

Sample Scorecard

Drug	
Tradename	Drug X
Generic Name	SytethisAQZ
Company	SciCorp LLC
Date of FDA Approval	January 1, 2020
Indication	To reduce antibiotic-resistant bacteria



Age



Sex



Race



Ethnicity

Age	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
≥65 years old	16.5%	52.1%	57	Increased	B

Sex	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of Disease or Condition	Grade
Female	50.8%	25.7%	31	Similar	C

Race	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Black or African	13.4%	0.5%	0	Similar	D
Asian	5.9%	39.5%	40	Decreased	A

Ethnicity	% in U.S. Population	% in Clinical Trials	Number treated with new drug	Incidence of disease or condition	Grade
Hispanic or Latino	18.5%	12.5%	17	Similar	D

OVERALL GRADE

C

Based on US population, the 30% range means that the trial should have had between 35.6% and 66.0% female participation. More women would have needed to participate for this subgroup to get a higher grade.

Though the percentage is good, trials in which fewer than 300 members of the subgroup are tested are unable to detect a "common" adverse reaction, hence the B.

Though the number of individuals tested is less than 300, this grade is an A is due to the Decreased incidence. Had it been Increased, the grade would have been a B.

The reason the score is a D, rather than a C, is because fewer than 30 Hispanic and Latino people were treated with the drug, meaning even a "very common" adverse reaction might not be detected.

If this incidence had been Increased, the grade would have been an F (although the difference between this D vs. F would not have changed the overall C grade, due to the other better grades).