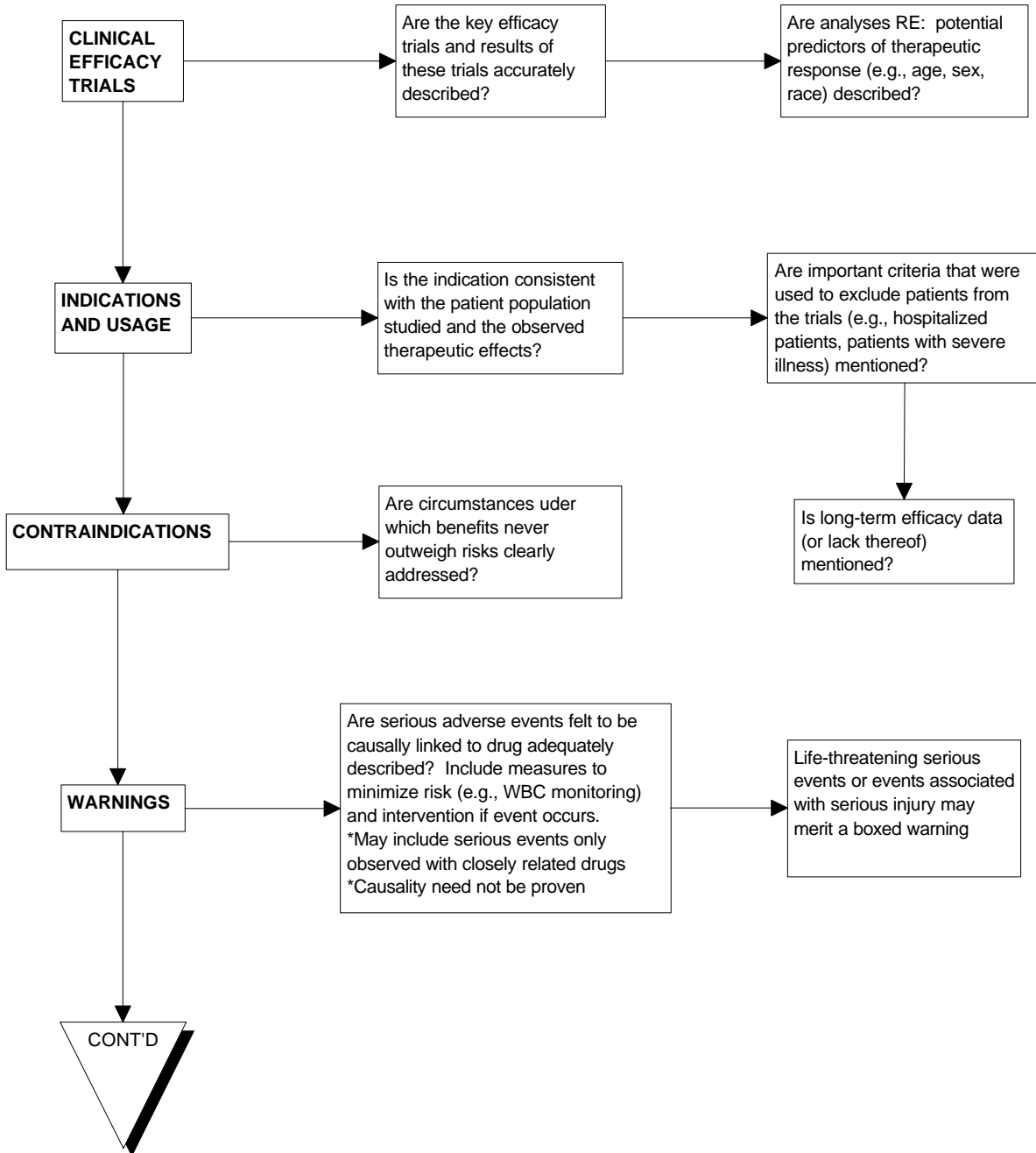
EXAMINE EFFICACY DATA



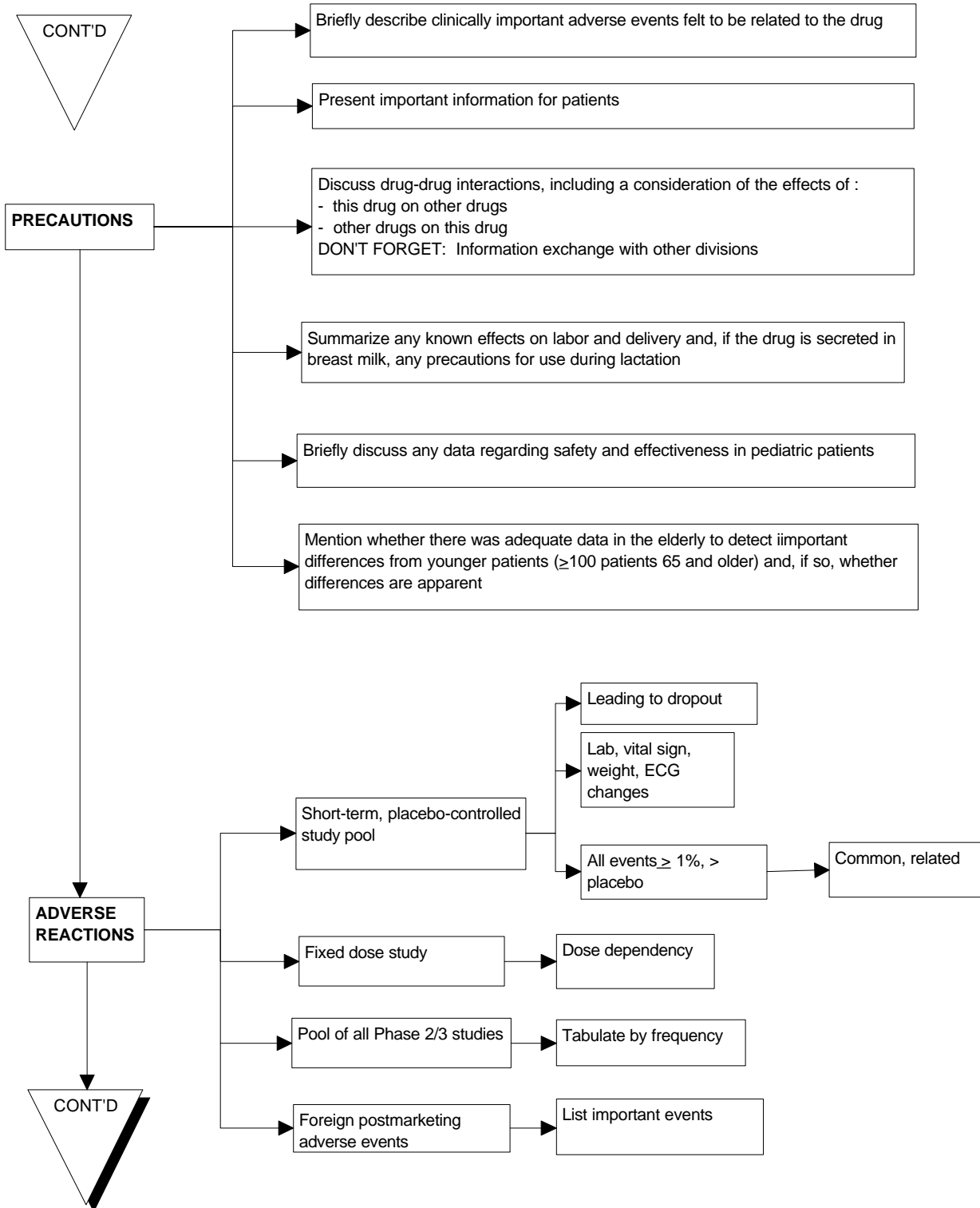
SUMMARY EVALUATION OF EFFICACY DATA FROM ALL ADEQUATE STUDIES



LABELING REVIEW (clinical)



LABELING REVIEW (clinical - cont'd)



CONT'D

