

Question

How is HTE information typically presented in prescription drug labeling, and are there opportunities available for enhancement?

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Prescription drug labeling



- Is FDA's primary communication tool
- Contains the essential information for safe and effective use of a drug
- Serves as the basis for many other streams of information aimed at the medical and patient communities

HTE information in labeling



Clinical Studies

- Results of required explorations by age, gender, race
- Findings of analyses that had a reasonable ability to detect differences; and when sample sizes were too small
- A cautionary statement of the inherent risks of any unplanned subgroup analyses

Use in Specific Populations

- Pregnancy
- Lactation
- Females and Males of Reproductive Potential
- Pediatric Use
- Geriatric Use
- Others as needed

Variety of approaches

Most common

- Statement at the end of study results

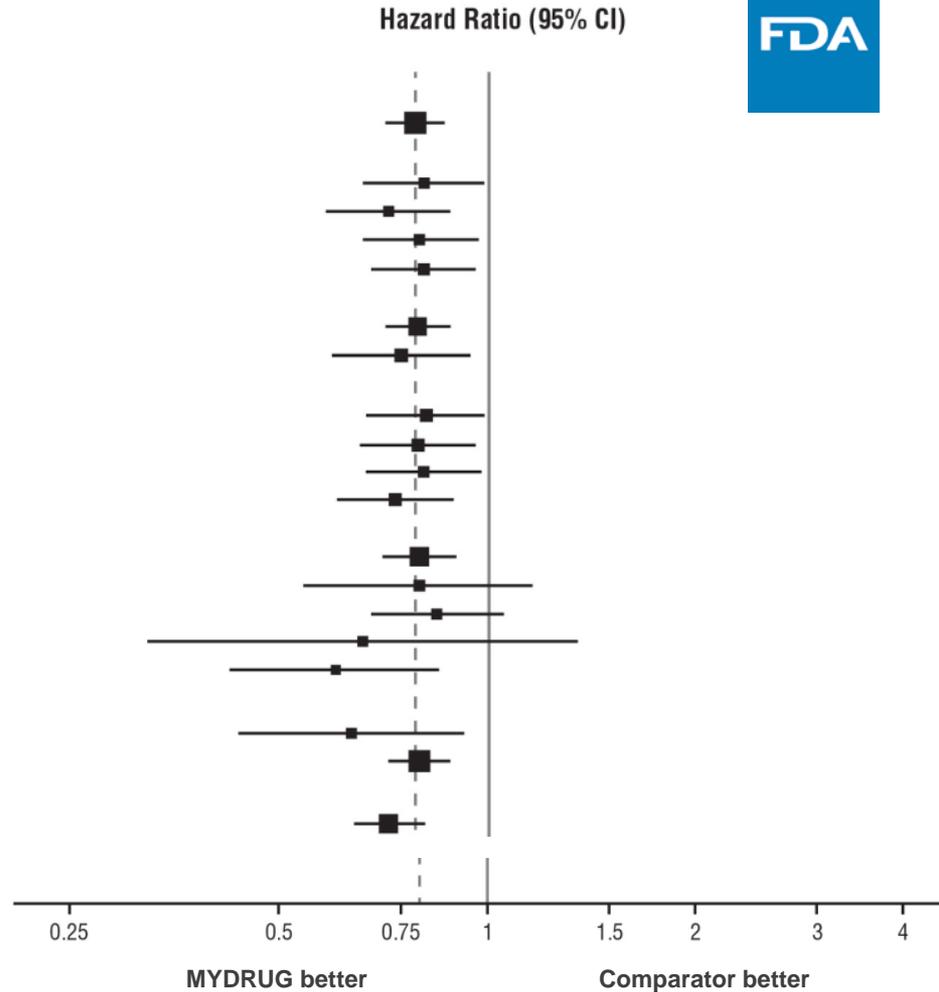
An examination of population subgroups did not reveal any clinically significant differences in responsiveness on the basis of gender, age, or race.

Alternative presentation

- Forest plot showing results of primary outcome measure in overall population and numerous subgroups



	Total population	MYDRUG		Comparator	
	(%)	n/N	(%)	n/N	(%)
Overall	100	914/4,187	(21.8)	1,117/4,212	(26.5)
Age (years)					
<57	24.3	222/1,043	(21.3)	248/ 994	(24.9)
57 - <64	22.7	182/ 917	(19.8)	263/ 992	(26.5)
64 - <72	25.8	229/1,084	(21.1)	273/1,081	(25.3)
≥72	27.2	281/1,143	(24.6)	333/1,145	(29.1)
Gender					
Male	78.2	756/3,308	(22.9)	902/3,259	(27.7)
Female	21.8	158/ 879	(18.0)	215/ 953	(22.6)
Weight (kg)					
<67.5	25.0	221/1,037	(21.3)	269/1,061	(25.4)
67.5 - <79	24.8	241/1,041	(23.2)	287/1,038	(27.6)
79 - <91.7	25.2	231/1,048	(22.0)	283/1,069	(26.5)
≥91.7	25.1	221/1,060	(20.8)	278/1,044	(26.6)
Race					
Caucasian	66.0	598/2,763	(21.6)	717/2,781	(25.8)
Black	5.1	58/ 213	(27.2)	72/ 215	(33.5)
Asian	18.0	179/ 759	(23.6)	204/ 750	(27.2)
Native American	2.0	15/ 84	(17.9)	22/ 88	(25.0)
Other	8.9	64/ 368	(17.4)	102/ 378	(27.0)
Region					
US	5.2	58/ 225	(25.8)	77/ 209	(36.8)
Outside-US	94.8	856/3,962	(21.6)	1,040/4,003	(26.0)
NYHA Class					
NYHA class II	70.5	578/2,998	(19.3)	742/2,921	(25.4)



Example of an accompanying “cautionary statement”



Note: The figure above presents effects in various subgroups, all of which are baseline characteristics. The 95% confidence limits that are shown do not take into account the number of comparisons made, and may not reflect the effect of a particular factor after adjustment for all other factors. Apparent homogeneity or heterogeneity among groups should not be overinterpreted.

Need to strike a balance...

Informing

Overinterpreting

